

MAR 2 1992

Dr. John W. Bartlett, Director  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy, RW-1  
Washington, D.C. 20585

Dear Dr. Bartlett:

SUBJECT: LIFTING OF SITE CHARACTERIZATION ANALYSIS OBJECTION 2

The U.S. Nuclear Regulatory Commission (NRC) staff identified in its Site Characterization Analysis (SCA) transmitted to Sam Rousso by my letter of July 31, 1989, SCA Objection 2 related to the lack of an acceptable U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) quality assurance (QA) program. My letter to you dated July 31, 1991, discussed the progress DOE was making in closing this objection; the enclosure to my letter identified the specific status of the issues forming the basis of the objection, as of July 1991, including those QA programs requiring further acceptance review by the NRC staff.

DOE stated in Dwight Shelor's letter to John Linehan dated August 21, 1991, that it believed the issues of SCA Objection 2 were resolved and requested that the NRC lift this objection. The August 21, 1991, letter also transmitted information required by the NRC staff to evaluate acceptability, with no exceptions, of the OCRWM QA program. This evaluation was completed in December 1991, subsequent to the October 1991 audit of OCRWM, and is documented in Joseph Holonich's letter to John Roberts dated December 20, 1991. Additional time was required for the NRC staff to complete its evaluation of the acceptability of the Raytheon Services Nevada QA program, which was accepted by Joseph Holonich's letter to John Roberts dated January 27, 1992.

The NRC staff has evaluated the DOE request, and agrees that SCA Objection 2 concerning DOE's QA program can be lifted based on DOE progress since July 1991 as follows.

- ° The remaining organizations participating in site characterization activities have developed and are implementing a QA program that meets NRC requirements .
- ° QA management positions have been filled with full-time DOE personnel.
- ° DOE has demonstrated the QA aspects of an acceptable design control program which will be applied to the Title II design of the Experimental Studies Facility and other quality-related design activities.

The analysis of SCA Objection 2 contained in the July 31, 1991, letter (which identified DOE progress up to July 1991) has been updated as of February 21, 1992, and is enclosed.

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While the NRC staff has determined that all organizations participating in the site characterization activities have developed and are implementing a QA program that meets NRC requirements, the NRC staff will continue to monitor implementation through future audits and surveillances.

Please feel free to contact me or Mr. Joseph Holonich of my staff, if you have any questions. I can be reached at (301) 504-3352, or Mr. Holonich can be reached at (301) 504-3391.

Sincerely,

(Signed) Robert M. Bernero

Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: Analysis of SCA Objection 2

- cc: R. Loux, State of Nevada
- C. Gertz, DOE/NV
- S. Bradhurst, Nye County, NV
- M. Baughman, Lincoln County, NV
- D. Bechte, Clark County, NV
- D. Waice, GAD
- P. Medzielski-Eichner, Nye County, NV
- C. Thistlethwaite, Inyo County, CA
- V. Poe, Mineral County, NV
- F. Sperry, White Pine County, NV
- R. Williams, Lander County, NV
- P. Goicoechea, Eureka County, NV
- L. Vaughan II, Esmeralda County, NV
- C. Shank, Churchill County, NV

## Analysis of SCA Objection 2

Section 8.6 of the SCP describes the quality assurance (QA) program to be applied to site characterization activities including the exploratory shaft design and construction. Prior to conducting activities in the various program areas, it commits to having an appropriate program which meets Subpart G of 10 CFR 60 in place for those site characterization activities, and to qualify site exploration data supporting the license application. DOE has developed an acceptable approach for qualifying its QA program, but some of the milestones are not yet completed. In addition, although the information presented and referenced in the SCP on the responsibilities and independence of the QA managers is acceptable, the NRC staff is concerned that DOE will be impeded in demonstrating the ability to implement the approach because the QA management positions in DOE's headquarters (OCRWM) and field (YMPO) offices have not been filled with full time individuals with appropriate knowledge and experience. Also, staff QA concerns on the Design Acceptability Analyses (DAA) will need to be resolved. Finally, the Overview of the Site Characterization Plan incorrectly states that all organizations participating in the site characterization program have developed and are implementing a QA program that meets the NRC's requirements.

### EVALUATION OF DOE RESPONSE

Before the DOE QA program could be determined to be acceptable for start of new site characterization activities, it was necessary for OCRWM to verify and NRC to agree that the QA program as described in the QARD and QAPD was being effectively implemented. After an initial round of audits of participants' QA program implementation, NRC and DOE agreed at the April 27, 1990, QA meeting on the criteria to demonstrate that a QA program was being effectively implemented. The criteria included the following:

- ° Review and resolve open QA program deficiencies identified by the DOE auditors that could have quality or technical impact on output products;
- ° Identify the extent of the program implementation since the last DOE audit, including the areas of activity audited or surveilled and the end products produced;
- ° Determine whether the QA program can be effectively implemented;
- ° Identify what areas of the QA program are on hold; and
- ° State the DOE position on whether the QA program is adequate for further implementation to conduct new site characterization activities.

Based upon the NRC staff: (a) review of the QARD, QAPD, and participant's QAPPs, (b) observations of audits/surveillances, and (c) evaluation of information submitted by DOE addressing each of the above criteria, the

ENCLOSURE

status of the QA program acceptance by NRC for new characterization activities is as follows:

- Sandia National Laboratory and Lawrence Livermore National Laboratory - accepted (October 1990)
- Fenix & Scisson, Holmes & Narver - accepted with minor exceptions (October 1990) - no longer involved in DOE program
- Reynolds Electrical & Engineering Company - accepted (August 1990)
- Los Alamos National Laboratory - accepted (May 1991)
- U.S. Geological Survey - accepted (August 1991)
- Office of Civilian Radioactive Waste Management/Headquarters and Yucca Mountain Site Characterization Project Office - accepted (December 1991)
- Science Applications International Corporation/Technical and Management Support Services - accepted (October 1991)
- Raytheon Services Nuclear - accepted (January 1992)

The NRC staff considers 301 Objection 2 closed based on the information stated in the August 21, 1991, letter from D. Shelor to J. Linehan and the following:

- The NRC staff evaluations of the DOE and DOE participant QA programs have determined that these QA programs are acceptable for implementation of site characterization activities and other quality-related activities for the Yucca Mountain Site Characterization Project, with no exceptions.
- DOE has demonstrated that it is capable of evaluating and correcting deficiencies in the overall QA program.
- The QA management positions in OCRWM Headquarters and the Yucca Mountain Site Characterization Project Office have been filled with full-time DOE personnel with appropriate knowledge and experience.
- DOE has demonstrated the QA aspects of an acceptable design control program which will be applied to Title II design of the Experimental Studies Facility and other quality-related design activities.