



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 1, 1998

Mr. Lake Barrett, Acting Director  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy  
RW-2, Room 5A-085  
1000 Independence Avenue, S.W.  
Washington, DC 20585

Dear Mr. Barrett:

Thank you for agreeing to meet with us promptly on May 6, 1998, to discuss the U.S. Nuclear Regulatory Commission (NRC) quality assurance (QA) concerns noted in the recent NRC On-Site Representative (OR) reports, as well as, the April 14, 1998, letter from the State of Nevada. The purpose of this letter is to document the agreements and commitments discussed at the May 6, 1998, meeting held at NRC Headquarters in Rockville, Maryland, between representatives of my staff and the U.S. Department of Energy (DOE).

As stated at the opening of the meeting, DOE's implementation of an effective QA program continues to be a top priority for the NRC. The DOE QA program was originally reviewed and found to meet the requirements of 10 CFR Part 50, Appendix B on May 2, 1989, and, as recently as March 16, 1998, the NRC accepted Revision 8 to the Quality Assurance Requirements Document (QARD). DOE is responsible for implementing its QA program at Yucca Mountain, and the NRC, both OR and Headquarters QA staff, monitor DOE's implementation of the program. The open items discussed in the March 16, 1998, OR report were identified as part of this process by review of information derived from DOE's QA audits. DOE's QA program is, therefore, capable of finding problems, but DOE needs to be more effective in preventing QA concerns from occurring and resolving problems in a timely manner. The NRC considers such a program, which is effective in finding and correcting quality problems, essential for DOE to prepare a high quality license application.

The NRC agrees with the DOE opening remarks stated at the beginning of the meeting that QA is important and should be a line responsibility in order to be effective. DOE also stated that they recognize issues are not being closed as quickly as they should be and there is room for improvement in this area. The following are the agenda items discussed at the meeting:

**LENGTH OF TIME TO CLOSE DEFICIENCIES (NRC OPEN ITEM 98-1):**

DOE's QA Director stated that although some deficiencies have taken long periods to close, this has had no impact on waste isolation or radiological safety since there is no nuclear material currently on site. DOE restated its intention of closing most deficiencies within a 12 month time frame. The line organization has added resources to assist in this effort. NRC management suggested that DOE consider defining a more specific goal of closing some percentage of the open items, for example 80%, within a shorter time period with only minimal items remaining open for 12 months. DOE indicated that it will consider such a provision. The NRC will be following the changes being considered by DOE regarding the closure of future issues. In addition, DOE indicated that they will also categorize those deficiencies open for more than one year based on their importance to safety and waste isolation and provide the results to NRC by June 15, 1998.

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**INCREASED DEFICIENCIES IN SCIENTIFIC NOTEBOOKS (NRC OPEN ITEM 98-2):**

DOE indicated that they are extremely concerned about the continuing QA issues regarding Scientific Notebooks (SNs). DOE indicated that they are currently reviewing active SNs for compliance with requirements. NRC management noted the repeated occurrence of errors in SNs and requested corrective action be effective to avoid future occurrences. NRC management also noted that when scientists at different organizations are writing procedures, there can be differences and perhaps inconsistent procedures. DOE replied that there is an effort underway to consolidate procedures that is planned to be in place by October 1, 1998.

**TRENDING PROGRAM:**

The NRC OR has followed the recent revisions to the trending program and has indicated that the revisions are favorable. DOE stated that this revised program could be completed and ready for implementation by June 1998. The NRC OR indicated that DOE, upon completion of the revised program, should schedule a presentation to the NRC.

**DOE QARD SUPPLEMENT I GUIDANCE (NRC OPEN ITEM 97-1):**

NRC noted that the clarification to statistical analysis in the DOE QARD was closed and no further discussion was needed.

**DEFICIENT SUPPLIERS-VALIDITY AND QUALITY OF SUPPLIER DATA (NRC OPEN ITEM 97-2):**

The subject of the validity and quality of supplier data and products from those suppliers whose programs had been found deficient as a result of DOE audits has been documented in two DOE Corrective Action Requests (CARs). DOE is currently investigating the overall impact upon the products produced by the respective suppliers. DOE indicated its evaluation will focus first on determining the significance for data to be used for licensing.

Next, NRC management reviewed examples from the NRC OR list of deficient suppliers and requested DOE to respond as to the product and potential impact the deficient supplier may have. The supplier product was listed on the OR list, but the actual impact can not be determined until the DOE evaluation is completed. NRC requested this discussion continue at the forthcoming management meeting being planned for early summer .

**DATA QUALIFICATION (NRC OPEN ITEM 96-1):**

NRC indicated that the agenda item on data qualification was closed for DOE purposes based on the NRC review of Revision 8 to the QARD. NRC is currently evaluating a question regarding cited literature as defined in NUREG-1298 and will be responding to DOE in the near future. DOE requested that data qualification, in general, and as it relates to the supplier issue, be discussed either at the next QA meeting or the upcoming NRC/DOE management meeting.

**LEVEL OF QUALITY OF WORK PRODUCTS (NRC OPEN ITEM 96-2):**

Of the four Deficiency Reports (DRs) originally covered by the NRC open item, only a portion of one DR currently remains open. In the meeting, NRC stated that the report to resolve the remaining portion of this open item had recently been received and was under review by the NRC staff. The document is a DOE Level 3 report which means the report has gone through a DOE acceptance review. DOE has accepted the report and Los Alamos National Laboratory

(LANL) is expected to publish the report in near future. However, when DOE gave NRC the report (after their acceptance review), they indicated that there were QA issues regarding some of the data sets referenced in the report. The DOE and NRC leads on volcanology have discussed the nature of these issues. DOE lead (T. Sullivan) informed NRC that DOE is working on a plan for qualifying these data sets. DOE expects this plan to be completed within the next few weeks and will make it available to the NRC as soon as its complete. However, until such time as these QA issues are resolved, the NRC will not be in a position to close this open item.

**LENGTH OF TIME TO ISSUE FY 98 CORRECTIVE ACTION REQUESTS:**

DOE explained that the extended length of time to issue three FY 1998 CARs, was due to the complexity of the associated issues. DOE stated that they will try to improve the time period for CAR issuance in the future. NRC management suggested that DOE consider specifying a time frame in which a CAR must be issued, similar to that suggested for closure of open items.

**SCP QUESTION 55/SP 8.3.1.5.2.2 COMMENTS:**

NRC explained that this issue was presented to DOE in September 1997. Since part of the information necessary to resolve this issue was information regarding the adequacy of scientific notebooks, this item will need to remain open until NRC Open Item 98-2 regarding increased deficiencies in scientific notebooks is resolved.

**GRADED QA:**

The NRC has recently issued for reactors draft Regulatory Guide DG-1064, "An Approach for Plant Specific, Risk Informed Decision Making: Graded Quality Assurance." The NRC OR is in the process of scheduling a meeting between the NRC author of the draft regulatory guidance, NRC High-Level Waste (HLW) representatives, and appropriate DOE representatives to discuss how graded QA guidance may be applied to the high-level waste program. The results of this meeting will be reported to the NRC HLW Management Board for further direction.

**UNSATURATED ZONE FLOW VERTICAL SLICE REPORT FINDINGS  
(NRC OPEN ITEM 98-3):**

The DOE line organization performed two vertical slices reviews in September 1997 through October 1997; and December 1997 through January 1998, to assess weaknesses in the documentation and traceability of the DOE's Performance Assessment process. NRC management was pleased to see the line organization perform two vertical slices and identify deficiencies. It is important that the line organization is identifying quality problems on its own. Due to the nature and substance of the findings, NRC requested a time frame in which they can review the plans to address these findings. DOE indicated they will be available in 30 to 60 days and possibly available for discussion at the NRC/DOE July Management meeting.

In summary, as stated during the meeting, DOE's implementation of an effective QA program continues to be a top priority for NRC and, as such, we are concerned about the number and type of deficiencies that have occurred recently. The repeated deficiencies regarding scientific notebooks are especially troubling and are not an acceptable trend. We expect DOE will

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address these concerns expeditiously and look for ways to close deficiencies in a timely manner.

I believe your participation at the May 6, 1998, NRC/DOE QA meeting indicates your personal commitment to ensuring the effectiveness of DOE's QA program and NRC looks forward to observing improvement in your process by both DOE's QA and line organizations to prevent and resolve QA concerns in a more timely fashion. Should you have any questions about this matter, please contact me or Dr. Michael Bell, Acting Branch Chief, Performance Assessment and High-Level Waste Integration Branch, at (301) 415-7286.

Sincerely,

[Original signed by:]  
John T. Greeves, Director  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards

cc: See attached list

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Thank you again for your prompt response to the NRC concerns and your personal participation at the May 6, 1998, NRC/DOE QA meeting. Should you have any questions about this matter, please contact me or Dr. Michael Bell, Acting Branch Chief, Performance Assessment and High-Level Waste Integration Branch, at (301) 415-7286.

Sincerely,

John T. Greeves, Director  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards

cc: See attached list

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Letter to L. Barrett from J. Greeves dated: June 1, 1998

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J. Meder, Nevada Legislative Counsel Bureau  
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N. Slater, DOE/Wash, DC  
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