

Summary  
U.S. Nuclear Regulatory Commission/U.S. Department of Energy  
Quarterly Quality Assurance Meeting  
Rockville, Maryland  
December 5, 2001

MEETING PLACE AND ATTENDEES

The December 5, 2001, U.S. Nuclear Regulatory Commission (NRC)/U.S. Department of Energy (DOE) Quarterly Quality Assurance Meeting was held at the NRC office in Rockville, Maryland. Participants included staff from the NRC Headquarters in Rockville, Maryland and NRC Region IV office; staff from DOE Headquarters in Washington, D.C. and its Yucca Mountain Site Characterization Office (YMSCO) in Las Vegas, Nevada; and staff from the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas.

PRESENTATION AND DISCUSSION SUMMARY

Manny Comar (NRC) opened the meeting and attendees at all locations identified their affiliation. Attachment 1 to this summary identifies the attendees.

Quality Assurance Management Assessment (QAMA) Report Findings

[The QAMA's primary purpose is to determine the adequacy and effectiveness of the Office of Civilian Radioactive Waste Management's (OCRWM's) QA Program. The FY 2001 QAMA Report was prepared by Quality Service Associates, Inc.]

John R. Longenecker (QAMA Team Leader) discussed the QAMA report for FY 2001 and its key findings. The findings included: a) a need to improve the corrective action program; b) a need to maintain management initiatives to improve performance, which may tend to fade over time); c) a need to improve the self-assessment program; and d) a need for restructuring OCRWM's Yucca Mountain Site Characterization Office (YMSCO) organization to accommodate the license application phase.

John Greeves (NRC) discussed that the FY 2001 QAMA report appears to have the same pattern and tone as past QAMA reports and that the report identified a number of problems. Further, Mr. Greeves asked a number of questions that were responded to as follows:

DOE discussed that it would be responding to the QAMA report in January 2002 and would provide the NRC a copy of the response.

QAMA will review the DOE and Bechtel SAIC Company, Inc. (BSC) performance measures/metrics during its FY 2002 assessment to determine if they are adequate and are working.

QAMA discussed that its Recommendation No. 98-4 was identified as closed, and that the decision to close this recommendation was based on the issuance of a new recommendation (FY 2001 YMSCO Recommendation No. 4) addressing the problem from Recommendation No. 98-4.

Larry Campbell (NRC) discussed the fact that OQA is satisfactorily implementing certain elements of the QARD because it has been successful in identifying and documenting problems. Mr. Campbell further stated that this is an indication that other elements of the QARD, where deficiencies have been identified, are not being successfully implemented by DOE and its contractors. DOE acknowledged this and noted that the software and model corrective action report root causes, and the Performance Improvement Transition Plan will address the program and implementation weaknesses.

#### Quality Assurance (QA) Program

Robert Davis (DOE) discussed the DOE QA organization status and the anticipated increased BSC QA activities. Mr. Davis emphasized that the additional BSC QA activities should not reduce the current DOE, Office of Quality Assurance (OQA), oversight activities during the next 12 months and that OQA will continue its oversight role to assure contractor performance. Further, Mr. Davis stated that the expected results of the additional BSC QA activities will be an increase in the oversight of quality activities. Mr. Davis and Mr. Murthy stated that DOE would notify the NRC before it implements any changes to DOE OQA current activities. Additionally, Mr. Davis and Mr. Ram Murthy (DOE) agreed that the DOE Quality Assurance Requirements and Description (QARD) document would be revised to reflect DOE OQA and BSC QA organizational structure.

Robert Davis discussed the status of open deficiency reports and significant conditions adverse to quality including: a) the average closure days for these documents; b) management of conditions adverse to quality; c) accomplishments in this area, including the closeout of several deficiency reports; and d) new corrective action requests (CARs). Mr. Davis reported that several deficiency reports had been closed and that two new CARs had been issued to document deficiencies in training and the failure of a supplier to maintain traceability during the fabrication of test specimens. Because there were several questions about the supplier's failure to maintain traceability, it was agreed that there would be a future NRC/DOE meeting or conference call to discuss the details of this issue.

Further, Mr. Davis discussed that DOE was evaluating its program for trending deficiencies and that upon completion of this evaluation will assess the need to revise its trending procedure. During this discussion, Mr. E. von Tiesenhausen (Clark County) discussed that he is aware of a National Lab that may not be documenting all deficiencies and as a result DOE may not have all deficiencies in its trend program. Mr. Davis will meet with Mr. von Tiesenhausen to discuss this subject and will update the NRC Onsite Representatives on this subject.

Also, Mr. Davis discussed that a revision to the QARD is in process to strengthen the requirements for model validation. Larry Campbell (NRC) asked if the revised QARD text would be consistent with the model validation provisions contained in NRC NUREG 1636, and Mr. Murthy answered yes.

Mr. Davis reported that OQA had performed a review and prepared a white paper on problems occurring during the last 20 months on scientific notebooks. It was reported that although there were several problems, they were not significant enough to warrant the issuance of a CAR. John Greeves (NRC) expressed a concern that DOE was still finding problems with scientific notebooks. DOE acknowledged this concern and will continue to monitor scientific notebook

performance through audits and surveillances. Larry Campbell stated that the NRC will continue to follow the progress being made in this area.

Mr. Davis discussed that OQA has successfully identified the major QA program deficiencies. Also, Mr. Davis indicated that OQA will continue to provide oversight of contractors and seek improvements in its oversight of project activities.

Relative to the proposed changes to the QA Organization, Bob Latta (NRC) asked if it was anticipated that OQA would continue to conduct performance based audits. Robert Davis, the acting Director of OQA, indicated that the specific scope of future OQA audits had not been established. Mr. Latta stated that given the indefinite scope and execution schedule for the implementation of BSC's audit plan that it might be prudent to wait for the selection of the Director of OQA before instituting the proposed change to the QA oversight program. Mr. Horton (DOE) responded that because of performance issues delineated in their Performance Improvement Transition Plan, DOE preferred to begin implementation of changes prior to the selection of the new Director of OQA. However, Bob Latta stated that the Onsite Representatives were unaware of any specific performance issues identified in the open model and software CARs that would necessitate the proposed QA program changes in the audit scope and performance based audit functions currently conducted by OQA.

#### Performance Improvement Transition Plan: Purpose and Strategy

Suzanne Mellington (DOE) discussed the following strategy and elements for the preparation and implementation of the Performance Improvement Transition Plan (the Transition Plan): a) the rationale and purpose; b) the differences between the Transition Plan and previous plans; c) an overview of the Transition Plan development; d) inputs, management, structure, and implementation; e) objectives and strategies; f) performance measures; g) progress, status, and path forward.

Don Horton (DOE) stated that it was DOE's goal to provide the NRC a copy of the Transition Plan by December 15, 2001. Further, Mr. Horton stated that because the Transition Plan needed to be a quality document, there is a possibility that this date may slip. Also, Ms. Mellington noted that the detailed planning of activities would continue into 2002. Mr. Greeves requested that DOE keep the NRC informed of the status of the Transition Plan.

#### OQA/BSC QA Planned Overview Activities to Oversee the Transition Plan

Mr. Robert Davis discussed OQA and BSC QA activities to monitor the implementation of the Transition Plan. Mr. Davis indicated that elements of the Transition Plan, under the jurisdiction of the QARD, would be subject to OQA and BSC QA oversight (e.g., the corrective actions addressed by the transition plan for the model validation and software CARs). Mr. Ram Murthy also indicated that QA would be providing oversight to ensure that the performance measures/metrics, addressed by the Transition Plan, accurately reflected the progress being made in a given area. Don Horton stated that the line management has the responsibility to ensure that the Transition Plan is properly implemented.

#### Status of Data and Software Qualification and Model Validation

Dr. Robert Andrews (DOE) discussed the status of data and software qualification and model validation. Also, Dr. Andrews discussed the status of the model validation, including recent

model validation procedure changes. In response to a question from Bob Latta about procedure changes addressing software resolution, Mr. Robert Clark (DOE) stated that clarification of definitions for routines, macros, and programs would be emphasized as part of the procedure changes. Also, Dr. Andrews stated that it was the project's position that Technical Work Plans would be appropriately revised to reflect work scope descriptions for model validation in accordance with the new procedure requirements.

Further, Dr. Andrews discussed the past deficiency reports and CARs, identifying model validation problems, that resulted in the need to revise the model validation procedure, and the QARD. Dr. Andrews reported that the procedure has been revised and that training of personnel will be completed in a few weeks.

Dr. Andrews reported that as of December 5, 2001, 1197 of the 1200 Data Tracking Numbers (DTNs) used to support the Total System Performance Assessment for Site Recommendation Report (TSPA-SR) were qualified and that 100 percent of the software codes used to support the TSPA-SR were qualified.

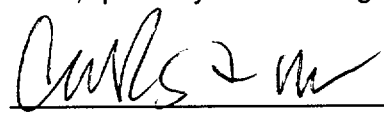
Dr. Andrews discussed the status of the model validation review (as presented in DOE's November 30, 2001 report to the NRC). Jim Firth (NRC) indicated that the staff will be reviewing the report and will continue its discussions with DOE on the model validation impact assessments.

#### Action Item Status

The status of previous action items was presented by Tim Gunter (DOE) and accepted by the NRC.

#### New Action Items

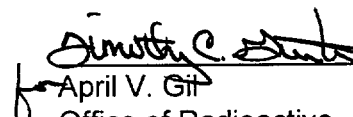
During the meeting DOE agreed either to provide additional information requested by the NRC or to have subsequent meetings with the NRC to discuss issues relating to the December 5, 2001, quarterly QA meeting. These specific items are detailed in Attachment 2 to this summary.

 date 12/10/01

C William Reamer  
Division of Waste Management  
Office of Nuclear Material  
Safety and Safeguards  
U.S. Nuclear Regulatory Commission

 date 12/6/01

Robert Davis  
Office of Civilian Radioactive  
Waste Management  
U.S. Department of Energy

 date 12/07/01  
for April V. Gil  
Office of Radioactive  
Waste Management  
U.S. Department of Energy

**QA: N/A**

## ATTENDANCE LIST

**DOE - NRC Quarterly Quality Assurance & Key Technical Issues Meeting**  
**Rockville, MD**  
**December 5, 2001**

[illegible]

NRC/DOE QA/KTI MEETING  
NRC HEADQUARTERS  
DECEMBER 5, 2001

NAME	ORGANIZATION	TELEPHONE
LARRY L. CAMPBELL	US NRC /NMSS	(301)-415-5000
WAYNE E. BOOTH	QSAE	410-571-7976
JOHN R. LONGENECKER	QSAI	(858) 792-6031
Stan Echols	Echols Consulting Group	202-537-1468
Steve Hanauer	DOE	202-586-6850
Larry Saraka	BSC	202-488-6745
WILKINS SMITH	USNRC/NMSS	301-415-5788
KAMAL NAIDU	USNRC I	301-415-2980
Jackie Chestnut	DOE	202-586-5481
TED CARTER	NRC	301-415-6684
DON KRISHA	BSC	702-295-6242
King Stablein	US NRC/NMSS	301-415-7445
DONALD PEARMAN	BSC	702 295-0528
DAVID SIEFFEN	BSC	(202) 479-2104
Bob Gamble	MTS/Bor Allen	702-794-1440
Susan L. Rives	DOE/YMSCO	702-794-5519
0 Donald Beckman	BSC	702-295-4382
STEVE GOMBERG	DOE-HQ/Reg. Coord.	202 586-6497
TIM GUNTER	DOE/YMSCO	702-794-1343
SUZANNE MELLINGTON	DOE/YMSCO	702-794-1454
STEPHAN BROCCUM	DOE/YMSCO	702-794-1359
DONALD G. HORTON	DOE/YMSCO	702-794-1301

NRC/DOE QA/KTI MEETING  
NRC HEADQUARTERS  
DECEMBER 5, 2001

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## ATTENDANCE LIST

**DOE - NRC Quarterly Quality Assurance & Key Technical Issues Meeting  
Rockville, MD  
December 5, 2001**

[illegible]



QA: N/A

**ATTENDANCE LIST**  
**DOE - NRC Quarterly Quality Assurance & Key Technical Issues Meeting**  
**Rockville, MD**  
**December 5, 2001**

Name	Organization	Telephone
Pusan Lynch	State of Nevada	775-647-3744
Bill Burke	NRC	45047
Barbara McKinnon	MPS	4-5480
Reina Downing	Nye County	775-727-7727
Jim Linhart	NSNFP	702-295-6366
Bob Clark	DOE YMSCO	702-794-5583
RVM LATTIN	US NRC	702 794-5048
E. J. TIENHARTSEN	CLARK COUNTY	702 455-5181
M. P. MURRAY	Nye County	360 943-5610
R. P. Fiele	BSC QA	702-295-2208
Veronica Cornell	BSC/LAP	702-295-5342
Robert Craig	USCIS	702-295-6756
S. J. CEREGHINO	BSC	702-295-4251
MARK WISENBURGER	BSC	702 245 5316
PAMELA DAHL	BSC/BAA	702 295 5334
Robert Hartstern	BSC/QA	702 295-2675
SAM HOBBS	BSC/LAP	702 295 6620
George Parnell	BSC/LAP	702-295-5472
Rod McEllen	NIEL	202-739-8082
Edward P. Opelski	NQS	702-794-1332

**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES  
MEETING ATTENDANCE**

SUBJECT OF MEETING DOE/NRC Quarterly QA Meeting

DATE: December 5, 2001 LOCATION: SWRI Building 189, Room A103

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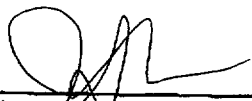
ATTACHMENT 2  
Actions from NRC/DOE Quarterly QA Meeting  
December 5, 2001

1. DOE will provide to NRC the project responses to the QAMA recommendations (Estimated Completion Date: January 2002)
2. DOE will provide follow-up information/status to NRC on deficiencies related to metal samples. This will be accomplished via an Appendix 7 meeting if appropriate.
3. DOE will request the QAMA team to include evaluation of the DOE/BSC performance measures/metrics in the scope of their FY 2002 assessment.
4. Director, OQA, will follow-up with Clark County, NV regarding information that some labs are not documenting all problems. The State of Nevada will also be informed of the outcome.
5. DOE agreed to inform NRC of any changes in OQA/BSC QA responsibilities prior to their implementation.

**NRC/DOE Key Technical Issues Meeting Summary**  
NRC Headquarters, Rockville, MD; DOE, Las Vegas, NV;  
NRC Region IV, Arlington, TX; CNWRA, San Antonio, TX  
December 5, 2001, 3:30 PM to 4:30 PM, ET

Jim Andersen (NRC) opened the meeting and summarized the status of the Key Technical Issue (KTI) subissues and agreements reached with DOE for resolution of the subissues. He indicated that NRC was working to provide more timely responses to the documentation DOE submits to satisfy the agreements. He also indicated that NRC wanted to begin discussing the next round of KTI meetings. Mr. Andersen said that the agreements, new information, and NRC/DOE letters pertaining to the agreements should be the focus of discussions at the future meetings. He stated that the NRC expected that these meetings might lead to more specific or new agreements for resolution of KTI subissues and preclosure topics. He also indicated that some existing agreements might be closed or modified based on discussion at these future meetings and risk insights developed. In closing, Mr. Andersen stated that the NRC KTI leads and DOE technical leads should increase their communications so that DOE responses to agreements would fully address the intent of the agreements.

Tim Gunter (DOE) summarized DOE's view of KTI status, noting that DOE agreed with NRC on the current status of agreement items. NRC and DOE agreed that a meeting in late January or February 2002 to discuss plans and procedures for the conduct of future KTI meetings would be appropriate. Steve Brocoum (DOE) indicated that meetings on specific KTIs should not be conducted until DOE has developed its multi-year schedule for work through completion of a potential license application and specific information and impacts on the KTIs are known. He noted that an initial version of the schedule is expected to be available for discussion in March 2002. Dr. Brocoum agreed that a general planning meeting would be appropriate for January – February 2002.



James W. Andersen  
Division of Waste Management  
Office of Nuclear Material  
Safety and Safeguards  
U.S. Nuclear Regulatory Commission



Timothy C. Gunter  
Office of Licensing and  
Regulatory Compliance  
Yucca Mountain Site  
Characterization Office  
U.S. Department of Energy

**Agenda  
DOE/NRC Quarterly QA Meeting  
December 5, 2001**

**11:00 AM- 3: 30 PM (ET)**

**8:00 AM- 12:30 AM (PT)**

**U. S. NRC**

**Room O3B-4**

**Rockville, MD**

**Bridge Number: (702) 295-6111**

**And via Videoconference to:**

**BSC  
9960 Covington Cross  
Room 915  
Las Vegas, NV**

**U. S. NRC  
Region IV  
611 Ryan Place Drive  
Arlington, TX**

**CNWRA, SWRI  
Building 189, Room A103  
6220 Colebra Road  
San Antonio, TX**

<b>11:00 AM</b>	<b>Introduction</b>	<b>ALL</b>
<b>11:10 AM</b>	<b>QA Program</b> <ul style="list-style-type: none"><li>• <b>Proposed Changes to QA Organization</b></li><li>• <b>Status of Open Cars – Deficiencies</b></li><li>• <b>Proposed Changes to QARD to Address Model Validation</b></li><li>• <b>Trends (Extent of Condition)</b></li><li>• <b>Other Emerging Issues</b></li></ul>	<b>Davis Davis/Krishna</b>
<b>NOON</b>	<b>Performance Improvement Transition Plan</b>	<b>Mellington Williams</b>
<b>12:45 PM</b>	<b>OQA/BSC QA Planned Overview Activities to Oversee Performance Improvement Transition Plan</b>	<b>Davis</b>
<b>1:00 PM</b>	<b>Lunch</b>	<b>ALL</b>
<b>2:00 PM</b>	<b>Data, Model, and Software</b> <ul style="list-style-type: none"><li>• <b>Status of Model Validation</b></li><li>• <b>Progress Made in Qualifying Data</b></li><li>• <b>Progress Made in Qualifying Software</b></li><li>• <b>Significance of Unqualified Data, Model, and Software</b></li></ul>	<b>Andrews</b>
<b>2:45 PM</b>	<b>QAMA Report Finding</b>	<b>Longenecker</b>
<b>3:00 PM</b>	<b>Action Item Status</b>	<b>Gunter</b>
<b>3:15 PM</b>	<b>Closing Remarks</b>	<b>ALL</b>
<b>3:30 PM</b>	<b>Adjourn</b>	

**Agenda  
DOE/NRC Quarterly KTI Meeting  
December 5, 2001**

**3:30 PM- 4:30 PM (ET)  
12:30 PM- 1:30 PM (PT)**

**U. S. NRC  
Room O3B-4  
Rockville, MD**

**Bridge Number: (702) 295-6111  
And via Videoconference to:**

**BSC  
9960 Covington Cross  
Room 915  
Las Vegas, NV**

**U. S. NRC  
Region IV  
611 Ryan Place Drive  
Arlington, TX**

**CNWRA, SWRI  
Building 189, Room A103  
6220 Colebra Road  
San Antonio, TX**

**3:30 PM      Status of KTI Subissues**

**NRC**

**4:00 PM      KTI Progress and Status Overview**

**Gunter**

**4:30 PM      Adjourn**



U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Quality Assurance Program Status

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Robert D. Davis**

**Acting Director, Office of Quality Assurance**

**Yucca Mountain Site Characterization Office**

**Office of Civilian Radioactive Waste Management**

**December 5, 2001  
Rockville, Maryland**

Enclosure 4

# QA Organization Status

**A plan (re-institution plan) has been drafted that establishes a change in the QA Organization's roles and responsibilities. Under the re-institution plan**

- **DOE retains responsibility for the QA Program**
- **Bechtel SAIC Company, LLC (BSC) is given authority to conduct the QA verification activities within their scope of work**
  - **BSC will conduct audits and surveillances with emphasis on in-process activities**



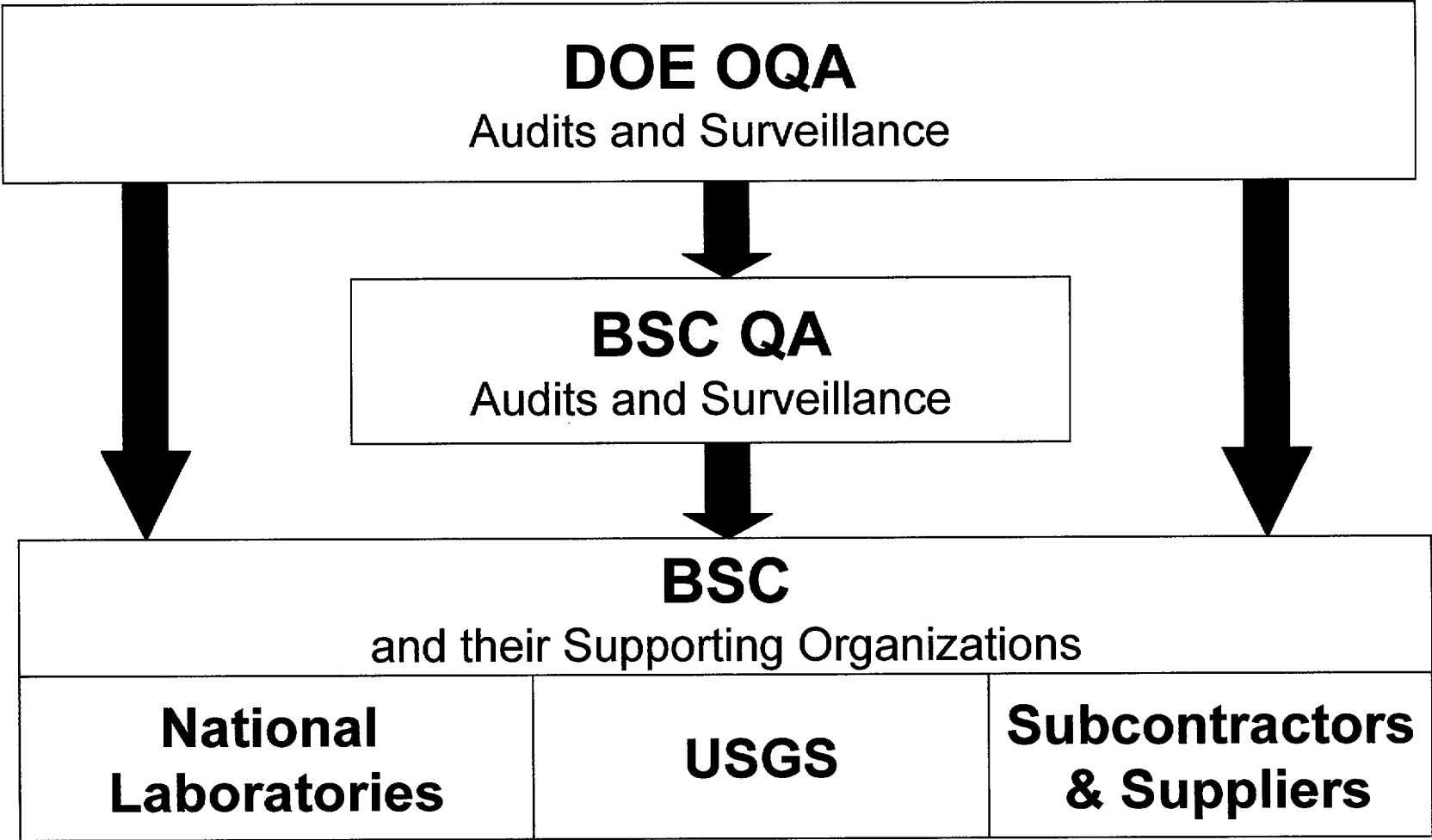
# QA Organization Status

(Continued)

- **OQA will continue its oversight role to assure contractor performance**
  - **OQA will also provide oversight of the BSC audit and surveillance program**
  - **No anticipated change in OQA support contractor**
- **No reduction in QARD commitment**



# QA Program Oversight



# Expected Results

- **Authorizing BSC to conduct verification activities provides the tools needed to internally assess their performance**
- **Net result will be an increase in oversight of quality-related activities with more time, activity, and eyes in the field**
- **Net increase in BSC ownership and accountability by application of self-critical, technically intrusive audits and surveillance of in-process work activities**



# Corrective Action Status

- **Average Closure Days**
- **Management of Conditions Adverse to Quality (CAQ)**
- **Accomplishments**
- **New Corrective Action Reports (CAR)**

# **Average Closure Days (06/30/01 - 11/26/01)**

**CAQ (CARs/DRs) issued: 21**

**CAQ closed: 56**

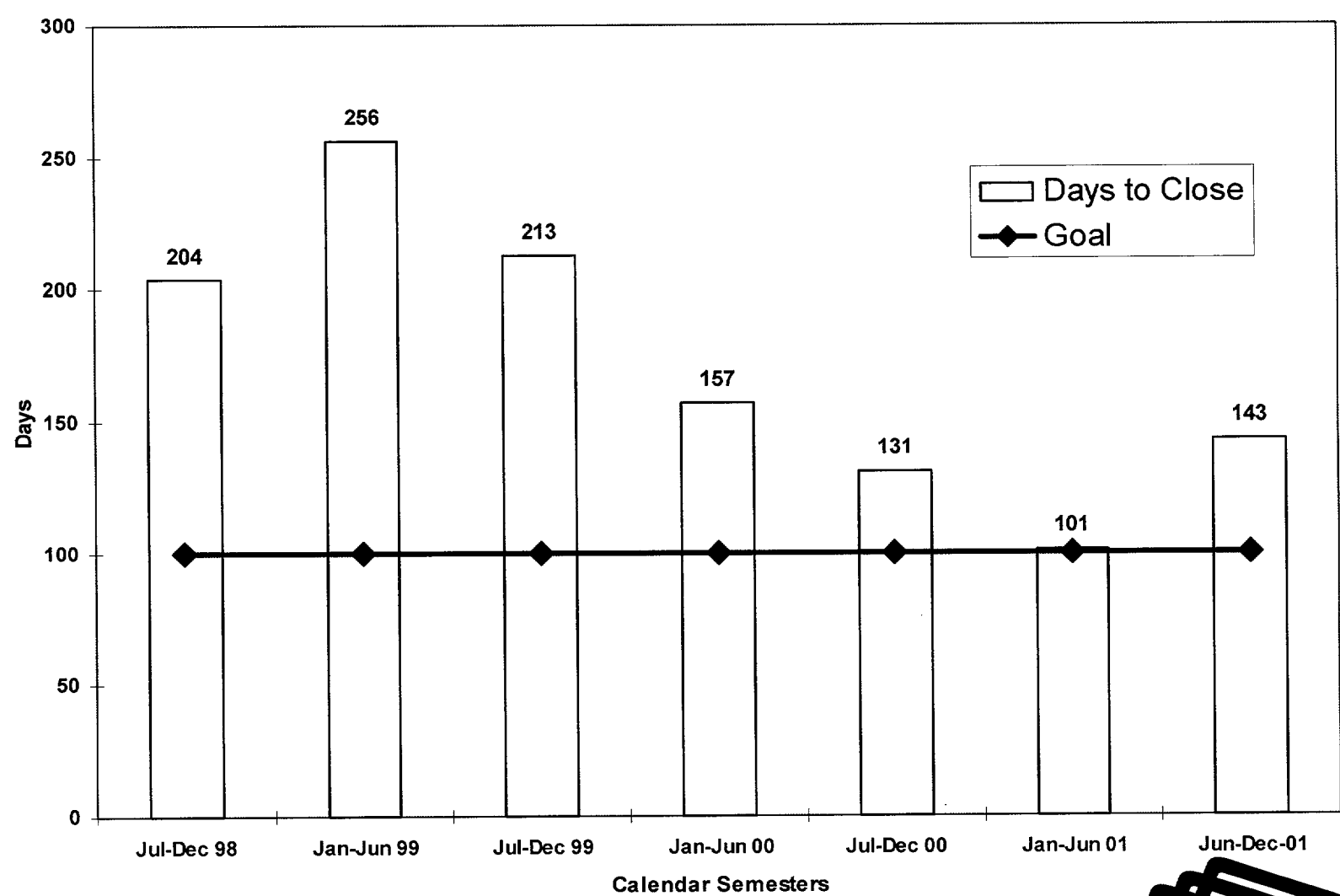
**Average time to closure: 143 days**

**Average time to closure goal: 100 days**

- **5 older (5 > 365 days) were closed this calendar semester**
- **Closure of older CAQ has negative impact on statistical representation**
- **Without 5 older CAQ, the average would be 107 days, which is a slight elevation over the last calendar semester**



# Average Closure Days for Conditions Adverse to Quality



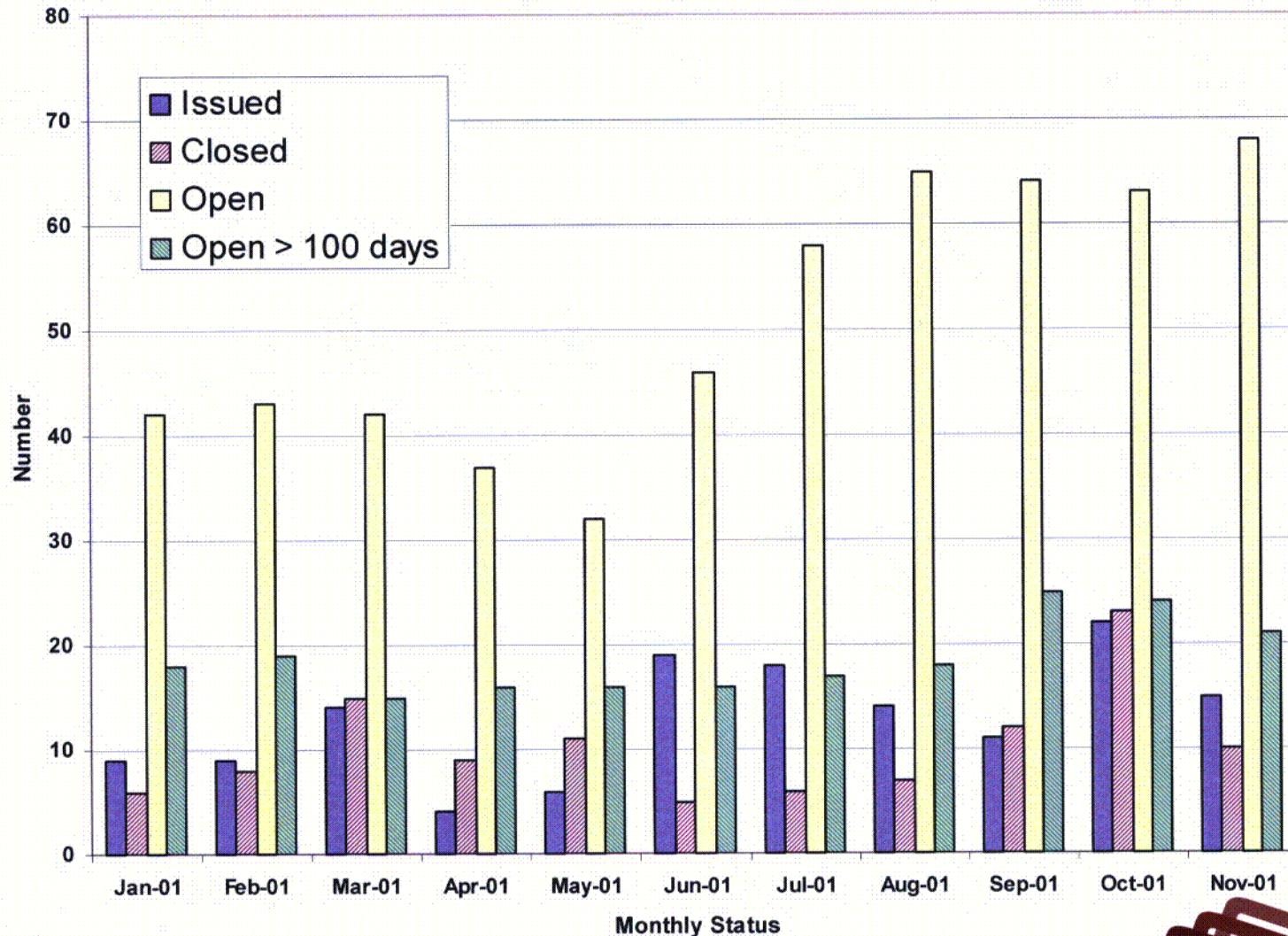
# **Management of Conditions Adverse to Quality**

- **OQA is measuring corrective action performance on a monthly basis**
- **The following chart represents all CAQ issued, both internal and external**
- **The chart depicts that in Calendar Year 2001**
  - **Number of issued CAQ has increased**
  - **Number of closed CAQ has increased**
  - **Number of open CAQ has increased**
  - **Number of open CAQ over 100 days has increased**



# Management of Conditions Adverse to Quality

(Continued)



C01



# Accomplishments

- **Closure of LVMO-D-00-039 (Software Routines)**
  - Software routines within technical products are defensible and reproducible
- **Closure of LVMO-D-00-099 (Software Installation)**
  - Software codes have been independently tested/installed
- **These older (> 365 days) DRs support resolution of CAR BSC-01-C-002 (CAR-002)**



# New CARs

**Two new CARs have been drafted, indicating significant CAQ:**

- **Documentation of Personnel Training (BSC-02-C-01)**
  - Training matrices and job function not prepared/assigned by Functional Managers
- **Welding Samples (Metal Samples) (BSC-02-C-02)**
  - Sample traceability to associated Certified Material Test Report could not be established



# Other Issues

- ***Extent of Condition/Trending***

- OQA is evaluating opportunities for improving the QA trend program, including ways to improve representation of the extent of condition for CAQ
- AP-16.1Q revision (ICN) will assure that upon completion of the extent evaluation, the QA Representative will reassess the significance determination. At that time, a DR may be converted to a CAR based on collective significance and/or repetitive condition

# Other Issues

(Continued)

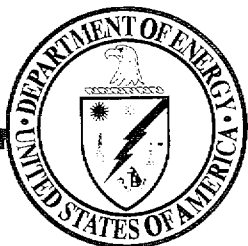
- ***QARD Revision***
  - Model validation requirements will be strengthened in Revision 11
  - Revision 11 was issued for review
  - Review comments are being resolved
- ***Scientific Notebooks (SN)***
  - Evaluation of discrepancies identified in SNs concluded that there is no impact on acceptability/usability of SNs
  - SN procedure and database improvements are in progress

# Conclusions

**OQA has successfully identified the major QA Program deficiencies; we need to:**

- **Recognize that improvements in the timeliness of corrective action are needed in preparation for a potential license application**
- **Seek continuous improvements in our oversight of project activities**
- **Develop additional performance indicators that will give us a better picture of performance, quality of products, and measurable results**
- **Continue to provide a strong QA presence and oversight**





U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Performance Improvement Transition Plan: Purpose and Strategy

Presented to:  
**DOE/NRC Quarterly QA Meeting**

Presented by:  
**Suzanne Mellington**  
Assistant Manager, Office of Project Execution  
Yucca Mountain Site Characterization Office

**December 5, 2001**  
**Rockville, Maryland**

# Performance Improvement Transition Plan

- **Rationale/Purposes for the Transition Plan**
- **What's Different This Time**
- **Overview of Plan Development**
- **Plan Inputs**
- **Plan Management**
- **Plan Structure / Implementation**
- **Objectives and Strategies**
- **Performance Measures**
- **Progress and Status**
- **Path Forward**



# Rationale for Plan

## Need for :

- **Comprehensive response to repetitive findings on QA and technical document deficiencies**
  - NRC
  - Independent reviews (root cause analyses)
  - Self-assessments
- **Multi-year improvement effort**
- **Project-wide integration with DOE ownership**





# **Performance Improvement Transition Plan Purposes**

- **Comprehensively address the root causes**
  - **Corrective Action Requests**
    - ◆ BSC-01-C-001
    - ◆ BSC-01-C-002
  - **Technical Document Deficiencies**
    - ◆ TSPA-SR
    - ◆ TSPA-SR Model Document Second purpose
- **Drive the organization to the level of expected performance for a potential license application**
  - **Cultural**
  - **Behavioral**
  - **Results**

# What's Different

THIS TIME	PREVIOUSLY
Early Root Cause - provided input to plan	Later Root Cause (1 year later) - confirmed ongoing actions
Comprehensive / detailed plan	Plan focus was on specific CARs and plan was less detailed
Proven techniques / external input	Corrective actions were developed purely internally
Activities in baseline	Activities largely level of effort
Senior management team commitment <ul style="list-style-type: none"><li>• line management <b>accountability</b></li><li>• intense planned follow-up</li></ul>	Lower degree of involvement <ul style="list-style-type: none"><li>• minimal focus on follow-up</li></ul>
Specific performance measures <ul style="list-style-type: none"><li>• indicators</li><li>• assessments/audits</li></ul>	Little focus on performance measures
High visibility	Part of ongoing work
Stand-downs planned	Not utilized



# Overview of Approach to Plan Development

- **Based on proven techniques for sustained improvement**
  - Used by other NRC-regulated facilities
  - Recognized best practice by industry
- **Addresses root cause reports, management initiatives over past three years**
- **Includes ongoing and forward-looking performance measurement**
- **Ongoing management oversight**



# Inputs to Plan

- **Recommendations from the Root Cause Analysis Report for CAR BSC-01-C-001 and CAR BSC-01-C-002, Revision 1, August 8, 2001**
- **Recommendations from the Root Cause Analysis Report for Yucca Mountain Project Technical Document Deficiencies, August 17, 2001**
- **Corrective actions in response to deficiencies identified in the BSC Integrated Safety Management System Annual review report, Revision 0, September 14, 2001**
- **NRC draft expectations, August 17, 2001**



# Inputs to Plan

(Continued)

- **Recommendations from the Safety Conscious Work Environment Final Report, Morgan, Lewis & Bockius LLP, August 28, 2001**
- **Quality Assurance Management Assessment reviews**
- **Lessons learned from previous corrective actions (DRs and CARs)**
- **Self Assessment results**
- **Adverse trends identified through the OCRWM Concerns Program**
- **Additional inputs as appropriate**



# Transition Plan Management

- **Effective Project Management at all levels**
  - **Senior management sponsor is designated for each objective**
  - **Activity sponsors for each strategy**
  - **Accountable managers for action summaries**
  - **Resource loaded, logic-tied schedule**
  - **Activities appropriately prioritized by the Senior Management Team and integrated into the baseline**

# Overall Plan Structure

- **Objectives**
  - **Strategies**
    - ♦ **Action Plans**
      - » **Performance measures will be an integral part of each action plan**



# Objectives/Strategies

- **Objectives**

- **Quality**
- **Safety**
- **Project Management**
- **Human Performance**

- **Strategies**

- **Broad actions that support each objective**
- **Generic, common, and root cause analysis recommendations**





# Quality

- **Fully and effectively implement established and documented procedures to successfully support the quality and defensibility of Project technical products and NRC licensing and compliance activities. Fully establish line organization accountability for quality and quality-related issues.**
- **Strategies**
  - **Minimize repeat conditions**
  - **Strengthen Quality Assurance Requirements Document (QARD) related processes**



# Safety

- **Protect the environment and the health and safety of the public and Project employees**
- **Strategies**
  - **Reinforce the Safety Conscious Work Environment**
  - **Increase proactive problem identification (by the line organization)**
  - **Heighten management support and direction to OCRWM Concerns Program**
  - **Improve Integrated Safety Management System performance**



# Project Management

- **Develop a logical, comprehensive, technical, cost and schedule baseline. Successfully develop and implement effective project management systems**
- **Strategies**
  - **Enhance program project management skills and implementation**
  - **Improve the configuration management program**
  - **Support the improvement of organizational effectiveness**



# Human Performance

- **Improve organizational effectiveness by implementing an understandable value system that maximizes individual and organizational performance and provides for training and continuous learning to ensure competencies. Communicate management expectations throughout the organization, monitor performance against expectations, and consistently and appropriately reward or discipline Project team members.**



# Human Performance

(Continued)

- **Strategies**

- **Establish team-oriented project management performance**
- **Improve individual performance and accountability**
- **Develop a critical mass of leadership experience**
- **Attract, train, and retain a professional, competent staff**



# Measuring Progress and Effectiveness

- **Three kinds of measurements**
  - Monitor implementation
  - Monitor effectiveness of actions
    - ♦ Focus on leading indicators
  - Monitor/confirm sustainability
- **Assessments/Audits/Surveillances**



# Plan Progress/Status

- **Plan is in development**
  - Managers have been assigned
  - Resource allocation is in progress
  - Resource loaded schedule is being prepared
- **Activities going into baseline**
  - In baseline
  - Will be priority baseline change proposals
  - Will be prioritized and put into baseline



# Plan Progress/Status

(Continued)

- **Plan structure is in place**
- **Action summaries are initially drafted**
- **More is being done on the action summaries**

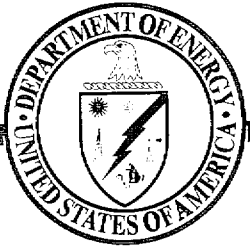




# Path Forward

- **Finalize plan**
- **Identify near- and mid-term milestones**
- **Continue management oversight**
- **Quarterly briefings**
- **Trend analysis of performance measures**
- **Ongoing assessments/audits/surveillances (both internal and external)**





U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Status of Data, Software and Models Qualification

Presented to:  
**DOE/NRC Quarterly QA Meeting**

Presented by:  
**Robert W. Andrews**  
Manager of Science and Analysis Projects  
Bechtel SAIC Company, LLC

**December 5, 2001**  
**Rockville, Maryland**

# Outline

- **Status of Data Qualification**
- **Status of Software Qualification**
- **Status of Model Validation Review**
- **Status of Model Procedure Changes**
- **Summary**



# Data Qualification Status

- **Status on 8/31/01 (used in Impact Assessment)**
  - 50 unique DTNs out of ~1200 were unqualified or TBV
  - These DTNs were used as input to 28 unique AMRs
  - 61 unique impact assessments were completed
  - Impacts were assessed with respect to
    - ♦ Output from the AMR
    - ♦ Input to TSPA-SR
    - ♦ Output from TSPA-SR
  - All 50 DTNs were found to have no significant impact on TSPA-SR results or conclusions

DTN = Data Tracking Number

AMR = Analysis Model Report

TBV = To Be Verified

TSPA-SR = Total System Performance Assessment - Site Recommendation



# Data Qualification Status

(Continued)

- **Status as of 11/28/01**
  - **Of the 50 DTNs, 45 have been qualified or verified**
    - ♦ **5 unique DTNs remain**
  - **22 AMR ICNs have been completed (4 AMRs required no ICN)**
    - ♦ **2 AMR ICNs remain**
      - » **I0040 - Rock Properties Model**
      - » **I0045 - Mineralogical Model**
  - **These 5 remaining DTNs have no impact on TSPA-SR because they are either corroborative to other data or have been replaced by qualified data and do not affect input to TSPA-SR**

ICN - Interim Change Notice



# Data Qualification Status

(Continued)

	09/05/01 Percent Data Qualified	09/05/01 Percent Data Verified	11/28/01 Percent Data Qualified	11/28/01 Percent Data Verified
PMR				
Biosphere	97	100	100	100
Disruptive Events	91	100	100	100
Engineered Barrier System	94	100	100	100
Integrated Site Model	87	100	92	100
Near Field	96	100	100	100
Saturated Zone	90	100	100	100
Unsaturated Zone	95	99	100	100
Waste Form	100	100	100	100
Waste Package	100	100	100	100
Total	94.4	99.8	99	100

**Note:** Percent complete statistics reflect the multiple use of a DTN in different AMR/PMR products

# Data Qualification Status

(Continued)

- **Questions associated with data qualification and impact assessments**
  - **Consideration of unused data in data selection process**
    - ♦ **Alternative data could affect AMR inputs and possibly outputs**
  - **Use of unqualified data in support of assumptions**
  - **Use of unqualified data in model validation efforts**
- **Further discussions planned on these questions**

# Software Qualification Status

- **100% of software codes used in support of TSPA-SR have been qualified**
- **All software codes qualified after use have met the qualification criteria with no impact on the analyses**
- **Software deficiency reports have been closed**
  - **DR-39: Inaccurate Documentation and Validation of Software Routines and/or Macros**
  - **DR-54: Incorrect/Incomplete Processing of Software**
  - **DR-99: Software Code Installation**
- **Software process modifications being developed to address BSC-01-C-002 Software**
- **Additional initiatives planned as part of the Performance Improvement Transition Plan**





# Software Qualification Status

(Continued)

	09/05/01 Percent Software Qualified	11/28/01 Percent Software Qualified
PMR		
Biosphere	100	100
Disruptive Events	100	100
Engineered Barrier System	99	100
Integrated Site Model	100	100
Near Field	99	100
Saturated Zone	93	100
Unsaturated Zone	98	100
Waste Form	100	100
Waste Package	100	100
Total	98	100

Software qualification is of 402 unique codes, consisting of 472 different variants

# Model Validation - Background

- **LVMO-98-C-010 addressed lack of consistent quality control processes for models and analyses**
  - AP-3.10Q, Rev 00 was effective in February 1999
- **Verification of LVMO-98-C-010 closure identified model validation issue in January 2000**
  - AP-3.10Q, Rev 02 was effective in February 2000
  - LVMO-98-C-010 was closed in April 2000
- **Several deficiencies related to model validation were subsequently identified**
- **BSC-01-C-001 addressed this recurring model validation issue**



# **BSC-01-C-001 Model Validation Recommended Actions/Actions to Date**

- **Recommended Actions**
  - Identify all models developed in AMRs
  - Develop unique identifier for each model
  - Revise AP-3.10Q to further clarify requirements
  - Proposed revision to QARD
- **Actions completed to date**
  - Root Cause Analysis
  - Reviewed all AMRs supporting TSPA-SR
    - ♦ Model Validation Status Review (following slides)
      - » Identified all models used in AMRs
      - » Determine compliance to AP-3.10Q requirements
  - Revised AP-3.10Q
    - ♦ AP-SIII.10Q - Models (following slides)
    - ♦ AP-SIII.9Q - Scientific Analyses



# Model Validation Status Review (MVSR)

- **Systematic review of all the AMRs that support the TSPA-SR by an independent team under the direction of the BSC Chief Science Officer**
  - 125 AMRs plus other documents were reviewed
  - The review team identified the unique models documented in the AMRs
  - The review team assessed the compliance of the models to the criteria in AP-3.10Q

# **Status of Model Validation Status Review**

- **Interim results submitted to NRC on October 19, 2001**
- **Final results submitted to NRC on November 30**
- **Additional time was devoted to product development**
  - **More checking was required as a result of the use of over 225 references and detailed information from all parts of the science program**
  - **More time was allowed for inter-disciplinary review to assure the review findings are accurately stated**



# Model Validation Status Review (MVSR)

(Continued)

- **The models were assigned to 3 categories (“bins”) according to the extent to which model validation was achieved in compliance with AP-3.10Q:**
  - **Bin 1 - Validation was achieved in a single, principal AMR considering the entire report, not just the model validation subsections**
  - **Bin 2 - Validation was not achieved in a single AMR, but other reports, data, publication, etc. provide adequate confidence to support compliant model validation**
  - **Bin 3 - Validation was not achieved, and cannot be readily achieved because additional work (e.g., model development, testing, data collection) is needed to support compliant validation**



# Model Validation Status Review (MVSR)

(Continued)

- **A total of 128 models were identified:**
  - 17 assigned to Bin 1
  - 77 assigned to Bin 2
  - 34 assigned to Bin 3
    - ♦ **For all 34 Bin 3 models, impact assessments were conducted.**
      - » 15 do not support TSPA-SR, i.e., the output was not used as input to the system model. Of these, 6 were used for screening of FEPs
      - » 5 additional Bin 3 models were originally intended as analyses or calculations (i.e., not requiring validation)
      - » 3 additional Bin 3 models were embedded within the GENII-S dose-assessment code and were not previously recognized as discrete models
      - » 11 remaining Bin 3 models supported TSPA-SR

# **Example Model Validation Impact Assessment: TSPA-SR Model**

- **Model Validation Status Review determined the TSPA-SR Model was Bin 3, because:**
  - **Validation criteria chosen are inconsistent with intent of AP-3.10Q; more consistent with code verification**
  - **Output is not tested with real data or formally peer reviewed**
  - **Some model aspects are not clearly defined, including**
    - ♦ **Approach to uncertainty analysis**
    - ♦ **Integrated treatment of parameter uncertainty**
    - ♦ **Monte Carlo sample size**





# **Example Model Validation Impact Assessment: TSPA-SR Model**

(Continued)

- **Impact assessment determined that the model was appropriately valid for its intended use, because:**
  - **Output (both system and intermediate) are tested**
  - **TSPA-VA and TSPA-SR have been formally peer reviewed**
  - **Uncertainty analysis method and parameter uncertainty are presented in the Technical Report**
  - **Sample size was investigated for system performance analyses and for multiple sensitivity and barrier importance analyses**



# Status of Model and Analyses Procedures

- Recognizing the interpretive nature of transparency and model validation the Project has initiated a major replacement of AP-3.10Q and associated revision of the QARD
- Procedure change resulted in 2 new procedures and a Scientific Guidelines Manual
  - AP-SIII.10Q - Models
  - AP-SIII.9Q - Scientific Analyses
- During the review, the draft procedures underwent a table top implementation review
- Procedures will be effective 12/21/01



# Model Procedure Change: Background

- **Changes to model development and validation processes are to address, in part:**
  - **BSC-01-C-001 “Validation of AMRs not documented in accordance with AP-3.10Q”**
  - **LVMO-01-D-007 “Inadequate Implementation of Procedures for Project Transmittal Inputs, Model Verification, and Identification of Developed Data”**
  - **BSC-01-D-050 “Alternative Approach to Model Validation Not in Accordance with AP-3.10Q, 5.3.c”**
  - **LVMO-00-D-118 “Rationale for Excluding/Deviating from Uncertainty/Variability Values, Assumptions, and Alternative Models, Addressed in Process Level AMRs, Not Addressed at the Abstraction Level”**



# Model Procedure Change: Background

(Continued)

- BSC-01-D-078 “Model Parameters Used Outside Documented Initial and/or Boundary Conditions”
- LVMO-00-D-119 “Validation of Models Not Documented in Accordance with AP-3.10Q”



# **QARD III.2.6**

## **Model Development and Use**

- **Draft changes to the models section of the QARD are under development within OQA**
- **Changes are expected to expand on existing QARD requirements**
  - **Additional text being added to clarify documentation and validation requirements**
  - **Additional requirements being added for model documentation and use**
  - **Additional definitions being added**



# **AP-SIII.10Q, *Models* - Model Validation**

- **Model validation/validation criteria will be included in Technical Work Plan (TWP)**
  - TWP lays out validation approach and criteria
  - TWP will be independently reviewed to ensure plans for model validation are appropriate/adequate
- **Model validation begins at model conception**
  - Mathematical models shall be confidence building exercises completed during model development (input selection, initial condition runs, run convergences, etc.)

# AP-SIII.10Q, *Models* - Model Validation

(Continued)

- **Additionally, mathematical models will complete one or more post-development validation activities**
  - **Corroboration**
    - ♦ **Model results with acquired data**
    - ♦ **Results with alternative models**
    - ♦ **Published data**
    - ♦ **Abstraction model results to results of validated process model(s) from which abstraction was derived**
    - ♦ **Model predictions to data collected during the associated testing**



# **AP-SIII.10Q, *Models* - Model Validation**

(Continued)

## **– Review**

- ♦ **Peer Review**
- ♦ **Technical review by independent reviewers**
- ♦ **Technical review by an international/other technical organization, documented in open literature**
- ♦ **Technical review through publication in a refereed professional journal**





# Status of Model and Analyses Procedures

- Procedure has been completed and will be in effect on 12/21/01
- Training has been conducted in LV (11/26), LANL (11/27), SNL (11/28), LBNL (12/3), LLNL (12/4) to over 150 staff
- Additional training is planned for LV (12/10), LV (12/11), and USGS (12/18)



# Summary

- **Data qualification efforts for SR are virtually complete**
  - AMR ICNs are nearly complete
- **Software qualification efforts for SR are complete**
- **Model validation review and impact assessments for SR are complete**
  - Additional discussion may be required on model validation status review report
- **Procedure changes are complete**
- **Ongoing process improvement being addressed as part of Performance Improvement Transition Plan**

# Backup



# Verification/Qualification Status as of 11/28/01

	<u>Total</u>	<u>Completed</u>	<u>To-Go</u>	
VL1 DIRS (Verif. Checklists)	250	250	0	(Q-TBV) ("actual citations")
VL1 Sources (Verif. Checklists)	332	332	0	(Q-TBV) ("daughters")
VL2 (No Verification Checklists)	182	182	0	(Q-TBV)
Accepted Data (Fact)	78	78	0	(e.g., handbooks, textbooks)
Accepted Data approved by Assistant Manager, Office of Project Execution	32	32	0	(e.g., journal articles)
Qualified by procedures established after 6/30/99	34	34	0	
Unqualified DTNs	<u>287</u>	<u>282</u>	<u>5</u>	
Totals	1195	1190	5	
Percent of Total Data Citations		99.6%	0.4%	

Note: Document Input Reference System VL1+VL2+AP-SIII.2Q+Accepted (863) + Source VL1 (332) = Total Data Citations (1195)  
VL1 = Principal Factor Related DTN  
VL2 = Non-Principal Factor Related DTN



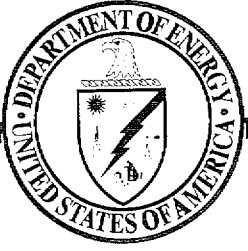
# Data Confirmation Results as of 11/28/01

<u>ORG</u>	<u>Completed Checklists</u>	<u>Verified Q</u>	<u>Verified UQ</u>	<u>Reject Rate**</u>
<b>USGS</b> (U. S. Geological Survey)	<b>295</b>	<b>282</b>	<b>13</b>	<b>4.4%</b>
<b>LANL</b> (Los Alamos National Laboratory)	<b>107</b>	<b>107</b>	<b>0</b>	<b>0%</b>
<b>LBNL</b> (Lawrence Berkeley National Laboratory)	<b>10</b>	<b>9</b>	<b>1</b>	<b>10.0%</b>
<b>LLNL</b> (Lawrence Livermore National Laboratory)	<b>37</b>	<b>37</b>	<b>0</b>	<b>0%</b>
<b>BSC*</b> (Bechtel SAIC Company, LLC)	<b>54</b>	<b>52</b>	<b>2</b>	<b>3.7%</b>
<b>SNL</b> (Sandia National Laboratories)	<b>79</b>	<b>78</b>	<b>1</b>	<b>1.3%</b>
<b>Total</b>	<b>582</b>	<b>565</b>	<b>17</b>	<b>2.9%</b>

\* Data (DTNs) generated by previous Yucca Mountain Site Characterization Project (YMP) organizations (i.e., Raytheon Services Nevada and Technical and Management Support Services) are now considered BSC data, and the results for these data are included in the BSC totals.

\*\* Reject is defined as a determination that the data submitted under the associated DTN cannot be qualified. There are two principal causes for rejection. Either the data acquisition/development process did not meet QARD requirements or data-/record-related issues discovered during checklist preparation could not be resolved.





U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Quality Assurance Management Assessment Report Findings

Presented to:  
**DOE/NRC Quarterly QA Meeting**

Presented by:  
**John R. Longenecker, Team Leader**  
**Quality Assurance Management Assessment Team**

**December 5, 2001**  
**Rockville, Maryland**

# Assessment Team

- **Wayne E. Booth**
  - Program Manager
- **Thomas R. Colandrea**
  - QA Specialist
- **Robert N. Ferguson**
  - Management/QA Specialist
- **John R. Longenecker**
  - Management Specialist



# Organizations Assessed

- **Sandia**
- **Los Alamos**
- **Berkeley**
- **Livermore**
- **USGS**
- **M&O Las Vegas**
- **YMSCO**





# Two QAMA Reports

- **M&O Interim Report**
  - 9 Recommendations for BSC
- **OCRWM Final Report**
  - 6 Recommendations for YMSCO



# Key Findings

- **Corrective Action Program needs improvement**
  - **Better sense of corrective action ownership is needed by line organization at both M&O and DOE**
  - **Effectiveness of previous corrective actions need to be assessed by the line organization**
  - **Cultural barriers must be overcome**
  - **Better metrics are needed to measure performance**



# Key Findings

(Continued)

- **Management initiatives, intended to improve performance, tend to fade over time**
  - **Focus should shift to improving human performance and enhancing professionalism**
  - **An enduring, common theme (DOE/M&O) should be developed**
  - **Use INPO guidelines**



# Key Findings

(Continued)

- **Self-assessment Program needs improvement**
  - **Need to**
    - ♦ **Define scope, philosophy, and objectives**
    - ♦ **Establish requirements and management expectations**
    - ♦ **Assign organizational responsibilities**
  - **Need specific requirement**
    - ♦ **Evaluate the effectiveness of previous corrective actions**



# Key Findings

(Continued)

- **YMSCO organization needs restructuring to accommodate license application phase**
  - **Clear responsibility for all business and technical functions**
  - **Delegate authority to lowest possible level**
  - **Better alignment with M&O**
    - ♦ **Roles, responsibilities, authorities, and functional**



# Summary

- **DOE and BSC senior management commitment to implement positive change**
- **QAMA team will measure progress in 2002**





U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Key Technical Issues Progress and Status Overview

Presented to:  
**DOE/NRC Quarterly QA Meeting**

Presented by:  
**Timothy C. Gunter**  
**Yucca Mountain Site Characterization Office**  
**Office of Civilian Radioactive Waste Management**

**December 5, 2001**  
**Rockville, Maryland**

# Status of KTI Agreements

- A total of 293 agreements have been reached
- The 293 agreements require 456 deliverables
- To date 159/456 (35%) of the deliverables have been submitted to NRC
  - 2 in FY 2000
  - 157 in FY 2001
- KTI deliverables for FY 2002 and beyond are being incorporated in Resource-Loaded Plans
- 16 due completion during December 6, 2001 through March 2002





# Status of KTI Agreements

(Continued)

Projected Delivery	Original Date	KTI ID	Deliverable
31-Jan-02	31-Jul-01	TEF 2.09	AMR - ANL-EBS-MD-000049, Multiscale Thermohydrologic Model
31-Jan-02	30-Sep-01	ENFE 2.12	REPORT - Crushed tuff hydrothermal column experiment report
28-Feb-02	30-Sep-01	USFIC 5.09	DOCUMENT - USGS Regional Model
Re-plan	31-Mar-01	TEF 2.07	AMR - ANL-EBS-MD-000030, Ventilation Model
Re-plan	31-Mar-01	RDTME 3.01	AMR - ANL-EBS-MD-000030, Ventilation Model



# Status of KTI Agreements

(Continued)

KTI Title	Agreements Reached (1)	Agreements Complete (2)	Documentation Received for Agreement (3)	Documentation Partly Received for Agreement (4)	Documentation Not Received for Agreement	Need Additional Information (5)	Actions	Actions Delivered
USFIC	27	4	0	1	22	0	33	7
IA	22	7	0	1	14	0	25	6
CLST	58	0	21	4	33	0	104	41
SDS	10	0	6	2	0	2	14	10
RT	29	0	5	2	22	0	49	15
ENFE	41	0	14	7	20	0	102	59
TEF	15	4	0	4	7	0	29	18
RDTME	23	0	0	2	21	0	31	2
TSPAI	58	0	1	0	57	0	58	1
PRE-C**	9	0	0	0	9	0	10	0
GENERAL	1	0	0	0	1	0	1	0
TOTAL	293	15	47	23	206	2	456	159
** Note: Pre-closure Safety is not considered a Key Technical Issue, but is listed as a topic of interest to the NRC.								
1. The total of agreements reached between NRC and DOE at technical exchange meetings.								
2. Agreements closed by NRC for which it has reviewed all documentation and has no further questions.								
3. Agreements for which NRC has received all documentation but has not completed its review.								
4. Agreements for which NRC has received a portion of the documents agreed to.								
5. Agreements for which NRC has received complete or partial documentation, but has requested further information via a formal letter.								

