

SUMMARY OF MAY 4, 2004
U.S. NUCLEAR REGULATORY COMMISSION/U.S. DEPARTMENT OF ENERGY
QUARTERLY QUALITY ASSURANCE MEETING
Las Vegas, Nevada

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 May 4, 2004. The purpose of the meeting was to discuss the implementation of DOE's QA program regarding the geologic repository at Yucca Mountain, Nevada. 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, and members of the public. The list of attendees is Enclosure 1 to this meeting summary.

Presentations:

Staff from the DOE and BSC 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 reviewing an Office of Repository Development (ORD) organization chart, a graph highlighting condition reports (CRs) identified by line organizations; and charts showing positive trends in areas such as adequacy of QA requirements in implementing documents, adequacy of process in QA procedures, acceptable corrective action plans, successful verification of CR closure, and open/closed CR's. The slides he presented depicted the number of Quality Assurance Requirements and Description (QARD)-related CR's being identified by the line organization, the number of corrective action plans approved the first time through and verification activities for CR closure. Mr. Brown provided a status of the QARD revisions indicating that DOE approved QARD Revision 14 on April 1, 2004, and submitted Revision 15 to the NRC on April 30, 2004. The next revision of the QARD will incorporate 10 CFR 63, Subpart G, requirements and will address guidance criteria in NUREG-1804, "Yucca Mountain Review Plan." He also noted that Corrective Action Reports (CAR) 002 regarding "Software Qualification and Development Activities" and CAR 007 regarding "Data Management" have been closed, and that DOE will attempt to close CAR 001 regarding "Model Validation" by August 2004.

Mr. Brown summarized his presentation with a brief discussion of the Corrective Action Program (CAP); performance based audits, and the Regulatory Integration Team (RIT). Mr. Brown briefly mentioned the joint audits being conducted with DOE, Environmental Management (EM) on the Spent Nuclear Fuels (SNF) and High Level Waste (HLW) work. Mr. Brown concluded by stating that QA would be involved in Phase 1 and Phase 2 of the RIT activities.

The NRC questioned Mr. Brown regarding QA oversight and procedure stability. Mr. Brown responded that QA oversight of quality affecting activities will continue and that the number of identified QA procedure inadequacies have stabilized. The NRC specifically asked if BSC QA was considered a line organization or if BSC Quality Engineers (QEs) were considered a part of a line organization. DOE responded that BSC QA was not considered a line organization and that BSC QEs were not considered a part of the line organization, but are part of the BSC QA organization. The NRC requested clarification of the percentage of CRs issued by the line

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organizations. The response was the CRs issued by the line organizations were approximately 85% of the total number of CRs identified.

Mr. Michael Mason (BSC) highlighted recent noteworthy practices by the Project such as the development of trending training, a trending and analysis handbook, and an auditor's handbook.

The NRC questioned DOE regarding the transition plan for the Corrective Action Program (CAP). The NRC specifically asked if the transition plan was addressed in the QARD submittal, and who the point of contact was for the transition plan. DOE and BSC responded that the transition plan was addressed in the QARD submittal, and Mr. Mike Ulshafer was the point of contact for questions that may arise during NRC's review. The NRC requested an update on the transition at the next quarterly meeting.

Corrective Action Program

At the beginning of the CAP presentation, Messrs. Dick Spence (DOE) and Mike Carmichael (BSC) highlighted organizational changes related to the CAP. Mr. Carmichael discussed the objectives of the CAP enhancements such as improving software system usability, increasing line organizations' ability to manage their corrective action scope, simplifying the process for low significance issues, and refining metrics. Near term and long term enhancements include additional training for managers and supervisors on CAP, subsequent rollout to the workforce, and issuing a CAP users guide to assist personnel with computer manipulations. Mr. Carmichael also presented an overview of CAP significance levels and ways to measure program effectiveness.

The NRC asked what goals the DOE had in mind to consider this program successful. Mr. Carmichael responded that removing unnecessary steps was one goal. This would improve the system so that it would not be so cumbersome for the user. The NRC also requested an explanation of how the ability of the line organization to manage its corrective action scope would be enhanced. Mr. Carmichael responded that DOE has encouraged feedback from CAP users and improved CAP reports and information access. The Safety Conscious Work Environment (SCWE) program has also encouraged feedback. The NRC asked about the current level of user frustration in using the CAP. Ms. Peggy McCullough (BSC) responded that the amount of effort required to fix a minor problem has been a frustration. In her response she also stated that the CAP has received positive feedback from users after changes were made. The NRC asked about the expectations for usage by the line organizations. DOE responded that the intent is to give the line organization responsibility for managing their CAP scope.

The NRC asked questions regarding the CR significance level designations. The NRC asked what the difference was between Level C and Level D CRs. DOE and BSC responded that a Level C CR is a condition adverse to quality (CAQ) while a Level D CR is not. Approximately half of the CRs are Level D.

The NRC asked whether data existed which documented an increase or decrease in the number of revisions to individual CR significance levels. The DOE responded that there was no data regarding this, however, they believed that very few CR significance levels were revised downward. The NRC asked whether an originator was notified when the significance level of his/her CR was revised. The DOE responded that the CR initiator was notified of such a revision. Further, the DOE and BSC noted that the initiator had some responsibility in determining the initial significance level; however, the condition screening team (CST) reviewed the CR and recommended the significance level to the CAP Manager, who made the final determination. The NRC asked about CST member qualifications. DOE responded that one of the program enhancements addresses team member qualifications. Wes Patrick (CNWRA) questioned how risk was used in the context of determining significance levels of CRs. BSC responded that risk is factored into the determination of significance levels; specifically, risk factors are tied to public safety, plus observed and potential risk is considered. When questioned about project cost, and

health and safety considerations in determining significance levels, DOE responded that these factors are also considered in determining a CR significance level, and that the CAP categorization was being revised to consider impact to waste isolation and impact on systems, structures, and components identified as important to safety.

Mr. Robert Latta (NRC) commented on his observations of significant improvements in the implementation of the corrective action program. He mentioned that management's involvement was encouraging.

Mr. Carmichael discussed several Performance Indicators regarding CAP activities including the timely screening of CAQs, self-identified CAQs, time to plan CAQs, acceptable corrective action plans, cycle time for CAQs, and successful verification of CR closure.

Corrective Action Program Improvement Initiatives

Ms. Peggy McCullough (BSC) gave a presentation regarding CAP improvements. She discussed recent CAP initiatives intended to increase management attention and accountability for timely and effective corrective action. She stated that new management oversight practices implemented by BSC produced a measurable improvement in the overall CAP performance. Ms. McCullough outlined additional actions now taken by line managers, which should further enhance CAP improvements. Ms. McCullough also discussed the differential between planned and actual time to complete corrective actions, CRs closed by month, and average time to complete CAs.

The NRC questioned Ms. McCullough regarding the overall effect of revising the significance levels. The NRC also asked her about the timeframe involved for changing those Level B CRs that needed to be revised to a new category. She responded that Level A and Level B CRs require more time to correct than Level C CRs. DOE and BSC explained that specific criteria are involved in changing CR significance levels and that line managers are an integral part of this level change process. Ms. McCullough described the expectation that revising the significance levels would enhance management's ability to focus on the more important issues and avoid diverting resources to less significant issues. The NRC also asked whether planned time to correct issues was going up and if there were instances of adding extra resolution time. Ms. McCullough responded that adding extra time or "padding" is discouraged when extensions are requested. Further, she said that she reviews extension requests when they are sent to the Management Review Committee (MRC). The NRC asked which procedure provides criteria for changing significance levels. The DOE responded that AP 16.1, "*Condition Reporting and Resolution*," describes these criteria.

Trend Evaluation and Reporting Activities

Mr. Gary M. Grant (BSC) summarized the trend evaluation and reporting process. His presentation highlighted first quarter and second quarter (FY 2004) trending activities such as developing a trend analysis reporting handbook and conducting trending skills training. Several graphs were used to discuss procedure-related trends and causal factors.

The NRC asked whether line organizations in this presentation included the National Laboratories and the U.S. Geological Survey (USGS). Mr. Grant responded that the labs and the USGS are included as line organizations. NRC asked Mr. Grant how schedule over quality issues were handled. The response was that, if specific instances were identified, the individuals would be counseled on the importance of quality over schedule. When asked whether trend codes and cause codes were the same thing, Mr. Grant responded that the two are similar; cause codes are a subset of trend codes. When asked at what point were codes assigned, DOE responded that codes may be recommended at CR initiation, would be recommended by the CST, and may be revised during further CR management review.

Human Performance Problems

Dennis Sorensen's (BSC) presentation summarized information from CR 1497, "Human Performance Problems," and CR 1772, "Coordinated Approach to Human Performance." CR 1497 identified no adverse trends or patterns of errors. The intent of CR 1772 was to develop a coordinated approach to human performance improvement. The path forward for the two condition reports was to monitor performance indicators, adopt program elements from industry leaders, continue developing knowledge and understanding, and reinforce desired behaviors. The NRC questioned how the human performance improvement efforts are being implemented at the labs and USGS. BSC said that they will roll out the human performance improvement program at the labs and USGS the same as at BSC.

The NRC questioned whether there was a link between the CAP and SCWE. Mr. Sorensen responded that there was a link. The NRC questioned the performance indicators being communicated to the labs, and the USGS. The DOE and BSC responded that YMP was working on this issue to assure the performance indicator expectations are communicated equally to project organizations. The Regulatory Integration Team (RIT), for example, was starting to focus on this and the labs were part of the Leadership Council.

Revisions to the Quality Assurance Requirements and Description

Mr. Mike Ulshafer (DOE) gave a presentation regarding revisions to the QARD. He indicated that QARD Revision 14 became effective April 1, 2004, and that Revision 15 was submitted to NRC on April 29, 2004, for review and acceptance. He also stated that items not important to waste isolation or not related to systems, structures, and components identified as important to safety would be moved out of the QARD. Mr. Kerry Grooms (DOE) also presented part of this presentation. Mr. Mason discussed BSC QA transition monitoring plans. It was mentioned that the OQA and BSC QA plans would be similar. The NRC questioned the DOE concerning 100% inspection of Level C CRs processed. The DOE indicated 100% inspection of Level C CRs would be performed. The NRC questioned the DOE concerning QARD revisions and asked about the impact of a hypothetical change of the prime contractor would have. The DOE responded that a new prime contractor would be required to implement the QARD. The NRC questioned how DOE plans to implement 10 CFR 20. Mr. Wisenburg responded that this would be discussed at the upcoming Technical Exchange scheduled for May 12, 2004. NRC asked DOE whether the CAP procedures would reach above what was required in the QARD and DOE responded affirmatively. The NRC observed that DOE endorsed NQA-1, 2000, "Quality Assurance Program Requirements for Nuclear Facilities," while it endorsed an earlier version, NQA-1 1983. Mr. Warren Dorman (Navarro Quality Services) responded that for software QA purposes NQA-1 2000 would be used as described in NUREG-1804. For the next revision of the QARD, NQA-1 1983 will be endorsed. Some discussion occurred regarding the possibility of confusion between line organizations if the next revision of the QARD were Revision 0 instead of Revision 16. The DOE noted that if it were designated as Revision 0, it would also have a new document number. The DOE stated that it is their intention to have a Technical Exchange with NRC regarding the proposed Revision 0 to the QARD in the July 2004 time frame.

Model Development and Validation

Mr. Mason discussed the model validation and verification process as related to CR 99 (also known as CAR 001), issued in May 2001. DOE conducted an audit to verify completion of CR 99 in October of 2003. The audit of 20 model reports identified 6 model reports that had model validation issues. BSC provided supplemental corrective actions to resolve issues adversely affecting the closure of CR 99. These actions included self-assessments, surveillance of additional model reports, and steps to prevent recurrence of similar model report problems. The NRC asked for a general description of the problems affecting the unsatisfactory model reports. Ms. Jean Younker (BSC) provided the NRC with a categorization of the problems affecting these model reports, such as, discussion of criteria not being clear and the conceptual

model not being adequately described. The NRC also questioned if some of the problems could be characterized as involving transparency issues. The DOE, BSC, and NRC discussed transparency involving the model reports. NRC asked whether "Time Out for Quality" was being implemented. The DOE responded that it was covered in a Technical Work Plan at this time and was being considered for inclusion in the procedure.

Software Qualification

Mr. Al Atkisson's (BSC) presentation highlighted software qualification, qualified software categories, and gave a status of legacy software retesting, transition software remediation, and QARD Revision 13 software qualification activities. He summarized by indicating that CR 102 (also known as CAR 002) was closed and the DOE/BSC team has successfully addressed issues involving "Q" software management.

The NRC questioned Mr. Atkisson concerning the expected June 30, 2004, completion schedule. He responded that both the legacy software identified to date and transition software are expected to meet that schedule. The NRC asked how many software packages were still under development and Mr. Atkisson responded that 17 were still under development. The NRC questioned Mr. Atkisson regarding the 14 software packages escalated to the independent verification and validation (IV&V) Manager. Mr. Atkisson responded that there are cases where the data may have to be qualified if software or supporting operating system(s) are no longer available. The NRC also asked if any software codes would be impacted following implementation of QARD Revision 15. DOE and BSC responded that neither QARD Revision 14 or Revision 15 would have any effect on software codes.

Audits

Messrs. Larry Vaughan (DOE) and Kerry Grooms summarized the joint audit efforts of DOE's Office of Environmental Management (EM) and the OCRWM. The scope of the audits focused on High Level Waste (HLW) and Spent Nuclear Fuel (SNF) QA programs and verifying compliance with the QARD. The completed HLW and SNF audits to date identified several CAQs and two noteworthy practices. This presentation was concluded with a discussion of the audit schedule.

The NRC asked for a description of the two CAQs found at the Idaho facility mentioned in Mr. Vaughan's presentation. Mr. Vaughan described these CAQs. The NRC questioned how OCRWM would invoke the QARD revisions at EM and the sites. DOE responded that a process was being developed to address this. The NRC also wanted to know the scope of the scheduled performance assessment audits and requested to be notified for the purpose of planning potential observation activities. The DOE agreed to provide the information when it is available.

Public Comments

Public comments included a range of comments and concerns regarding technical terms used during the presentations, the RIT, requests for information, qualification of the CST, and general comments concerning the YMP.

Ms. Susan Lynch (State of Nevada) requested Mr. Brown provide an explanation of rolling averages; Mr. Brown explained that we are using trend management to allow managers to see how their organizations are doing. Ms. Lynch also asked whether causal codes were documented in a procedure. The DOE responded that they are documented in a procedure and the trending manual describes how the codes are applied. Ms. Lynch requested a copy of the trending handbook and a copy of the CR Screen Team Charter. The DOE agreed to provide a copy of these documents. Regarding the RIT process, Ms. Lynch inquired whether the scientists are provided an opportunity to review the process. The DOE replied that scientists are a part of the RIT process.

Ms. Sally Devlin commented that she never received any of the QARD revisions. She stated that DOE and BSC have got to do the proper science and stop the rhetoric.

Ms. Judy Treichel stated that a glossary and acronym list was needed to clarify the technical terms used in the presentations. She also expressed a concern about revising the QARD from Revision 16 to Revision 0.

Mr. Grant Hudlow provided general comments regarding the DOE and BSC presentations. In reference to the presentations, he stated that DOE and BSC were wasting the public's time and money. Mr. Hudlow commented that the reason that DOE has QA programs is to cover up for twenty years of bad science.

Closing Remarks

In closing remarks by the NRC, Mr. Thomas Matula stated that the QA meeting was productive. He expressed an interest in future updates regarding human performance initiatives discussed earlier. Mr. Matula noted that the NRC would likely begin reviewing QARD, Revision 15 on May 7, 2004. He agreed that a technical exchange might be held to discuss the changes in QARD Revision 0. He said the NRC wanted to be involved in surveillance or closeout regarding CAR 001.

Mr. Frederick Brown (NRC) asked if the information and programs described in the meeting were applicable to the labs, the USGS, and the Navy. Mr. R. Dennis Brown responded that DOE should have been explicit about the limitation of the information presented at today's meeting regarding the applicability to the labs, the USGS, and the Navy. In the DOE's closing remarks, Mr. R. Dennis Brown thanked the NRC for their questions and said that products must satisfactorily meet the NRC's expectations. He also mentioned that DOE is proud of the accomplishments of the previous months and has aggressive short-term goals. Mr. Brown concluded by offering to add a discussion regarding performance consistency involving the labs, the Navy, and the USGS at the next quarterly QA meeting. Ms. April Gil (DOE) adjourned the meeting.

 Date: 6/1/04
Fredrick D. Brown, Section Director
Project Management Section A
Division of High-Level Waste Repository
Safety
U.S. Nuclear Regulatory Commission

 Date: 5/18/04
Joseph D. Ziegler, Director
Office of License Application and Strategy
Office of Repository Development
U.S. Department of Energy

 Date: 5/17/04
R. Dennis Brown, Director
Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

**Consolidated Action Items
From The
NRC/DOE Quarterly QA Meetings
(May 4, 2004)**

Item No.	Description	Status
QA-0402-01	Discuss human performance issues and indicators and the effectiveness during the next Quarterly QA Meeting. Consider elevating human performance as a metric in the annunciator panel or otherwise raising visibility.	Closed. Human Performance Issues and indicators were scheduled as agenda topics and presented during the May 4, 2004 Quarterly QA Meeting
QA-0402-02	Discuss at a future meeting details and makeup of specific performance indicators.	Closed. Details and make up of performance indicators and specific examples of performance indicators were discussed during a DOE/NRC Technical Exchange on Performance Indicators on May 3, 2004.
QA-0402-03	Provide to the NRC an updated audit schedule showing additional performance based audits.	Closed. The updated schedule of audits was presented during the May 4, 2004 Quarterly QA Meeting.
QA-0402-04	Provide to the NRC OR a package including details and history of the EM audit (Condition Report 97).	Closed. Details and history of the EM audit were provided to the NRC OR on April 22, 2004 and discussed during the May 4, 2004 Quarterly QA Meeting.
QA-0405-01	Provide an update on results of the Corrective Action Program (CAP) transition plan during the next Quarterly QA Meeting	Open.
QA-0405-02	Provide copies of the trend reporting handbook and the Condition Screening Team (CST) charter to the State of Nevada (Susan Lynch)	Open.
QA-0405-03	Provide the scope of scheduled performance-based audits to the NRC On-site (OR) representative.	Open.

Note: The Quarterly QA Meeting action items are designated as "QA yy-mm-nn" where yy is a two digit year, mm is a two digit month and nn is a two digit action item number from that meeting.