**SUMMARY OF U.S. NUCLEAR REGULATORY COMMISSION (NRC) /
U.S. DEPARTMENT OF ENERGY (DOE) QUARTERLY QUALITY ASSURANCE
MEETING ON NOVEMBER 12, 2003
LAS VEGAS, NEVADA**

Introduction:

The U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Energy (DOE) held a public Quarterly Quality Assurance (QA) Meeting regarding the Yucca Mountain Project (YMP) on November 12, 2003. The meeting was held at the DOE office in Las Vegas, Nevada, and via video teleconference to the NRC office in Rockville, Maryland, and to the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas. Participants in the meeting included representatives from the NRC, DOE, Bechtel SAIC Company, LLC (BSC), the State of Nevada, Clark and Lincoln Counties, and members of the public. Copies of the agenda and a list of attendees are Enclosures 1 and 2, respectively.

Presentations:

DOE and BSC personnel made a series of presentations during the course of the QA meeting as described below. A copy of the presentations is Enclosure 3 to this meeting summary.

Dennis Brown (DOE) presented an overview of the DOE QA program. During his presentation, Mr. Brown discussed improvements in the QA program, and assessments and surveillances performed since the last quarterly QA meeting, which was held on July 15, 2003.

Some of the improvements in the QA program that Mr. Brown discussed included: (1) increased senior management involvement in QA program accountability through, among other things, off-site management meetings and Monthly Operating Reviews; (2) increased line management involvement through implementation of a single point entry corrective action program; (3) an increased percentage of self-identified Condition Reports (CRs); (4) the further development of performance indicators; (5) development and implementation of an updated corrective action program; and (6) the development and implementation of an improved trending program. Mr. Brown reported that BSC performed 18 internal surveillances and 7 supplier surveillances, and DOE performed 3 internal surveillances during the past four months.

Michael Mason, BSC, outlined some of the noteworthy practices which included the development of causal analysis training, a causal analysis handbook, QA performance indicators, quality engineering checklists, quality engineering handbook, and a QA training needs matrix. Thomas Matula, NRC, asked for additional information regarding the causal analysis training and how BSC determines the accuracy of the assigned cause codes. Mr. Mason stated that approximately 150 BSC staff, from all disciplines, were trained in the proper use of the new causal analysis tree and how to assign cause codes. He said that a Screening Team, comprised of senior level people, review assigned cause codes to assure consistency. Robert Latta, NRC, added that the Screening Team is performing this quality affecting review process without a procedure and that there were no specific training or qualification criteria for the members. Mr. Mason stated that the team performs their review of cause codes based on their extensive experience. Mr. Matula stated that causal analysis is a

very important quality-affecting activity and requested that additional information regarding the screening process be provided by the next quarterly QA meeting. At this point, Susan Lynch, State of Nevada, asked who has the final authority for causal code identification and how those decisions are documented. Mr. Mason responded by saying that such disagreements are brought to senior management's attention for review and decision, but that the process is not currently documented.

Jean Younker, BSC, provided information regarding the model validation process. Ms. Younker said that the Office of Quality Assurance (OQA) initiated Corrective Action Report (CAR) BSC-01-C-001 because the process for controlling model development had been less than adequate and that BSC's November 2001, independent review results categorized the validation of 87 percent of models as less than adequate. Ms. Younker described corrective actions taken by BSC regarding upgrading the procedure AP-SIII.10Q for modeling to include incorporating explicit methods and criteria for model validation. BSC established an independent model validation overview function, trained more than 500 staff in the new modeling process, and developed metrics to evaluate the effectiveness of model development. A sample of models was reviewed during the DOE/OQA verification activities in October 2003, to determine the effectiveness of the corrective action that BSC took regarding the model development. During that audit, the audit team found 75 percent of the models reviewed to be substantially improved. Mr. Matula questioned the effectiveness of the corrective action because DOE/OQA found validation problems with 25 percent of the models. At this point, Ms. Lynch stated that identifying that 4 models were inadequate shows a continuing problem. Ms. Lynch also observed that DOE has had continuing problems in procedural compliance since 1989. Ms. Lynch then stated that DOE's QA program is still broken and that DOE is having the same problems with the same people. Mr. Brown responded to Ms. Lynch by stating that DOE will not submit a licence application if the codes are not qualified, the data are not qualified, and the models are not properly validated.

Mr. Brown discussed the results of the Model Audit performed on October 21-31, 2003. The audit was led by the OQA and was comprised of 14 members. The scope of audit included processes and related Analysis Model Reports (AMRs) that support License Application (LA). The results of the audit showed that requirements flow-down to procedures was adequate but that procedure implementation was unsatisfactory.

Michael Jaeger, BSC, provided information about CAR BSC(B)-03-107 and the management of data. Mr. Jaeger said that BSC initiated the CAR because of ineffective corrective actions found regarding data issues. The root cause analysis identified that the BSC management team was not held accountable for assuring effectiveness of corrective actions, a timely and effective corrective action program was not established, data management and usage was not performed in a consistent and compliant manner, and data requirements were not adequately defined.

Mr. Jaeger also provided a summary of corrective actions for CAR BSC(B)-03-107 which included the implementation of a Data Confirmation Project. Phase I in this project involves review of citation of data inputs and completion of document input, reference systems entries, and content correction for cited Data Tracking Numbers (DTNs). Phase II in this project involves the review of data suitability for intended use in Analysis Model Reports and completion of remediation plans. During the execution of this project, the applicable data

procedure was updated and management accountability was emphasized. Mr. Matula stated that this CAR has been open for more than 200 days and asked for the anticipated completion date. Mr. Jaeger indicated that the corrective actions are substantially complete and will be reviewed in January 2004.

Mr. Jaeger presented some metrics for the Data Confirmation Project. Approximately 130 AMRs support LA; 95 (73 percent) products have completed Phase I review; 10 (8 percent) products have completed Phase II review; and 10 (8 percent) product remediation plans are completed. Approximately 1,352 data sets support LA products; 689 data sets are fully qualified and verified; 453 data sets need either qualification, Records Roadmap Verification, or further evaluation. Ms. Younker added that the data checking portion of the Data Confirmation Project has been integrated into the data development process and that newly developed data will be confirmed.

Mr. Matula mentioned that the root cause evaluation for CAR BSC(B)-03-107, completed in September 4, 2003, states that "Accountability for following procedures was not implemented" and that "Management was not held accountable for assuring corrective actions." It is understood that DOE is verifying the data used in the license application. However, Mr. Matula asked how DOE will address these behavior-based issues to achieve consistent implementation of requirements. Mr. Brown responded by saying accountability issues are being addressed by recent senior management initiatives that involve the corrective action process, and that personnel will be held accountable for their actions through the performance evaluation process.

Mr. Brown discussed the results of the data audit which was performed on September 8-19, 2003. OQA led the integrated audit team comprised of 9 members. The audit team focused on technical product input related to LA models and analyses. The audit results showed the data process was adequate and effective, but procedure compliance was unsatisfactory. As a result of this audit, DOE initiated 12 Condition Reports (CRs). Mr. Matula observed that the DOE audit team determined that, overall, performance is unsatisfactory in technical product input, control, and selection, and that procedure compliance related to data input and development was unsatisfactory. Mr. Matula suggested this is indicative of ineffective corrective actions and behavior-based issues related to procedure implementation. Mr. Matula asked how DOE will address behavior-based issues to achieve consistent implementation of requirements. Mr. Brown again emphasized that accountability issues are being addressed by senior management through the corrective action process, and that all personnel will be held accountable for their actions through the performance evaluation process. Mr. Brown added that the behavior-based issues will be discussed during the Quarterly Management Meeting scheduled for November 13, 2003.

Richard Atkisson, BSC, discussed CAR BSC-01-C-002, which involved ineffective implementation of software QA management requirements. The corrective actions taken by BSC include revising and developing procedures, emphasizing training and complying with procedures, and implementing management improvement activities. OQA verified corrective action and found that BSC completed 23 of 28 actions satisfactorily. Five actions were judged to be unsatisfactory. As a result of a software performance-based audit conducted in June 2003, DOE confirmed the need for software development procedure changes.

Mr. Brown discussed the results of the OQA June 3-13, 2003, software audit. During that audit, OQA found that software procedures and processes was adequate, implementation of software procedures was marginally satisfactory, and software processes were marginally effective. However, OQA identified 8 Conditions Adverse to Quality during the audit. Mr. Matula noted that the DOE audit team found that the critical elements of software design, implementation, and testing were "Not Effective" or "Indeterminate," and indicated that the overall results of the software process could easily be marginally ineffective rather than marginally effective. Mr. Matula suggested that DOE investigate whether there is a bigger problem in the areas of software design, implementation, and testing. Mr. Brown said that DOE will consider this in future audits of software. Mr. Atkisson stated that DOE initiated CRs 177, 178, and 179 regarding the software design, implementation, and testing problems identified during the software audit. Mr. Latta indicated that these issues appear to be repetitive in nature and indicative of ineffective corrective action.

Mr. Brown discussed the use of unqualified software to generate preliminary data feeds. He stated that the Quality Assurance Requirements and Description (QARD), Section 1.2.4, requires that "Software shall not be used in activities identified under Section 2.2.2 or 2.2.3 (i.e., quality-affecting activities) of this document unless it is obtained, and limited to received copies, from software configuration management." Mr. Matula emphasized that the primary issue is BSC used unqualified software to generate preliminary data feeds to other AMRs prior to approval of the AMRs. Mr. Brown responded by saying that in the area of data, to the extent that BSC is using unqualified data in AMRs, any unqualified data would be qualified before submittal of the LA. He further stated that he has the authority to interpret quality assurance requirements in the QARD to allow the use of unqualified software to generate preliminary data feeds in the same way, in that unqualified software can be used if the software is qualified before LA. Mr. Matula stated that in the BSC Management Directed Software Stand-Down, November 16, 2001, signed by Nancy Williams, BSC Manager of Projects, it states that "The provision in AP-SI.1Q for the interim use of unqualified software was limited to those that support site recommendation products. This means that all software which supports an LA product must be qualified before any of the output from the software can be produced for use in an LA supporting document." Mr. Latta expressed a concern that the deficiency related to the use of unqualified software has remained open for over 4 months. Mr. Latta stated that procedure AP-SI-1.Q, "Software Management", requires that "Software items subject to QARD requirements cannot be used in quality affecting activities prior to the software being baselined and qualified." Additionally, Mr. Campbell, NRC, indicated that unlike the use of unqualified data, for which specific QARD controls were established prior to its use in quality affecting activities, no such provisions have been established by DOE and accepted by the NRC for the use of unqualified software. Therefore, the projects "use" of unqualified software to generate primary data feeds to other technical products would not only require a documented interpretation of the quality requirements but an accepted change, reflecting a reduction in commitments, to the existing process controls specified in the QARD. Mr. Brown indicated that he will provide his interpretation of the QARD requirements to the NRC Onsite Representatives (ORs) in the next few weeks.

Ms. Williams emphasized that neither data confirmation activities nor the legacy software verification have resulted in a technical issue requiring a revision to an AMR. Problems identified are related to traceability, transparency, and defensibility of the data and software qualification processes.

Mr. Mason discussed the status of CAR BSC(O)-03-C-097 regarding procedure implementation. BSC's procedure on the development of procedures was not developed satisfactorily in accordance with procedure AP-5.1Q, Procedure Preparation, Review and Approval. The corrective actions included streamlining procedure AP-5.1Q, placing more responsibility on line management, conducting "Rolling Quality Focus Meetings" to emphasize the importance of Compliance with Procedures, and assigning subject matter experts for each procedure. DOE verified corrective action results on July 31, 2003, lifted the Stop Work Order, and closed the CAR on August 18, 2003. Mr. Latta noted that the root cause analysis for CAR-BSC(O)-03-C-097 determined that the identified deficiencies were the result of deliberate noncompliance with procedural controls which was indirectly tied to perceived schedule pressure. Accordingly, Mr. Matula stated that this represented another instance of failure to follow procedures and emphasized the need for holding individuals accountable for their actions.

Mr. Mason discussed CAR BSC-02-C-001 regarding training and qualification of technical staff. BSC found that in some cases the Training Organization did not develop or provide the Training Requirements Matrix/Job Function. Further, there was no Verification of Education and Experience (VoEE) for some subcontractor personnel, and training requirements were not identified for some subcontractor personnel. Mr. Mason reported that the corrective actions are complete and subcontractors now have training assignments, VoEE records have been generated, and the process is in place to ensure that subcontractor personnel receive training. Mr. Mason stated that CAR BSC-02-C-001 was closed on October 9, 2003. During the investigation, it was noted that not a single incident was identified in which the individual performing a task was not qualified to perform that task. Mr. Matula questioned why it took over 670 days to address the training and qualification issues that were identified in this CAR. Mr. Mason stated that several issues impacted the resolution of this activity, including the time required to check the records of the large number of personnel working on the project and the closure of related deficiency reports.

Mr. Mason discussed CR-756 regarding quality requirements flow-down. The CR was initiated on October 1, 2003, because a review of CRs from Fiscal Years 2002 and 2003 identified a number of instances where QARD requirements did not properly flow-down to implementing documents. A total of 12 CRs were initiated and 20 procedures were affected. BSC evaluated the CRs and found that the issue does not represent a Significant Condition Adverse to Quality. Flow-down issues identified represented approximately 1 percent of the QARD requirements in procedures reviewed, and there is no impact on quality. Mr. Brown also stated that the process of verification of requirements flowdown would be evaluated by OQA during a compliance-based audit scheduled for the week of November 17, 2003.

Mr. Brown discussed the status of the DOE audits of Environmental Management (EM) High-Level Waste (HLW) activities at Hanford and Savannah River. The DOE Office of Civilian Radioactive Waste Management (OCRWM) was not able to perform its required annual audits of EM HLW activities at Hanford and Savannah River which resulted in the initiation of CR-97. In the past, OCRWM performed audits of the EM Headquarters (HQ) QA oversight function and EM HQ performed direct oversight of HLW sites. However, elimination of the EM HQ QA

oversight function left OCRWM with no established interface to audit the HLW sites. This issue was first identified in Deficiency Report DR-EM-01-D-89, which noted that reorganization and policy decisions within EM resulted in the elimination of the EM HQ HLW QA oversight function.

Mr. Brown said that DOE will update interfaces and document them in a joint EM/RW memorandum which will be supplemented by an oversight procedure. DOE oversight of waste sites will be performed jointly by EM HQ and OCRWM staff beginning in approximately January 2004. Mr. Matula asked why DOE allowed EM to continue performing important-to-safety and quality-affecting activities without determining the status of their QA program implementation through required audits. Mr. Brown said that he was assured by EM management that their QA program was fully implemented and effective. Mr. Matula asked DOE to report its findings of the upcoming audits at Hanford and Savannah River at the next Quarterly QA Meeting

Mr. Brown discussed the new DOE Corrective Action Program (CAP). Improvements noted included: (1) CAP is a single entry point process; (2) Condition Reports, Nonconformance Report, Technical Error Report, and Condition/Issue Identification and Reporting/Resolution System processes are now merged into one process; (3) open items from merged databases have been migrated into the CAP; (4) causal analysis process is improved; (5) CAP procedure was revised to apply more rigor to causal analysis process; (6) apparent cause and root cause training was conducted; (7) corrective action plan development process was improved; (8) applicable procedures were revised to include guidance on corrective action plan development; and (9) causal training includes development of corrective action plans. DOE and BSC now identify issues in one of four Levels of Significance with Level A being Significant Adverse Condition; Level B being Adverse Condition; Level C being Minor Adverse Condition; or Level D being an Opportunity for Improvement. Mr. Brown stated that DOE will monitor the effectiveness of the CAP and evaluate the process enhancements. Mr. Matula inquired how DOE determines the effectiveness of corrective actions taken by DOE and BSC. Mr. Brown stated that one of the features of the trending program is to provide information regarding ineffective corrective action and recurring issues.

Michael Ulshafer, DOE, discussed QA program performance indicators and stated that the indicators are quantitative versus subjective. Supporting indicator data is available project wide, and indicator data feeds are updated monthly. Level 1 performance indicators pertain to the QA program and problem identification and resolution. Level 1 indicators are fed by Level 2 and Level 3 indicators which are weighted to feed next level up indicators. Mr. Ulshafer said that some of the indicators are currently weighted “0" until related data can be obtained and the performance indicators will continue to evolve.

Mr. Mason discussed Trending Program improvements and stated that the QARD requires that “Reports of nonconformances and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes, and that trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends.” Procedure AP-16.3Q, Trend Evaluation and Reporting, was revised and the process was changed to focus on trend evaluation and analysis through resolution of identified adverse trends. DOE has implemented uniform cause codes, new criteria, and processes for identifying repetitive problems and trends. Adverse and emerging trends are now documented in the corrective action system to track associated actions. A Causal Analysis Handbook has

also been developed to support the new causal analysis process, and improved training on causal analysis and root cause analysis process has been conducted to improve cause identification and subsequent coding. The electronic tracking system has improved capability for supporting the trend evaluation process, and new software has been purchased and is being deployed to aid real-time identification of emerging trends. Senior management will be briefed on trend results and recommended actions to address adverse trends. Mr. Matula asked how DOE will determine the effectiveness of root cause analysis performed by staff. Mr. Mason said that he will make that determination and report the results at the next Quarterly QA Meeting. Mr. Matula asked if recently identified issues, which indicate ineffective corrective action, are recorded as such in the Trending Program and trended. Mr. Mason stated that the Trending Program has this capability and that he will verify that this type of trending is being performed. The results will be reported at the next Quarterly QA Meeting.

Mr. Ulshafer discussed the in-process revision of the QARD and stated that the revision will incorporate the requirements of 10 CFR 63, Subpart G, Quality Assurance, and the guidance in NUREG 1804, Yucca Mountain Review Plan. He stated that the revision process is expected to be completed by DOE by the 2nd Quarter of Fiscal Year 2004.

Carl Weber, DOE, discussed the results of compliance audit of OQAP-BSC-03-13. OQA conducted this audit on September 22-26, 2003, to determine BSC's compliance with implementing procedures and the effectiveness of corrective actions related to closed deficiency documents. The audit team identified 13 Conditions Adverse to Quality (CAQ) and concluded that BSC was effective in its implementation of the QA Program. Mr. Latta asked if the cumulative impact of these CAQs had been evaluated for a pattern of inattention to detail or the lack of management support. Mr. Brown stated that all 13 of the CAQs have been evaluated and were considered isolated and/or minor in nature, and none appeared to impact technical work.

Public Comments:

Mr. Frishman, State of Nevada, requested that NRC be prepared to discuss at the NRC/DOE Quarterly Management meeting scheduled for November 13, 2003, why the upcoming NRC technical evaluation is closed to observation by the state and local government representatives. Mr. Frishman stated that he believed this was a departure from the long-standing protocol for participation in DOE and NRC interactions.

Closing Remarks:

In his closing remarks, Mr. Matula thanked DOE and BSC for their efforts in preparing and conducting the Quarterly QA Meeting. The meeting was informative and productive, however, Mr. Matula observed that, on several occasions during the meeting, DOE and BSC discussed issues that were recurrences of previously identified deficiencies which are indicative of ineffective corrective action. In addition, several times during the meeting, Mr. Matula expressed concern regarding issues identified by DOE and BSC that are attributed to failure to follow procedures, and the associated issue regarding personnel accountability. Therefore, areas of concern related to ineffective corrective actions and behavior-based issues were discussed at the November 13, 2003, NRC/DOE Management Meeting.

Mr. Brown commented that the meeting provided a valuable interaction on a working level. He stated that DOE recognizes that there are areas of the Project that need further improvement, and we are not yet where we need to be in several quality areas. However, there is evidence that significant progress is being made, and the Project is moving in the right direction. Mr. Brown reiterated from earlier discussions that the problems discussed did not represent any technical issues impacting conclusions or requiring revision to technical basis documents, and asked NRC if they agreed. Mr. Matula stated that NRC considers that DOE is headed in the right direction but that implementation is the key.

Timothy Gunter's (DOE) review of past open action items led to agreement that the remaining four are closed. Nine new action items were identified as indicated in Enclosure 4 to this Meeting Summary.

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