

## SAFETY EVALUATION SUPPLEMENT

## 1. INTRODUCTION

This Safety Evaluation Supplement (SES) documents the U. S. Nuclear Regulatory Commission (NRC) staff's review of the changes that the U. S. Department of Energy (DOE)/Nevada Operations Office has proposed to its "Quality Assurance Plan" (hereafter the 88-9 QA Plan), Revision 1. The 88-9 QA Plan establishes the Quality Assurance (QA) requirements for the Yucca Mountain Project Office (YMPO) (formally the Nevada Nuclear Waste Storage Investigations Project). These QA requirements will help determine whether Yucca Mountain is a suitable site for the high-level radioactive waste repository. The aforementioned changes will be incorporated in Revision 2 to the 88-9 QA Plan.

## 2. BACKGROUND

The NRC Safety Evaluation (SE) dated October 14, 1988 documented the staff's review of the 88-9 QA Plan, Revision 1. Section 5 of the SE contained six open items. The responses to address the six open items, along with other proposed changes for clarification and improvement to the QA program, were discussed with DOE at a November 18, 1988 meeting at the NRC Headquarters in Rockville, Maryland. Revision 2 to the 88-9 QA Plan was transmitted in a letter from R. Stein, DOE, to J. Linehan, NRC, dated December 13, 1988.

## 3. STAFF EVALUATION

The following two sections describe the staff's evaluation of Revision 2 of the 88-9 QA Plan. Section 3.1 addresses the Office of Civilian Radioactive Waste Management's (OCRWM's) response to the six open items in the SE, and additional changes to the 88-9 QA Plan are contained in Section 3.2.

3.1 OCRWM Response to Open Items

The NRC SE (dated October 14, 1988) of the 88-9 QA Plan identified six open items. Open Item One was concerned with the definition of "Corroborative Data" in Appendix A. DOE revised this definition to be consistent with the definition contained in NUREG-1298, as well as in Appendix G of the 88-9 QA Plan.

The peer review report in Section 6 of Appendix J was a concern documented as Open Item Two. DOE revised Appendix J to be consistent with NUREG-1297, by requiring that the peer review report be prepared under the direction of the peer review group chairperson and signed by each peer review group member, and also to indicate that the technical qualifications of individuals would be the primary consideration in the selection of peer reviewers.

Open Item Three was related to documentation of scientific work in Section III. DOE revised Section III to require that initial entries for scientific notebooks include identification of required levels of precision and accuracy.

The requirements for Q-List in Appendix I was a concern documented as Open Item Four. DOE made changes to Appendix I as well as to Appendix A and Section II of the 88-9 QA Plan, to be consistent with NUREG-1318.

The control of nonconformances generated by surveillances was a concern identified by Open Item Five. DOE revised Section XVIII to require that nonconformances identified in surveillance records be handled in accordance with the requirements of Section XV or XVI of the 88-9 QA Plan, as applicable.

Open Item Six concerned the controls applied to scientific investigations in Section III. DOE proposed, in the 88-9 QA Plan, two methods for documenting scientific investigations defined in study plans or scientific investigation plans--use of detailed technical procedures or use of scientific notebooks. Several concerns with approaches outlined were detailed in Section 3.3. of the SE. The NRC staff believed that the controls on the use of scientific notebooks needed to be strengthened and that the use of detailed implementing procedures needed to be less restrictive. In addition, the approach in the 88-9 QA Plan for using scientific notebooks appeared to conflict with a prior NRC/DOE agreement on study plans and their implementation. DOE has made appropriate changes to Sections III, V, and VI to address these concerns. The conditions under which detailed technical implementing procedures are to be used have been expanded; scientific investigations which are documented in notebooks have had additional controls added; and the information on study plans from the prior NRC/DOE agreement has been incorporated into the new Appendix K of the 88-9 QA Plan.

The NRC staff has reviewed all the changes made by DOE in Revision 2 of the 88-9 QA Plan to address the six open items in the SE and finds them acceptable. Therefore, Open Items One through Six in the SE are resolved.

### 3.2 Additional Changes

In Revision 2 of the 88-9 QA Plan, DOE has proposed changes in five areas, to clarify and improve the QA program. DOE made changes in the "Introduction" and Section II, to clarify reviews and approvals, made by OCRWM and YMPO, of lower-tier implementing QA administrative procedures and QA Program Plans.

In Section II, DOE made changes to clarify that QA requirements can be selectively applied to QA Level I items and activities, commensurate with their importance to safety and/or waste isolation.

DOE made changes to Appendix H to clarify software QA requirements and to focus on the flexibility for selective application of these requirements, and to require that methods for determining the applicability of requirements and managing interfaces be described in each organization's software QA plan and procedures. Section III was revised to provide for the use of, as well as identification and control of, portions of unverified/unvalidated software.

In Appendix A, "Terms and Definitions," DOE changed a title of one item and added two items -- "Authentication" and "Validation."

DOE made several editorial changes and a number of miscellaneous changes to the 88-9 QA Plan, Revision 1. DOE clarified: (a) the use of the 88-9 QA Plan requirements, when deviations exist between higher-tier QA documents (Section II); and (b) modifications to technical implementing procedures and final results of scientific investigations (Section III). In Section V, DOE clarified the use of scientific notebooks and their retention as QA records. The "tolerance" of measuring and test equipment for determining conformance to specified requirements was deleted in Section XII. In Section V, determination of the root cause analysis for the disposition of a nonconforming condition was deleted. DOE clarified, in Section XVIII, documentation justification for not auditing vendors who have been active for less than four months.

The NRC staff has reviewed all the additional changes in Revision 2 to the 88-9 QA Plan and found them acceptable.

#### 4. CONCLUSION

The NRC staff reviewed the 88-9 QA Plan, Revision 2 for the Yucca Mountain Project and has verified that it meets the applicable criteria of Subpart G to 10 CFR Part 60 and Appendix B to 10 CFR Part 50. The changes continue to meet the review criteria (reference Section 4 of the SE dated October 14, 1988) used by the staff in its initial review of the 88-9 QA Plan, Revision 1. In addition, the commitments made in Subsection 3.0, "Software Quality Assurance Requirements," of Section III, and Appendix H, "Requirements for Computer Software Used to Support a High-Level Nuclear Waste Repository License Application," in the 88-9 QA Plan, Revision 2 are consistent with the latest draft of NQA-2, Part 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."

On the basis of its detailed review and evaluation of the 88-9 QA Plan, Revision 2, the NRC staff concludes that this document contains adequate requirements and planned and systematic controls that address each of the criteria of Appendix B to 10 CFR Part 50 in an acceptable manner. This document can serve as adequate framework for DOE/NV and its contractors to develop specific policies, plans, and procedures to implement the QA Program for the Yucca Mountain Project.