SUMMARY OF SEPTEMBER 29, 2004
U.S. NUCLEAR REGULATORY COMMISSION AND U.S. DEPARTMENT OF ENERGY
QUARTERLY QUALITY ASSURANCE MEETING
Las Vegas, Nevada
September 29, 2004

Introduction:

Staff from the U.S. Nuclear Regulatory Commission (NRC) and the Office of Civilian Radioactive Waste Management (OCRWM), U.S. Department of Energy (DOE), held a public Quarterly Quality Assurance (QA) Meeting on September 29, 2004. The purpose of the meeting was to discuss the implementation of DOE's QA program regarding the geologic repository at Yucca Mountain, Nevada. During the meeting emphasis was placed on the DOE/RW-033P, Quality Assurance Requirements and Description (QARD), Revision 17. The meeting was held at the facilities of the DOE Management and Operations contractor, Bechtel SAIC Company, LLC (BSC), located in Las Vegas, Nevada, with videoconferencing provided for NRC Headquarters in Rockville, Maryland, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) in San Antonio, Texas. Those in attendance included representatives from the NRC, DOE, BSC, the State of Nevada, Clark County, industry, and members of the public. The list of attendees is Enclosure 1 to this meeting summary.

NRC staff clarified at the outset of the meeting that NRC was in its early stages of reviewing the QARD, Revision 17 and that none of the observations discussed or comments made at the meeting should be interpreted to indicate a complete review, acceptance, or any final decision regarding the QARD, Revision 17.

Presentations:

DOE and BSC staff made a series of presentations during the course of the QA meeting. The meeting agenda and presentations are Enclosures 2 and 3, respectively, to this meeting summary.

Quality Assurance Overview

Mr. R. Dennis Brown (DOE) presented an overview of the QA program. The overview consisted of discussion of Corrective Action Program (CAP) oversight, Level A Condition Reports, Office of Quality Assurance (OQA) audits and surveillances, activities related to DOE Environmental Management (EM), the Quality Assurance Management Policy (QAMP), trend evaluation and reporting, and human performance.

Revision 15 to the QARD was effective on August 13, 2004 and was accompanied by a revision to procedure AP-16.1Q, Condition Reporting and Resolution. The revision transferred ownership for Level C Condition Report (CR) processing from QA to the line organization. The QA organization still concurs on plans and verifies corrective action implementation for Level A and B CRs.

Both DOE and BSC QA organizations perform oversight of Level C CR processing. BSC QA currently reviews 100% of level C CRs processed by BSC, and OQA reviews 100 % of level C CRs processed by DOE. This oversight includes evaluation of the CRs for adequacy of the corrective action plan and implementation of the corrective actions. Review results are reported to BSC or DOE management, respectively. OQA also observes selected BSC QA oversight activities of CR processing. OQA is planning a surveillance and an audit of the CAP in Fiscal Year 05.

Mr. Michael Mason (BSC) reported briefly on BSC's oversight activities to date. In August 2004 BSC initiated transition plan activities that were included as part of the QARD, Revision 15. The intent of the oversight is to grade the line organizations on their implementation of handling the CAP for Level C CRs and to provide senior management feedback on performance. In September 2004 BSC closed approximately 16 Level C CRs. BSC identified some errors, primarily lack of definition and lack of detail.

There was some discussion in response to NRC questions of how levels are assigned to CRs and whether the levels can be changed. Levels are initially recommended by the CR initiator. The CAP screening team then assigns the level. Responsible managers can increase but not decrease the level of any CR without the agreement of the CAP screening team. A CR level can only be decreased by the CAP screening team or by the Management Review Committee (MRC). For QA-initiated CRs the CR level cannot be decreased without the concurrence of the CR initiator or the QA Manager or Director of OQA.

Mr. Brown noted that OQA is observing BSC QA surveillances, and the results show effective implementation of CAP by BSC. He also commented that OQA believes that the checklist that is being used by BSC QA to conduct their oversight is a very thorough approach that captures the requirements of procedure AP-16.1Q.

Presentation material included a listing of current Level A Condition Reports (CRs). Ongoing reviews of modeling relevant to CR-099 were discussed. There are 16 Analysis Model Reports (AMRs) required for review, with another 18 AMR's selected to review. Of these 34 AMRs, three have been evaluated and determined to be satisfactory. Another eight AMRs are in review at this time. DOE technical staff is assisting in AMR review efforts. In response to questions from Mr. Robert Latta (NRC) as to whether any problems were being found, Mr. Brown indicated that one or two AMRs might have problems; one AMR in particular is being discussed in more detail at this time during the conduct of the review. Mr. Latta asked if OQA had established acceptance criteria for the verification activities related to CR-099. Mr. Brown indicated that OQA would evaluate the number of AMRs that did not satisfy the verification process, on a case-by-case basis, and determine if an increased AMR sample size is necessary.

CR-1720 involved contracting authority. Specifically, a contract to design a welding machine for the qualification of the waste package closure weld was subcontracted to Idaho National Environmental Engineering Laboratory. DOE considers the work to be non-quality, and evaluations of the technical nature of the work demonstrate that it was completed satisfactorily. However, CR-1720 questioned whether the subcontracting

was done appropriately in accordance with procurement requirements. Mr. Latta asked if CR-1720 was self-identified; Mr. Brown confirmed that the condition was not self-identified and that an OQA Surveillance team wrote the CR.

Mr. Mason discussed CR-3235 (initiated as a Level A CR). It was later divided into three CRs. The portion of CR-3235 that was retained in the initial CR is still a Level A and primarily concerns the checking process. The root cause determination is nearly complete and senior management is validating the recommended corrective actions at this time. Since the report has not yet been issued, discussion of causes is premature at this time. In response to NRC questions, it was indicated that the root cause charter broadly encompassed the checking work process.

The presentation also included a discussion of completed, in progress, and planned audits and surveillances (including EM audits). Mr. Brown noted that although the viewgraphs indicate the Desktop Audit of Office of River Protection High Level Waste is complete, the audit is still in progress. In response to a question from Mr. Thomas Matula (NRC), it was noted that the EM audits are all compliance based audits.

Mr. Brown briefly discussed the QAMP which identifies the OCRWM approach to managing the quality of items and activities to meet the varied regulatory requirements and the various types of items and activities involved.

The QAMP is the upper tier DOE document that establishes the overall management policy for the QARD, the Augmented QA Program (AQAP) and the Cask Manufacturing QA Program (CQAP). In response to questions from Mr. Wes Patrick (CNWRA), Mr. Brown confirmed that the CQAP covers 10 CFR Part 71 requirements and deals strictly with transportation. Other activities fall under either the AQAP or QARD.

Mr. Mason discussed the most recent trend report covering the period April through June 2004. There have been about 42 CRs initiated per month for the past 12 months with an increase in the number of self-identified items. There is an adverse trend related to the Project Requirements Document for which actions are addressed in CR-2343. Plans are underway to conduct a self-assessment on trend reporting. Mr. Latta questioned why CR-2343, which identified 31 CRs concerning the flow-down of requirements into implementing procedures, was not characterized as a Level A. Mr. Mason said that this was a judgment call on the part of the CAP screening team chairman.

Mr. Mason also discussed the human performance areas, to which approximately 51 percent of causal factors for CRs are attributed. A substantial human performance improvement activity is underway that is anticipated to take approximately two years to implement. Workshops have been initiated and a human performance team has been formed. A Management Directive (GM-BC-14) has been written and a human performance improvement plan drafted. The NRC and the CNWRA both had general questions regarding the approach and how organizational factors are included in the plan. Mr. Matula requested that human performance activities be discussed at the next NRC/DOE Management Meeting.

Development of QARD, Revision 17

Mr. Mike Ulshafer (DOE) discussed the context of recent QARD revisions: Revision 14 that reflected Office of Repository Development (ORD) Organizational Realignment; Revision 15 that allowed for line ownership of the CAP and addressed the applicability of items important to safety and important to waste isolation; and Revision 16 which realigned OQA to report to ORD.

Mr. Ulshafer presented the development of QARD, Revision 17 and its purpose. The QARD, Revision 17 is the Yucca Mountain Project's QA Program that meets the regulatory requirements of 10 CFR 63.142, "Quality assurance criteria," and addresses the acceptance criteria of NUREG 1804, "Yucca Mountain Review Plan," Section 2.5.1, "Quality Assurance Program," with some exceptions, alternatives, and clarifications. DOE intends that the QARD, Revision 17 will serve as Yucca Mountain Project's QA Program up to time of receipt of license to receive and possess and stated that is similar to previous NRC accepted QARD revisions in the level of detail and the description of programs and processes. QARD, Revision 17 development activities included preparation of requirements matrices, technical product impact analysis, and internal and external reviews and comment resolution.

Regulatory basis changes in QARD, Revision 17 include the transition from the requirements of 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR 63.142 and from the 1989 Review Plan to NUREG-1804 (for which requirements are similar). Revision 17 also reflects industry consensus standards on level of detail and approach to QA programs and adoption of a number of specific Regulatory Guides and standards. The QARD continues to provide the QA controls for scientific investigation including data, models, and software in specific supplements

Notable program/process changes in QARD Revision 17 include the treatment of software, commercial grade dedication, electronic records, allowance for principal contractors to implement their own specific QA program, and the addition of a waste generator clarification statement.

Public Comments

At this point in the meeting, public comments were sought to accommodate the schedules of members of the public.

Mr. von Tiesenhausen of Clark County asked about the Total System Performance Assessment (TSPA) audit that DOE deferred and whether it had been rescheduled. Mr. Brown confirmed that the TSPA audit had been deferred and would be rescheduled for early 2005. DOE conducted an independent internal assessment of the TSPA during September 2004. Mr. von Tiesenhausen asked if the TSPA assessment had been observed by the NRC, and Mr. Brown responded the assessment was strictly internal and that it had not been observed by the NRC.

Exceptions/Alternatives

Messrs. Warren Dorman and Ed Opelski (DOE), and Jim Schmit (Navarro Quality Services (NQS)) led a presentation and discussion of Table 1A, "Regulatory/ Commitment Document Positions With Justification," submitted to the NRC with QARD, Revision 17. This discussion overlapped the later general discussion of NRC staff's preliminary review observations to some extent. (To the extent that there was such overlap, the individual issues are summarized in only one place in this meeting summary.) Many of the items were discussed in some detail with questions from the NRC and CNWRA and responses from OQA, NQS, and BSC personnel, primarily in clarifying the information, rationale, and justification contained in Table 1A.

Alternative record retention approaches were discussed based on the requirements of 36 CFR 12 which meet or exceed the records retention requirements covered by industry standards.

It was discussed that, as a group, audit team members have required qualifications covering the technical area of expertise needed for the audit in lieu of requirements for team leaders and team members to be individually qualified with regard to such technical expertise. It was clarified that qualifications as an auditor will be uniformly applied.

There was a question regarding why scientific investigations are still being included in the QARD, Revision 17. DOE responded, although there may be a smaller role for scientific investigations going forward, scientific investigations will continue as part of ongoing program work. In addition, there are activities covered by scientific investigations as part of the Performance Confirmation program.

Preliminary NRC QARD, Revision 17 Review Observation

Eleven broad areas were discussed where the NRC had preliminary questions in a number of areas: 1) general; 2) organization; 3) changes to the QARD; 4) interagency agreements; 5) training; 6) procurement; 7) 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 8) records; 9) inspections and audits; 10) personnel independence; and 11) corrective actions. Following are a few of the approximately 50 preliminary observations discussed by the NRC.

The NRC remarked on the lack of a detailed change history, and DOE explained that the individual change history will continue to be a part of the QARD and the records package for the document. The comprehensive version of the change history was eliminated due to its size.

NRC asked why an exception was being taken to identification of special processes. DOE stated that this exception is not needed. In addition, NRC inquired about the reasons and rationale for not including potential sources of test uncertainty and error. DOE replied that there is not a requirement that potential sources for error and test uncertainty be included in test planning.

In the organizational area, the NRC observed that lines of authority were not sufficiently clear in the absence of an organizational chart. DOE indicated that additional text description discussing the lines of authority can be added to the document.

The NRC questioned if interagency agreements were considered to be requirements. DOE responded that there will be interagency agreements but they are not QARD requirements. Those parts of the QARD should be considered to be statements and not requirements.

At least 10 sections of QARD, Revision 17 refer to Section 2.2.11 for personnel training, indoctrination, qualification, and certification requirements. The NRC inquired how section 2.2.11 is implemented. The QARD, Revision 17 identified a Training Plan, and the NRC is interested in more detail. DOE indicated that this would be an area needing future followup. The NRC was also interested in why verification of education and experience (VoEE) is not included in the QARD. DOE stated it is not the standard practice in the nuclear industry to call out VoEE in QA programs. However, VoEE is a good business practice and one that is carried out appropriately at YMP. Contractors must assure that each person being hired has adequate experience and education for their assigned responsibilities.

The NRC wanted additional information on procurement policies and how the NRC document SECY-03-117, “Approaches for Adopting More Widely Accepted International Quality Stnadards,” was being applied. DOE discussed that SECY-03-117 provides a basis for using ISO 9000 suppliers provided two additional criteria from Appendix B are specified in addition to ISO 9000 requirements. DOE agreed that this issue and the applicability of SECY-03-117 needed further discussion. The NRC also asked for a rationale regarding why commercial grade procurement is not called out in the QARD. DOE explained that commercial grade procurement is considered a “non-Quality” activity and does not need to be called out in the QARD, however, the dedication of commercial grade items is a “Quality” activity and is described in the QARD.

It was questioned why 10 CFR Part 21 requirements are not explicitly called out in the QARD. Although 10 CFR Part 21 is a regulation and does not need to be called out separately, DOE agreed that 10 CFR Part 21 flow down through procurement documents should be added to the QARD.

It was clarified during discussions that only properly certified inspectors are allowed to perform inspections.

NRC requested that DOE provide the independence requirements for personnel, other than QA, who perform verification activities. DOE clarified that this can be anyone (with appropriate qualifications) who did not perform the work.

The NRC inquired about the criteria to preclude recurrence of deficiencies. The QARD includes the requirement, but does not describe it. DOE very briefly discussed that detailed criteria are not practical due to the wide range of potential corrective actions. However, root causes are determined and corrective actions assigned by management to address the root causes. Management then uses those recommendations to

determine what actual corrective actions to implement. DOE will review the text and make sure the level of detail is consistent with other NRC approved QA programs.

Closing Remarks

An additional opportunity was extended for public comments at this time, but there were no further public comments or questions.

In closing remarks by the NRC, Mr. Matula stated the QA meeting was productive and the early impression on the NRC review team regarding QARD, Revision 17 is it appears to be basically a good document, but that their review was incomplete and at an early stage.

Mr. Elmo Collins (NRC) further reiterated that activities and NRC comments and questions at the meeting related to the QARD, Revision 17 should be kept in the context that the NRC was at an early stage in their review. None of the comments or discussions should be interpreted as reflecting a final NRC position regarding acceptance or completeness of the review.

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