August 4, 2005

Mr. Joseph D. Ziegler, Director
Office of License Application and Strategy
Office of Repository Development
U.S. Department of Energy
1551 Hillshire Drive
Las Vegas, NV 89134-6321

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION STAFF REVIEW OF REVISION 17 TO THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

Dear Mr. Ziegler:

This is in response to the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) September 17, 2004, request for the U.S. Nuclear Regulatory Commission (NRC) staff review and acceptance of the proposed Revision 17 to the DOE Quality Assurance Requirements and Description (QARD), DOE/RW-0333P. Enclosure 1 to this letter is a chronology of correspondence between OCRWM and the NRC regarding the proposed QARD, Revision 17.

The NRC staff reviewed the proposed QARD, Revision 17, as revised by the correspondence listed in Enclosure 1 to this letter, in accordance with the requirements of 10 CFR Part 63, "Disposal of High-level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada." The NRC staff has determined that, with the incorporation of the conditions and corrections identified in Enclosure 2 to this letter, the proposed QARD, Revision 17, as revised, is acceptable and is adequate for controlling DOE's present work activities.

Please be advised that NRC's acceptance of the QARD, Revision 17, for DOE's present work activities does not constitute NRC's approval of DOE's quality assurance program for the potential license application for a geologic repository. The NRC staff would perform a comprehensive review of the quality assurance program described in DOE's license application to assure compliance with the requirements of 10 CFR Part 63 and the guidance in NUREG-1804, "Yucca Mountain Review Plan." If you have any questions regarding this matter, please contact Mr. Thomas Matula of my staff at 301-415-6700.

Sincerely,

/RA/

C. William Reamer, Director
Division of High Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

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OFC	HLWRS	HLWRS	OGC	HLWRS	HLWRS
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DATE	07/28/05	07/28/05	08/03/05	08/04/05	08/04/05

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CHRONOLOGY OF CORRESPONDENCE BETWEEN THE U.S. DEPARTMENT OF ENERGY (DOE), OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM), AND THE U.S. NUCLEAR REGULATORY COMMISSION (NRC) REGARDING THE QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION (QARD), DOE/RW-0333P, REVISION 17

- On September 17, 2004, DOE submitted its QARD, Revision 17, to NRC for review and acceptance. In DOE's September 17 letter, DOE stated that the QARD, Revision 17, describes the quality assurance (QA) requirements for the construction phase of the Yucca Mountain Project (YMP) and that this revision re-baselines the YMP's QA program to meet the QA requirements of 10 CFR Part 63.

- On December 15, 2004, DOE submitted the YMP Positions and Justification taken in QARD, Revision 17. The NRC staff considered the YMP Positions and Justifications contained in DOE's December 15 letter during its review of the QARD, Revision 17.

- On December 22, 2004, the NRC staff stated in its letter to DOE that it had completed the initial review of the QARD, Revision 17. In the attachment to NRC's December 22 letter the NRC staff provided Additional Information Needs (AINs) that identified areas in the QARD, Revision 17, requiring clarification or additional information.

- On February 10, 2005, staff from the NRC and DOE held a Technical Exchange (TE) at which DOE discussed its approach to responding to the NRC's AINs identified in the NRC's December 22, 2004, letter. On March 10, 2005, the NRC staff issued a summary of the February 10 TE.

- On April 11, 2005, DOE submitted its revised QARD, Revision 17, with four enclosures: (1) Responses to AINs; (2) OCRWM QARD, Revision 17; (3) Table 1A - Regulatory/Commitment Document Positions with Justifications; and (4) NUREG-1804, Section 2.5.1, Office of Repository Development (ORD) Positions.

- On May 13, 2005, DOE submitted organization charts for the OCRWM, ORD, and the OCRWM Management and Operating (M&O) contractor. During the February 10, 2005, TE between staff from the NRC and DOE, DOE had agreed to provide the NRC with the OCRWM and M&O contractor organization charts to assist the NRC staff in their review of the QARD, Revision 17.

CONDITIONS REGARDING THE ACCEPTANCE OF THE U.S. DEPARTMENT OF ENERGY'S (DOE'S) PROPOSED QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION (QARD), DOE/RW-0333P, REVISION 17

The conditions listed below must be incorporated in to the proposed QARD, Revision 17, in order for the U.S. Nuclear Regulatory Commission (NRC) staff to find the QARD, Revision 17, acceptable and to find it adequate for controlling the DOE's present work activities.

1. On May 13, 2005, DOE submitted organization charts for the Office of Civilian Radioactive Waste Management (OCRWM), Office of Repository Development (ORD), and the OCRWM Management and Operating (M&O) contractor. During the February 10, 2005, Technical Exchange (TE) between staff from the NRC and DOE, DOE agreed to provide the NRC with the OCRWM and M&O contractor organization charts to assist the NRC staff in their review of the QARD, Revision 17, and to maintain organization charts under the DOE Quality Assurance (QA) Program. During its review of organization charts enclosed in DOE's May 13, 2005, letter the NRC staff found three areas requiring clarification.

   A. Enclosure 1, "OCRWM Organization," to DOE's May 13, 2005, letter, does not show the reporting relationship of the M&O contractor and waste custodians to the ORD. Enclosure 1 is controlled under the DOE QA Program in Line Procedure (LP)-1.1Q-OCRWM, "Organization." Specifically, Section 1.0, "Organization," of the QARD, Revision 17, states that:

      > The QARD establishes the relationships of organizations within the YMP [Yucca Mountain Project], including principal contractors, and waste custodians.... The ORD and principal contractors shall prepare one or more controlled documents that describe...internal and external organizational interfaces, organizational structures, and responsibilities.... Organization charts that clearly identify all OCRWM and principal contractor on-site and off-site organizational elements that function under the cognizance of the YMP QA Program shall be maintained.... The...M&O is currently the only principal contractor on the YMP.

      Because of the nature and importance of the work performed by the M&O and waste custodians on the YMP, the organizational relationships with ORD should be clearly depicted in OCRWM organization charts controlled under the DOE QA Program.

B. Enclosure 2, “BSC [Bechtal SAIC, LLC - M&O] Organization,” to DOE’s May 13, 2005, letter does not identify the organizational elements for the YMP or show the reporting relationships of those organizational elements. Enclosure 2 is controlled under the M&O QA Program in LP-1.0Q-BSC, “Organization.” Specifically, the M&O organization chart in Enclosure 2 shows only two organizational elements reporting to the General Manager; “Quality Assurance Manager” and “Line or Project Base Organization Managers.” Section 1.0, “Organization,” of the QARD, Revision 17, states that:

> The senior manager of the M&O organization is the General Manager. The General Manager is responsible for setting and implementing policies, expectations, and priorities to ensure that the functions being performed by the M&O are in accordance with the M&O QA program. Supporting the General Manager is an organization that is responsible for performing the design and construction of the geologic repository, including providing related support.

Because of the nature and importance of the work performed by the M&O on the YMP, the M&O organization chart, controlled under the M&O QA Program, should be expanded to clearly depict the organizational elements responsible for quality-affecting activities and show their relationships to the General Manager.

C. Enclosure 3 (untitled) to DOE’s May 13, 2005, letter relegates the QA organization to a minor organizational roll and the depicted organization chart in Enclosure 3 is not controlled under the M&O QA Program. Specifically, DOE obtained the organization chart depicted in Enclosure 3 from its intranet. The organization chart depicts seven organization elements with descriptions of their functions. However, the QA organization element is not among the seven organization elements depicted. Instead, the QA organization element is in a list of 12 other organization elements reporting to the General Manager. Section 1.0, “Organization,” of the QARD, Revision 17, states that:

> The M&O QA Manager reports directly to the M&O General Manager.... The M&O QA Manager...is sufficiently independent from cost and schedule when opposed to safety considerations...[and] has the organizational freedom to effectively communicate with other senior management positions.

Because of the nature and importance of the work performed by the M&O on the YMP and the relative importance of the QA organization element to the other M&O organizational elements, the M&O organization chart identified in Paragraph 1.B. above should be expanded to clearly depict the organizational elements responsible for quality-affecting activities, including the QA organization element, and their relationships with the General Manager and should be controlled under the M&O QA Program.

The NRC staff notes that DOE staff identified the issues described in Paragraphs 1.B. and 1.C. above in DOE Condition Report (CR) 5654 initiated on May 13, 2005.

2. On March 10, 2005, the NRC staff issued a summary of the February 10, 2005, TE. As documented in the March 10 summary DOE stated that "The term 'documentary evidence' has been removed from criterion 7, Table 1," of the QARD, Revision 17. The NRC staff notes that the correct reference in Table 1 regarding the removal of 'documentary evidence' is Item L. Therefore, the QARD, Revision 17, should be revised accordingly.

3. As documented in the March 10, 2005, summary of the February 10, 2005, TE, DOE stated that "The term 'site characterization' was eliminated since site characterization formally ended at the time of Site Recommendation." However, the NRC staff notes that DOE continues to perform activities associated with site characterization as defined in 10 CFR 63.2, "Definitions." Therefore, reference to site characterization should not be deleted from the QARD, Revision 17 (e.g., Sections 3.1B, 18.2.1A, III.2.4B, III.2.4C, and IV.1A.).

4. Table 1, Item 7, in the QARD, Revision 17, references Subsection 7.2.2D. The NRC staff notes that the correct reference should be Subsection 7.2.12B. Therefore, the QARD, Revision 17, should be revised accordingly.

For clarification, the March 10, 2005, summary of the February 10, 2005, TE states that "The proposed change...was to delete item G from [QARD] Section 3.2.6. That item currently states: 'Design changes [initiated after the construction authorization] shall be evaluated in accordance with 10 CFR 63.32 or 10 CFR 63.44.'" The NRC staff notes that, the "Introduction" section of the QARD, Revision 17, states that "The QARD establishes requirements for the YMP QA Program that meets the requirements of 10 CFR 63.142, 'Quality assurance criteria.'" In this regard, DOE commits to comply with the requirements of 10 CFR 63.142 when conducting quality-affecting activities. The NRC staff agrees that it may not be necessary to delineate the applicable regulatory requirements that must be met when conducting quality-affecting activities.