UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 8, 2002

Mr. R. Dennis Brown, Director
Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
PO Box 364829 MS 523
N Las Vegas, NV 89038

SUBJECT: MEETING SUMMARY FOR THE OCTOBER 16, 2002, QUALITY ASSURANCE MANAGEMENT MEETING

Dear Mr. Brown:

Enclosed is the meeting summary of the October 16, 2002, Quality Assurance (QA) Management Meeting between the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC). The purpose of the meeting was to discuss items of mutual interest and those areas contributing to the resolution of QA issues.

The meeting was held at the DOE office in Las Vegas, Nevada, and via video conference to the NRC office in Rockville, Maryland and via telecon to the DOE office in Washington, DC; the NRC Region IV office in Arlington, Texas; and the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas.

If you have any questions regarding this letter, please contact Ted Carter of my staff at (301) 415-6684.

Sincerely,

Janet R. Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: QA Meeting Summary

cc: See attached list

Letter to R. Dennis Brown from Janet Schlueter dated November 8, 2002

cc:

R. Loux, State of Nevada
S. Frishman, State of Nevada
M. Chu, DOE/Washington, DC
C. Einberg, DOE/Washington, DC
S. Gomberg, DOE/Washington, DC
N. Slater-Thompson, DOE/Washington, DC
C. Newbury, YMPO
W. J. Arthur III, YMPO
R. Dyer, YMPO
J. Ziegler, YMPO
D. Brown, YMPO
S. Mellington, YMPO
C. Hanlon, YMPO
T. Gunter, YMPO
K. Hess, BSC
D. Krisha, BSC
S. Cereghino, BSC
N. Williams, BSC
M. Voegele, BSC/SAIC
D. Beckman, BSC/B&A
B. Price, NV Legislative Committee
J. Meder, NV Legislative Counsel Bureau
W. Briggs, Ross, Dixon & Bell
E. von Tiesenhausen, Clark County, NV
A. Kalt, Churchill County, NV
G. McCorkell, Esmeralda County, NV
L. Fiorenzi, Eureka County, NV
A. Johnson, Eureka County, NV
A. Remus, Inyo County, CA
M. Yarbro, Lander County, NV
I. Zabarte, W.S.N.C.
C. Anderson, Las Vegas Paiute Tribe
J. Birchim, Yomba Shoshone Tribe
R. Massey, Lander County, NV
L. Stark, Lincoln County, NV
M. Baughman, Lincoln County, NV
A. Funk, Mineral County, NV
L. Bradshaw, Nye County, NV
M. Murphy, Nye County, NV
D. Chavez, Nye County, NV
D. Weigel, GAO
W. Barnard, NWTRB
R. Holden, NCAI
A. Collins, NIEC
R. Arnold, Pahrump Paiute Tribe
J. Larson, White Pine County
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
L. Lehman, T-REG, Inc
S. Echols, ECG
N. Rice, NV Congressional Delegation
T. Story, NV Congressional Delegation
J. Reynoldson, NV Congressional Delegation
S. Joya, NV Congressional Delegation
J. Pegues, City of Las Vegas, NV
R. Bahe, Benton Paiute Indian Tribe
C. Bradley, Kaibab Band of Southern Paiutes
R. Joseph, Lone Pine Paiute-Shoshone Tribe
L. Tom, Paiute Indian Tribes of Utah

L. Jackson, Timbisha Shoshone Tribe

C. Meyers, Moapa Paiute Indian Tribe

V. Miller, Fort Independence Indian Tribe

A. Bacock, Big Pine Paiute Tribe of the Owens Valley

R. Quintero, Inter-Tribal Council of Nevada (Chairman, Walker River Paiute Tribe)

M. Bengochia, Bishop Paiute Indian Tribe

J. Egan, Egan & Associates, PLLC

J. Leeds, Las Vegas Indian Center

K. Tilges, Shundahai Network

J. Triechel, Nuclear Waste Task Force

W. Boyle, YMPO

E. Smith, Chemehuevi Indian Tribe

J. Charles, Ely Shoshone Tribe

D. Crawford, Inter-Tribal Council of Nevada

H. Blackeye, Jr., Duckwater Shoshone Tribe

D. Eddy, Jr. Colorado River Indian Tribes

G. Runkle, DOE, Washington, DC

W. Briggs, Ross, Dixon & Bell

H. Jackson, Public Citizen

M. Smurr, BNFL, Inc.

Citizen Alert

November 8, 2002

Mr. Dennis Brown, Director
Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
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Sincerely,

/RA/

Janet R. Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: QA Meeting Summary

cc: See attached list

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LCamper	ACampbell	BSpitzberg	WMaier, RIV	LChandler	DDambly
MYoung	SFlanders	RKJohnson	TMatula		

S:\DWM\HLWB\gdh1\101602QAMtgMinutes **ADAMS:** ML023160437 *See Previous Concurrence

OFFICE	HLWB		HLWB		HLWB		HLWB	
NAME	DHiggs*		TCarter*		NKStablein*		JSchlueter	
DATE	11/7/02		11/8/02		11/8/02		11/8/02	

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SUMMARY OF
NRC/DOE QUARTERLY QUALITY ASSURANCE MEETING
October 16, 2002

Introduction:

This NRC/DOE Quarterly Quality Assurance (QA) Meeting for the Yucca Mountain Project (YMP) was held on October 16, 2002, in Las Vegas, Nevada, with video and audio connection to the NRC Headquarters Office in Rockville, Maryland and audio connection to the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas. Participants included representatives from the NRC, DOE, Bechtel SAIC Co. LLC (BSC), and the State of Nevada. Copies of the agenda and a list of attendees are attached as Enclosures 1 and 2 respectively.

The meeting was convened with opening remarks from Dr. Margaret Chu (DOE). Dr. Chu emphasized the importance of the DOE QA Program and thanked all DOE and BSC staff for their efforts to improve the implementation of this process. She mentioned that QA is a key element in the Management Improvement Initiative (MII). Dr. Chu also indicated that she is pleased with the progress, but there is a long way to go. Additionally, she stated that she would like to see future QA meetings focus on working issues and develop specific action items much like the current Key Technical Issues meetings and technical exchanges.

Dr. Chu introduced Dennis Brown as the new Director of the Office of Quality Assurance (OQA). Mr. Brown provided a brief description of his background that included ten years of experience in the commercial nuclear industry in the area of QA auditing and surveillance activities. He was also QA Director at the Waste Isolation Pilot Plant (WIPP) for over 5 years and has past experience with the YMP QA program. He noted that many of the QA problems that WIPP had are the same or similar to those being experienced at YMP. He plans to focus on fully implementing the QA procedures, to have OQA staff get more involved with line staff to implement procedures, and to work toward resolution of data and software issues. He stated that for DOE to have confidence in its technical products the data must be qualified and software must be appropriately verified and validated.

Presentations:

Ram Murthy (DOE) presented the OQA Quality Assurance Program Status, including recent audit and surveillance activities, and the status of the trend program. A copy of this presentation is provided in Enclosure 3.

Tom Matula (NRC) asked if Technical Error Reports (TERs) are being integrated into the trend program. Mr. Murthy said that all TERs submitted to OQA trend coordinator have been entered into the trend database and the data is being evaluated. The results of the evaluation will be reflected in the next Trend Report. Mr. Matula also asked if the timeliness requirements for

ENCLOSURE

closing TERs are proceduralized. BSC stated that procedure AP-15.3Q is being revised to include timeliness requirements related to dispositioning TERs. Also, with regards to the OQA Action Item QA 0207-01 from the July 2002 Quarterly QA meeting, it was clarified that Deficiency Identification and Referrals (DIR) were not being captured as individual inputs to the OQA Trend Program. Mr. Murthy stated that DIRs will be incorporated, as appropriate, in future trend reports.

Mr. Matula inquired about the use of unqualified data to support Key Technical Issue (KTI) agreement resolutions. Joe Ziegler (DOE) said that when doing risk sensitivity studies for issue resolutions, DOE uses the best information available, but the data may not be qualified. However, data used for license application (LA) will be appropriately qualified. Mr. Matula noted that DOE has stated its intent to issue, by the end of October 2002, a position paper on the use of unqualified data to support KTI agreement resolution. Mr. Matula asked to what extent OQA has been involved in the development of the DOE position paper. Mr. Murthy said that DOE OQA has not been involved in the development of the DOE position paper. However, Messrs. Ziegler and Brown (DOE) stated that OQA would be involved in review of the position paper.

Robert Latta (NRC) cited a recent OQA trend report that indicated that failures to implement procedures are increasing. Ken Hess (BSC) said that the issue is isolated. However, BSC has been encouraged by the increase in frequency of project personnel actively identifying possible deficiencies and that non-compliance was being addressed. Mr. Hess also indicated that BSC is not satisfied with procedure compliance but that an increasing trend indicates that compliance issues are being self identified and brought forward.

Larry Campbell (NRC) requested DOE OQA to provide the basis for delaying the annual audit of the Yucca Mountain Site Characterization Office (YMSCO). Mr. Campbell stated that the last audit report, YMSCO-ARC-01 -14, indicated that this organization was not effectively implementing the QA program. Further, Mr. Campbell stated that typically, audit frequencies are shortened rather than lengthened when adverse conditions are identified in an organization. Mr. Murthy explained that he agreed to delay the audit at the request of the YMSCO Project Manager because of various MII implementation reasons including the timing of the audit. Mr. Murthy also stated that the deficiencies identified in the previous audit have been verified and closed and that he approved delaying the audit for 3 months, as MII itself is a comprehensive action plan that needs to be accomplished. The audit has been rescheduled to be performed in December of this year. Mr. Brown (DOE) asked if any surveillances had been performed since the audit and Mr. Murthy said no. Mr. Brown stated that he would review the basis for the audit being delayed, and if appropriate generate a Deficiency Report (DR).

Dr. Gene Runkle (DOE) then presented an overview of MII implementation relative to QA programs and process (Enclosure 4). Dr. Runkle described the primary objectives of this improvement area as: 1) defining and clarifying roles and responsibilities, and 2) focusing on

quality at the working level where quality must be built into the products and not inspected-in. He also described progress on the QA program, review of the Quality Assurance Requirements Document (QARD), and project procedures. Dr. Runkle indicated that certain documents recently produced under the MII have been provided to the NRC's On-site Representatives. William Reamer (NRC) asked if those documents would be available to the public; Dr. Runkle replied yes.

Mr. Matula (NRC) reminded DOE that during the quarterly QA Meeting held in July 2002, DOE agreed to provide QARD revisions that reduce commitments to NRC for review and comment prior to implementation. DOE acknowledged this agreement. Dr. Chu (DOE) emphasized that the goal of MII is to clarify project procedures, determine how to best implement them, and then to facilitate their implementation.

During the discussion of the review of the QARD, Mr. Campbell (NRC) discussed that the draft NRC Yucca Mountain Review Plan issued in 1989 was for scientific investigation and site characterization activities and that the 2002 draft was applicable for the QA program to be submitted should DOE submit a license application. Further, Mr. Campbell pointed out that certain editions of NQA-1 (e.g., the 1983 edition) had been accepted by the NRC and that certain later editions may have changed, deleted, or made certain provisions non-mandatory. Specifically, Mr. Campbell cautioned the use of certain editions of NQA-1 that may have reduced provisions of NQA-1-1983.

Susan Lynch (State of Nevada) asked Janet Schlueter (NRC) if the NRC would be providing any more detailed comments on the MII than those contained in the October 3, 2002, letter from NRC to DOE. Ms. Schlueter briefly described the comments in the letter but said that there were no plans by NRC to provide any further detailed comments.

Russell Fray (BSC) made the next presentation on the BSC procedure action plan (Enclosure 5). The objective of the BSC procedure action plan is to improve efficiency of current processes, define procedure hierarchy, and establish separate DOE and BSC procedure sets. Mr. Fray stated that the procedure on TERs is currently in review. Mr. Campbell (NRC) noted that the lessons learned from the projects 1999 procedure revision activity should be taken into account. Mr. Latta (NRC) also mentioned that some recent procedure changes affecting Office of Civilian Radioactive Waste Management (OCRWM) activities have not been reviewed and concurred on by OQA. Robert Hasson, a representative from a DOE contractor, Navarro Quality Services, stated that this issue is being reviewed for a potential DR. Mr. Murthy (DOE) stated that OQA has scheduled a surveillance on the procedure preparation activities.

Mr. Fray (BSC) also made a presentation concerning the status of Corrective Action Reports (CARs) and stand-down activities (Enclosure 6). Mr. Fray indicated that eight of the 12 corrective actions described in the MII have been completed. The remaining four are 1) self-identification of model validation problems; 2) self-assessments of model development for LA;

3) evaluation of Bin 3 model impacts, and; 4) development of performance indicators. The CARs being addressed involve: 1) model validation; 2) software development; 3) training requirements and job functions; 4) preservation of records on electronic media, and; 5) tracers, fluids, and materials not recorded on required forms. Mr. Fray also discussed the site operations stand-down, related to a near-miss electrical incident that occurred in March 2002 at the Yucca Mountain site. This stand-down has been completed by issuance of a comprehensive recovery plan and the implementation of a new site operations management approach.

Mr. Murthy (DOE) gave a presentation on the verification of CARs (Enclosure 7). DOE's conclusion within this area is that corrective actions verified to date are satisfactory. Mr. Murthy stated that this a phased approach and should not be construed as final verification.

Mr. Matula (NRC) asked why software validation issues were documented on TERs rather than on DRs. Mr. Fray (BSC) said that TERs are used to document minor editorial errors while DRs are used to document non-compliance with QARD requirements.

Regarding software procedure status, Mr. Fray stated that new procedures will be piloted and put through a dry run before training of project staff on those procedures is completed. Mr. Fray also stated that based on the results of an ongoing BSC software surveillance, senior management is evaluating a decision to require all LA supporting codes to be re-tested as part of the new verification and validation process. Mr. Reamer (NRC) asked when, as a result of the software surveillance, DOE senior management would make a decision regarding the review of all computer codes supporting LA. Mr. Fray stated that this decision would be made in November 2002.

Mr. Campbell (NRC) asked for the definition of a Software Deficiency Notification (SDN), and if these documents are trended. Mr. Fray replied that these reports identify minor inconsistencies in software codes and that an impact evaluation is required for SDNs. Depending on the results of the impact evaluation, a DR may be written and the condition would be entered into the trend database. With respect to the CAR on degradation of electronic media, Mr. Campbell (NRC) asked if any of the electronic records were used to support either site recommendation or if they would be used for LA? In response to this question, DOE indicated that some of the electronic records could have been used to support SR and/or LA. However, DOE also indicated that they believe that hard copies of many of these records may exist.

Mr. Matula (NRC) inquired as to the possibility of having copies of all CARs and DRs initiated by both DOE and BSC formally submitted to NRC. Mr. Ziegler (DOE) stated that copies of CARS and DRs are now provided to the NRC On-site Representatives.

Don Krisha (BSC) then gave a short explanation as to the differences between non-QA and QA related stand-downs, when a DR or CAR would be issued, and the ability of BSC's QA organization to stop work if a QA related issue is not properly addressed by management.

Emily Cooper (DOE) gave a presentation on the status of the self-assessment (SA) program (Enclosure 8). The SA program has made progress by revising SA procedures, designating organizational points of contact, developing an SA handbook and new or improved training, screening of SA reports, providing SA mentoring, and by developing SA performance indicators. Ms. Cooper also described the results of recent SAs, and the program's goals for enhancements including incorporation of guidance derived from commercial nuclear experience.

Susan Lynch (State of Nevada) requested copies of DOE/BSC self-assessment reports. Mr. Ziegler (DOE) said they would consider these requests and noted that the self-assessments reports are not public documents.

Mr. Krisha (BSC) gave a status update of BSC's QA program (Enclosure 9). In FY02, 44 QA surveillances were completed and the FY03 first quarter schedule has been issued. The focus of surveillances is on repetitive past problems, real-time critical activities, and on any requested topic. Mr. Krisha also gave a status update on BSC's audit program. In FY02 36 external audits were completed and the FY03 first quarter schedule has been issued. Approval by the OCRWM senior management to perform internal audits was received in July 2002, and the first internal audit, regarding records management and document control, was conducted in early October 2002. The FY03 internal audit schedule has been issued.

Action Item:

Tim Gunter, DOE, presented the status of the action items from the past meetings. In addition, two new action items were agreed to:

1. DOE review the reasons for OQA delaying their audit of YMSCO, and whether a DR should be issued on that issue.
2. DOE is to consider the State of Nevada's request for copies of all self- assessment reports.

The current status of the action items is shown in Enclosure 10.

Closing Remarks:

None.

Date 11/8/02
Janet Schlueter, Branch Chief
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission

Date 11/5/02
Dennis Brown, Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

Date 11/4/02
Joseph D. Ziegler, Acting AM
Office of License Application
and Strategy
Office of Repository Development
U.S. Department of Energy

Enclosures

NRC/DOE QUARTERLY QUALITY ASSURANCE MEETING
October 17, 2002

Enclosure	Description
1	Agenda
2	Attendance List
3	Status of DOE QA Program
4	Status of MII Implementation
5	BSC Procedure Action Plan
6	Status of CARs and Stand-Downs
7	Verification of CARs
8	Self-Assessment Program Status
9	Status of BSC QA Program
10	Action Items

Enclosure 1

Agenda
DOE/NRC Quarterly QA Meeting
October 16, 2002
9:00 AM – 12:00 PM (PT)
12:00 Noon – 3:00 PM (ET)

BSC
Room 915
9960 Covington Cross
Las Vegas, NV

And via Videoconference to:

U. S. Nuclear Regulatory Commission
Room T-2B5
11545 Rockville Pike
Rockville, MD

INTERESTED PARTIES MAY PARTICIPATE VIA TELECON BY CALLING 702-295-6082

9:00 AM	Introduction/Opening Remarks	DOE/NRC
9:10 AM	OCRWM OQA Director • Introduction of New OQA Director • Approach to QA	 Dr. Chu Brown
9:25 AM	Status of DOE QA Program • OQA Audits/Surveillance • Semi-Annual Trend Report	Murthy
9:45 AM	Status of MII Implementation	Runkle
10:15 AM	Status of CARs and Stand Downs • Status of CARs • Status of Software Development Stand Down • Status of Site Operations Stand Down and Corrective Actions • QA Aspects of Stand Downs • Verification of CAR Corrective Actions	Fray Krisha Murthy
10:45 AM	Results of Semi-Annual Self-Assessment	Cooper
11:00 AM	Status of BSC QA Program • Update on BSC Audits/Surveillance Activities	Krisha
11:15 AM	Break	ALL
11:30 AM	Action Item Status	Gunter
11:45 AM	Closing Remarks	ALL
12:00 N	Adjourn	

Enclosure 2

QA: N/A

ATTENDANCE LIST
DOE/NRC Quarterly QA Meeting
Las Vegas, NV
October 16, 2002

Name	Organization	Telephone
William J. Glassea	OQA/NQS	7027945014
Jim Blaylock	OQA/DOE	794-1420
Kristi Hodges	OQA/NQS	794-1464
Ram B. Murthy	DOE/RW-3	794-5549
Bob Gamble	MTS/Bisz Allen	794-1440
Dan Harris	NQS/OQA	794-1467
Jim Cross	BA&A	256-459-9799
Veronica Cornell	MTS/Parallax	702-794-1392
Judy Gebhart	BSC QA	295-4774
Bob Bradburn	MTS/Shaw	794-5424
Tish Morgan	MTS/Boeing	794-1463
Robert Sweeney	BSC-CT	703-624-8032
Steve Frishman	NV NWPO	775-687-3744
Judy Treichel	NAWTF	202-248-1127
Robert Hartstein	BSC QA	702-295-2625
William Watson	BSC Performance Assessment	702-295-5550
Janet Schlueter	NRC/HLW	301-415-7264

QA: N/A

ATTENDANCE LIST
DOE/NRC Quarterly QA Meeting
Las Vegas, NV
October 16, 2002

Name	Organization	Telephone
Myrle Rice	Intertech/Lincoln County	702 263 6583
Ali Haghi	BSC/LAP	702-295-4019
Sam Horton	BSC-QA	702-295-0304
Bill Reamer	NRC	301-415-6537
Mal Murphy	Nye County	360 943-560
Jim Pegues	City of Las Vegas	702 229-6862
Emily Carpeci	DOE	702-794-5444
Mickey McDonnell	DOE	702-295-4023
George Parnell	BSC	702-295-3975
Susan Lynch	State of Nevada	775-687-3744
Robert Murray	MTS/Bath	702-794-5566
Tim Gunter	DOE	702-794-1343
Jack Parrott	NRC	702-794-5047
C. David Osborne	BSC-Site Quality	702-295-5912
Frank Kratzmeier	MTS	702-794-1369
Michael Jaeger	BSC/PA	702-295-4245
R.M. Latta	NRC/On Site Rep	702-794-5048
J.L. Harding	BSC-CIO	702-295-3840
R.W. Clark	DOE	702 794 5583
George Hellstrom	DOE	702-794-1419
Don Beckman	BSC	702-295-4358

QA: N/A

ATTENDANCE LIST
DOE/NRC Quarterly QA Meeting
Las Vegas, NV
October 16, 2002

Name	Organization	Telephone
Robert P. Hasson	OQA/NQS	(702) 794-5023
Marilyn Kavchak	OQA/NQS	702-794-5423
Pamela Dahl	BSC	702 295-0427
Donald T. Krisha	BSC	702-295-6242
Russell Frey	BSC	702-295-5526
Rod McCullum	NEI	202-739-8087

ATTENDANCE LIST
NRC/DOE QUARTERLY QUALITY ASSURANCE MEETING
NRC HEADQUARTERS
October 16, 2002

NAME	ORGANIZATION	TELEPHONE
TED CARTER	NRC-HQ	301-415-6684
King Stablein	NRC	301-415-7445
JACK SORENSEN	NRC	301-415-6804
Yen Chen	NRC	301-415-5615
WILKINS SMITH	NRC	301-415-5788
LARRY L Campbell	NRC	301 415-5000
Tom MATULA	NRC	301 415-6700
Larry Saraka	BSC	202-488-6745
MEKE LEE	NRC	301-415-6887
MITZI YOUNG	NRC	301-415-1523
Andy Campbell	NRC	301-415-6897

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
MEETING ATTENDANCE

SUBJECT OF MEETING: DOE/NRC Quarterly QA Meeting

DATE: 10/16/02 LOCATION: CNWRA to Las Vegas via Telecon

PERSON	ORGANIZATION	TITLE/FUNCTION	TELEPHONE NUMBER
R. Weber	SwRI IQS	Manager	(210) 522-3161
Mark N. Thornton	SwRI IQS	Sr. QA Technologist	(210) 522-3530
Bruce Mabrito	CNWRA QA	Dir QA	210-522-5149
Robert Pickett	SwRI IQS	Assistant Mgr.	(210) 522-3537

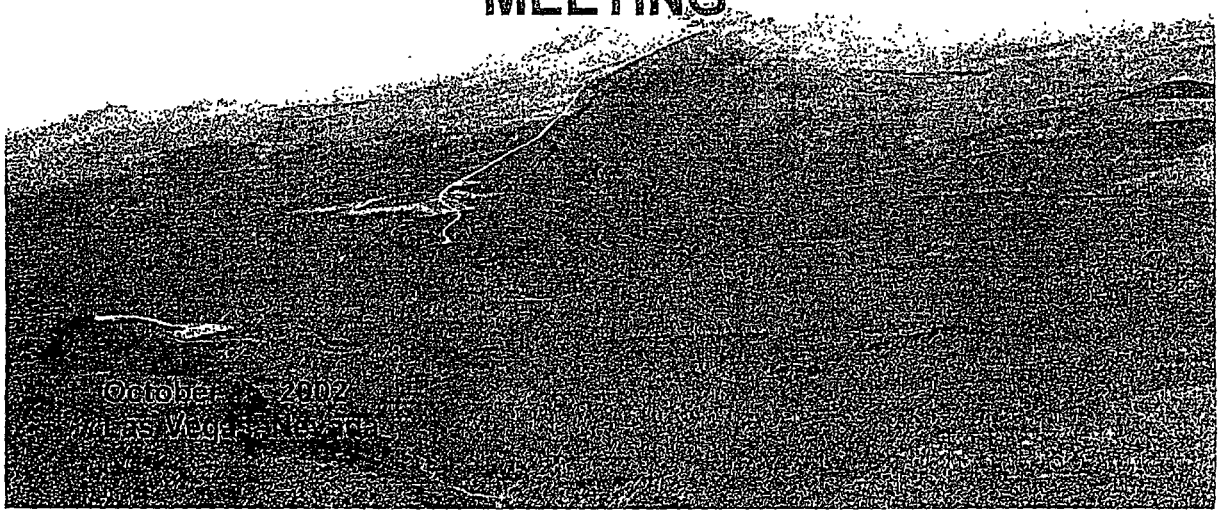
CNWRA Form AP-5

FAX To: 702-295-4545

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

YUCCA MOUNTAIN PROJECT

DOE/NRC QUARTERLY QUALITY ASSURANCE MEETING



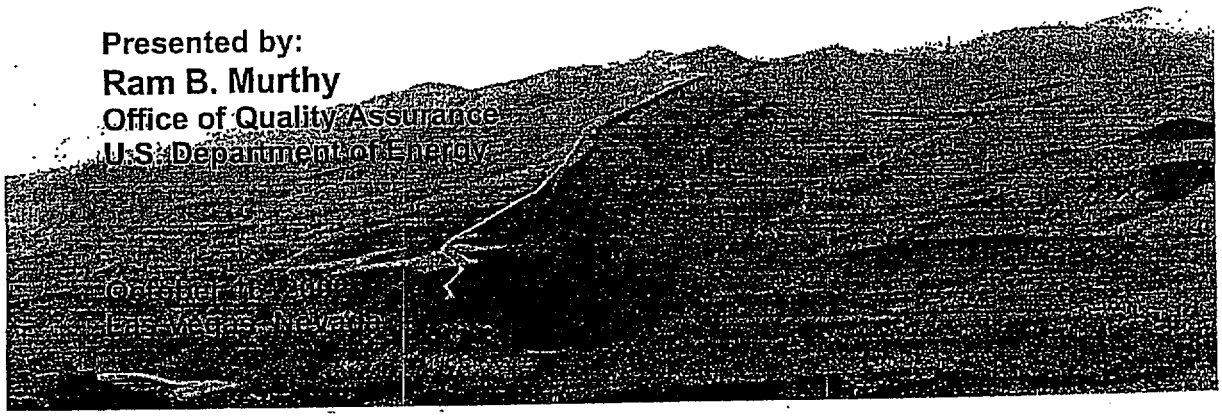
U.S. Department of Energy
Office of Civilian Radioactive Waste Management

YUCCA MOUNTAIN PROJECT

Quality Assurance Program Status

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Ram B. Murthy
Office of Quality Assurance
U.S. Department of Energy



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DOE/NRC Quarterly QA Meeting
October 16, 2002
9:00 AM – 12:00 PM (PT)
12:00 Noon – 3:00 PM (ET)

BSC
Room 915
9960 Covington Cross
Las Vegas, NV

And via Videoconference to:

U. S. Nuclear Regulatory Commission
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11545 Rockville Pike
Rockville, MD

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	• Approach to QA	Brown
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	• OQA Audits/Surveillance	
	• Semi-Annual Trend Report	
9:45 AM	Status of MII Implementation	Runkle
10:15 AM	Status of CARs and Stand Downs	Fray
	• Status of CARs	
	• Status of Software Development Stand Down	
	• Status of Site Operations Stand Down and Corrective Actions	
	• QA Aspects of Stand Downs	Krisha
	• Verification of CAR Corrective Actions	Murthy
10:45 AM	Results of Semi-Annual Self-Assessment	Cooper
11:00 AM	Status of BSC QA Program	Krisha
	• Update on BSC Audits/Surveillance Activities	
11:15 AM	Break	ALL
11:30 AM	Action Item Status	Gunter
11:45 AM	Closing Remarks	ALL
12:00 N	Adjourn	

10/15/02 ~0017620.doc

Outline

- Audit and Surveillance Activities
- Status of the Trend Program

Office of Quality Assurance Audit & Surveillance Activities

- Compliance Audit BSC-ARC-02-15 of the BSC Repository Design Project (July 2002)
  - Two Deficiency Reports (DR) were identified
    - Justification not documented for not conducting impact reviews of design drawings
    - AP-3.13Q, Design Control, contained inappropriate references (Supp. V, Configuration Audits, and Client Design Reviews)
    - Both DRs have been verified and closed
  - One Quality Observation (QO) was identified for omission of a reviewer's organization/discipline from review record
  - Overall, Quality Assurance (QA) program implementation was determined satisfactory

Office of Quality Assurance Audit & Surveillance Activities

- Office of Quality Assurance (OQA) conducted 24 surveillances during Fiscal Year (FY) 2002 and will continue its surveillance program for FY 2003
- OQA has issued its FY 2003 audit schedule

Status of the Trend Program

- **Office of Civilian Radioactive Waste Management (OCRWM) QA Trend Report (January 2002 - June 2002)**
  - Two emerging issues identified:
    - Emerging issue identified in area of timely submittal of quality records to the Records Processing Center
      - » BSC is evaluating this issue through current audit/surveillance activities
    - Emerging issue identified in area of compliance with requirements in the field
      - » BSC investigation determined there are sufficient controls in place to ensure compliance and issues were isolated in nature
      - » OQA will continue to monitor

Status of the Trend Program
(Continued)

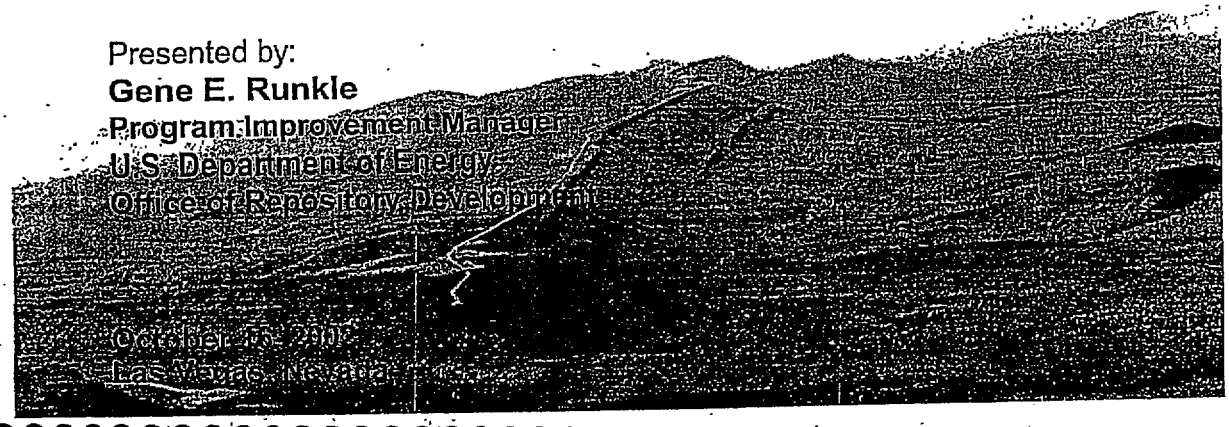
- Pending trend program changes
  - OQA has not included Deficiency Identification and Referrals (DIR) as individual trend inputs; however, they were captured as extent of condition
  - OQA will revise procedure(s), as appropriate, and incorporate DIRs as individual inputs into its next trend report

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

YUCCA MOUNTAIN PROJECT

Management Improvement Initiatives Implementation

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting



Presented by:
Gene E. Runkle
Program Improvement Manager
U.S. Department of Energy
Office of Repository Development

October 7-8, 2002
Las Vegas, Nevada

Outline

- History & Background
- Quality Assurance Program Progress
- Review Quality Assurance Requirements and Description (QARD)
- Realignment and Review of Project Procedures
- Conclusions

History and Background

- 1998: Senior managers began transition from work technically sufficient for site suitability to traceability needed for licensing
- 2001: Office of Quality Assurance (OQA) identified recurring conditions adverse to quality (BSC 01-C-001 & -002)
  - Root cause analysis identified weaknesses in management systems, quality processes, & roles & responsibilities
  - Management recognized need for sustained initiative to:
    - Clarify roles, responsibilities, authority, & accountability
    - Improve effectiveness of Quality Assurance (QA) program implementation
    - Drive culture to consistency with Nuclear Regulatory Commission (NRC)-regulated environment

History and Background

(continued)

- July 2002: Management Improvement Initiatives (MII) submitted to NRC
- Five key areas for improvement were identified:
  - Project Roles, Responsibilities, Authority, & Accountability (R2A2)
  - Quality Assurance Programs & Processes
  - Project Procedures
  - Corrective Action Program
  - Safety-Conscious Work Environment
- Action plans were developed for each area
- Appendix B contains action plans for BSC 01-C-001 & -002

Quality Assurance Programs and Processes

- Primary objectives for this improvement area:
  - Define & clarify roles & responsibilities
  - Focus on quality at working level
- Action statements for this improvement area:
  - Issue DOE policy statement on expectations
  - Clarify R2A2 for OQA
  - Orient DOE & BSC staffs on R2A2
  - Review Quality Assurance Requirements & Description
  - Reflect QA requirements in implementing procedures
  - Revise DOE annual performance appraisals

Quality Assurance Program Progress

- Director, Office of Quality Assurance on board
  - Denny Brown joined Office of Civilian Radioactive Waste Management (OCRWM) Program on 10/7/02
- R2A2 for QA requirements and implementation clarified
  - OQA Director responsible for Corrective Action Program
  - Line management is responsible for effective implementation of the QA program
  - DOE and BSC QA responsibilities identified
  - Management and staff have been oriented on R2A2
- Continuing steps include review and revision of QARD and implementing procedures

Review of QARD

- QARD currently in review for consistency with applicable regulatory requirements and guidance
  - Including NQA-1; 10 CFR Part 63; Review Plans (1989; 2002 draft)
- Review will identify which sections would most benefit from revisions, possibly including:
  - 1.0 Organization – Clarify roles and responsibilities
  - 2.0 QA Program – Clarify document review process
  - 16.0 Corrective Action – Clarify roles of QA organizations
  - Appendix C Mined Geologic Repository – Write non-conformance reports only against systems, structures, and components
  - Supplement 3 Scientific Investigation – Bring model validation in line with requirements (e.g., NQA-1, Supplement 3s-1; NQA-3)
  - Data Management – Consolidate requirements

Project Procedures

- Primary objectives for this improvement area:
  - Review & revise procedures to be more effective & efficient
  - Realign R2A2 to implement revised procedures sets
- Action statements for this improvement area:
  - ✓ Clarify OCRWM R2A2
  - ☐ Review existing procedures
  - ☐ Issue new or revised procedures
  - ☐ Train personnel prior to implementation
- Impacts to procedures from QARD review:
  - DOE: select set of procedures for DOE activities
  - BSC: about 200 procedures being prioritized for review and revision

Conclusions

- DOE and BSC are implementing the Management Improvement Initiatives
- Completion of Action Statements on schedule in accordance with implementation plans
  - OQA Director on board
  - QA Program policies in place and R2A2 communicated
  - QARD currently in review against regulatory requirements and guidance
  - Project procedures being realigned and reviewed

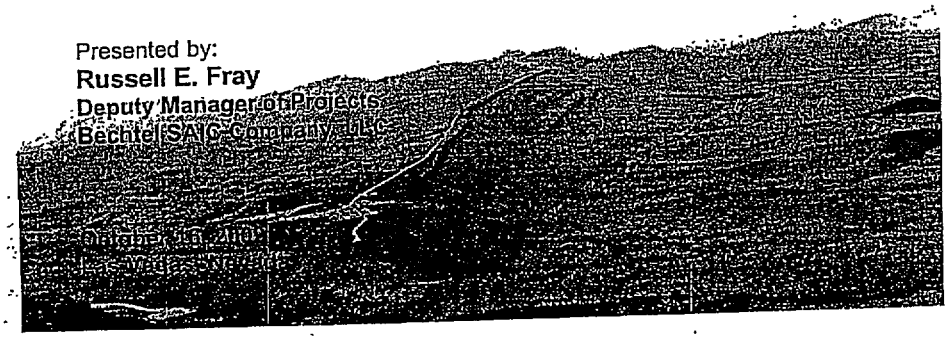
U.S. Department of Energy
Office of Civilian Radioactive Waste Management

YUCCA MOUNTAIN PROJECT

BSC Procedure Action Plan

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Russell E. Fray
Deputy Manager of Projects
Bechtel SAIC Company, LLC



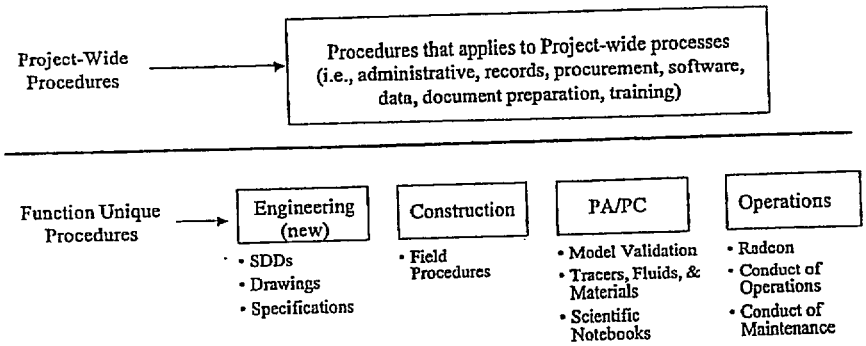
Objectives

- Improve efficiency of current processes
  - Current procedure set is compliant
  - Improvement will decrease schedule risk
- Define procedure hierarchy (October 2002)
- DOE/BSC establish separate procedure sets (begin November 2002)

BSC Approach

- Multi-path approach
  - Incremental improvement to existing procedures based on current Quality Assurance Requirements and Description (QARD)
  - Significant improvement in the critical few processes
  - Bring in industry standard procedures where appropriate (i.e., new engineering procedures)

Procedure Scope

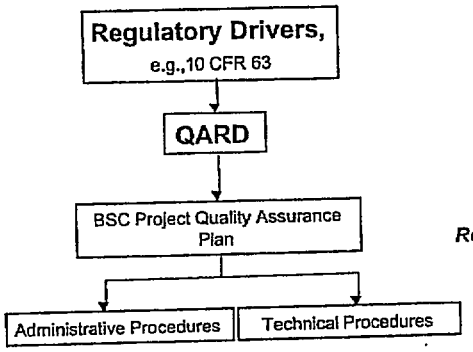


A majority of procedures are not unique to scientific activities. Most procedure enhancements are generic to process level activities across the Project, such as technical document preparation and approval.

Status

- Hierarchy defined
- 269 total BSC procedures
  - 69 are being evaluated for revision

BSC Procedure Hierarchy



Requirements Level

Critical Procedures Under Review for Improvement

- Project Wide Procedures
  - Report Preparation, Review, and Approval
  - Software
  - Data Qualification
  - Corrective Action Program
  - Procedure Change Process
- Function Unique Procedures
  - Scientific Notebooks
  - Model Preparation and Validation
  - New Engineering Processes
    - Import industry standard

Path Forward

- BSC off-line team working on procedure revisions (off-project membership)
  - Conducting interviews and scoping
  - Mapping out detailed procedure revision plan
- DOE reviewing QARD for incremental changes
- Future issuance of modified procedures will be checked for compliance with current QARD revision prior to issue

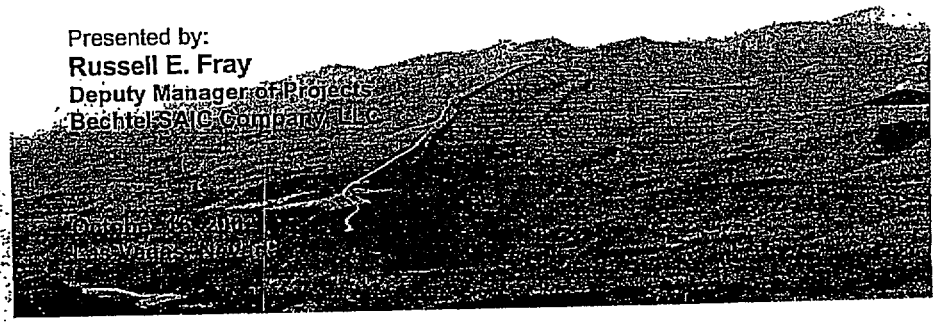
U.S. Department of Energy
Office of Civilian Radioactive Waste Management

YUCCA MOUNTAIN PROJECT

Status of Corrective Action Reports and Stand-Downs

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Russell E. Fray
Deputy Manager of Projects
Bechtel SAIC Company, LLC



Corrective Action Report BSC-01-C-001 Model Validation

- Eight of the twelve corrective actions in Management Improvement Initiatives (MII) have been completed
  - Recommendations on process improvements for corrective actions
  - Model Validation Status Review (MVSR)
  - Root Cause evaluation
  - Validation issues documented as Technical Error Reports (TERs)

Corrective Action Report BSC-01-C-001
Model Validation
(Continued)

- Developed AP-SIII.9Q (analyses) and AP-SIII.10Q (models) and trained on AP-SIII.10Q
- Modeling activities scheduled
- AP-SIII.10Q (models) added to Chief Science Office (CSO) training matrix
- Review of new Analysis and Model Reports (AMRs) for revisions to AMRs

Corrective Action Report BSC-01-C-001 Model Validation

(Continued)

- The remaining four corrective actions currently in process are:
  - Self identification of in-process model validation problems per new procedure
  - Self-assessments of model development during license application (LA) development
  - Evaluation of Bin 3 model cumulative impacts
  - Develop performance indicators

Corrective Action Report BSC-01-C-002
Software Development

- Topics
  - CAR action items
  - Software procedures
  - Software procedure training
  - BSC Quality Assurance (QA) Surveillance Preliminary Results
  - Stand-down and progress toward lifting the stand-down
  - Self-Assessments

Corrective Action Report BSC-01-C-002
Software Development

- Topics
  - CAR action items
  - Software procedures
  - Software procedure training
  - BSC Quality Assurance (QA) Surveillance Preliminary Results
  - Stand-down and progress toward lifting the stand-down
  - Self-Assessments

Corrective Action Report BSC-01-C-002
Software Development
(Continued)

- CAR action status
  - Out of 25 CAR actions, 9 actions are complete
  - Another 3 actions are complete and BSC is preparing a request for verification
  - Actions associated with the following are in process
    - Software procedures
    - Training
    - BSC QA surveillance on software baseline

Corrective Action Report BSC-01-C-002 Software Development

(Continued)

- Software procedure status
  - Software procedures AP-SI.1Q, AP-SI.2Q, and AP-SI.3Q are undergoing final comment resolution
  - New procedures will be validated by a "Pilot" program
  - Procedures will be effective upon completion of training of essential personnel

Corrective Action Report BSC-01-C-002
Software Development
(Continued)

- BSC QA surveillance status
  - The BSC QA surveillance of the qualified baselined codes will complete on October 24, 2002. Preliminary results:
    - 55 codes tested
    - 35 codes passed by replicating previous testing results without recourse to the originator
    - 20 codes required the assistance of the originator and require additional evaluation

Corrective Action Report BSC-01-C-002 Software Development

(Continued)

- BSC QA Surveillance path forward:
  - Complete the surveillance
  - Prepare amended response to CAR to address adverse surveillance results
  - Senior Management evaluating decision to require all LA supporting Codes be retested as part of the new process unless they passed the surveillance
    - » Ensure codes taken forward to LA are fully qualified and documented

Corrective Action Report BSC-01-C-002
Software Development
(Continued)

- Software stand-down status
  - The stand-down is still in effect and exemption from the stand-down is required by management policy for any new software development
  - 143 exemption requests approved since the beginning of the stand-down
    - Exemption process used to provide additional management oversight
    - Approximately 30 have been baselined

Corrective Action Report BSC-01-C-002 Software Development

(Continued)

- Requirements to lift the software stand-down
  - Training during 2001 on AP-SI.1Q (completed)
  - Root Cause Evaluation (completed)
  - Actions to Correct Root Causes
    - Revise procedures (in process)
    - Training of essential personnel on the new procedures (pending procedure approval and any final changes to training modules)
  - BSC General Manager formally lift the stand-down (after all above actions complete)

Corrective Action Report BSC-01-C-002 Software Development

(Continued)

- Self-Assessments
  - Self-Assessments are planned to test the effectiveness of training and the new process
    - Training self-assessment (Forecast start December 1, 2002)
    - Process self-assessment (Forecast start January 15, 2003)

Corrective Action Report
CAR-02-C-001

- CAR-02-C-001 – Training requirements matrix/job function not determined/not provided to Human Resources or Training
- OQA verification in progress

Corrective Action Report
BSC(B)-02-C-129

- BSC(B)-02-C-129 – Preservation of Records on Electronic Media
  - Self-Assessment SA-CIO-IRM-2002-001, Self-Assessment of Acceptance of Electronic Submittals to the Records Processing Center, identified a condition-adverse-to-quality
  - Electronic records have not been preserved as required
- BSC(B)-02-C-129 was initiated to address this condition

Corrective Action Report BSC(B)-02-C-129

(Continued)

- Extent of condition
  - No procedure exists to ensure that QA records on electronic media are periodically refreshed/migrated
  - An inventory of electronic records was performed and the following identified:
    - 5,500 records as electronic
    - 15,600 items associated with these records (i.e., a record may have more than one item)
- Path forward
  - Procedures being developed
  - Records will be refreshed/migrated
  - Data on potentially degraded media being assessed

BSC-02-D-090, Tracers/Fluids/Materials Not Recorded on the Required Forms

- DR-90 issued in April 2002
- Action taken October 4, 2002 to upgrade to CAR
  - 8 recorded deficiency reports since 1998 (spanned several contracts)
  - DR-90 is 9th recorded instance
  - 10th recorded instance – a Deficiency Identification and Referral (DIR) incorporated with DR-90
  - Immediate stand-down of Tracers/Fluids/materials (TFM) activities followed by implementation of compensatory measures

Site Operations Stand-Down

- Background
  - March 26, 2002 near-miss electrical incident
  - Physical work immediately stood down
    - Essential work activities selectively restarted with heavy independent oversight
  - Formal root cause investigation convened and completed
  - Reorganized and re-staffed management to reflect a stronger operations and maintenance perspective

Site Operations Stand-Down
(Continued)

- Current status
  - Completed a comprehensive recovery plan based on results of the root cause investigation - August 2002
    - Recovery actions integrated into the multi-year baseline
  - All work activities underway under new management approach
    - Independent oversight of work activities
    - Operations control
    - Maintenance and site engineering functions established

Site Operations Stand-Down
(Continued)

- Independent oversight and management response proving to be effective
  - Lockout/Tagout (LOTO) stand-down
  - Tracer/Fluid/Materials stand-down

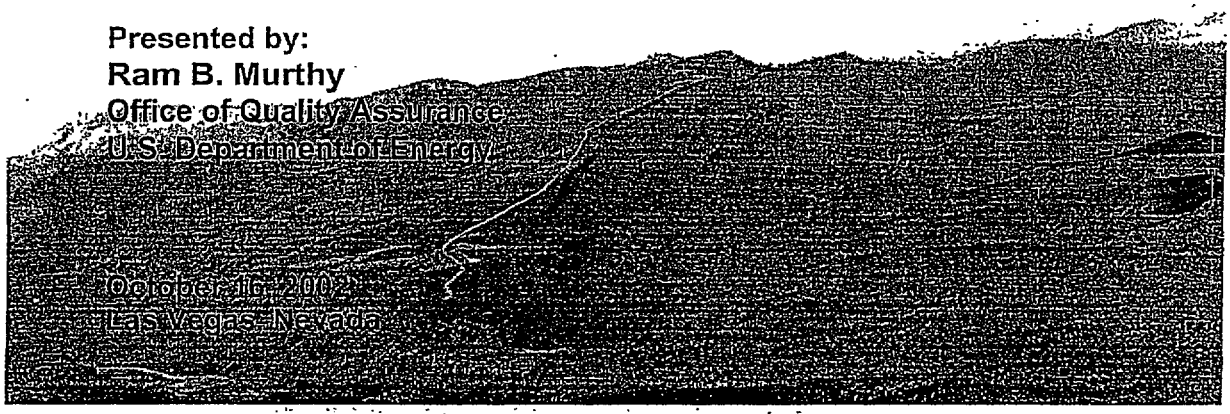
U.S. Department of Energy
Office of Civilian Radioactive Waste Management

YUCCA MOUNTAIN PROJECT

Verification of Corrective Action Reports

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Ram B. Murthy
Office of Quality Assurance
U.S. Department of Energy



October 16, 2002
Las Vegas, Nevada

Verification of Corrective Action Reports

- Corrective Action Reports (CAR) BSC-01-C-001 (Model Validation)
  - Five (5) actions completed and verified:
    - Root Cause Analysis
    - Model Validation Status Review
    - Bin 2 and 3 models tracked per AP-15.3Q (technical errors)
    - Development and training to AP-SIII.9Q (analyses)
    - Development and training to AP-SIII.10Q (models)
  - Verification to date is satisfactory

Verification of Corrective Action Reports

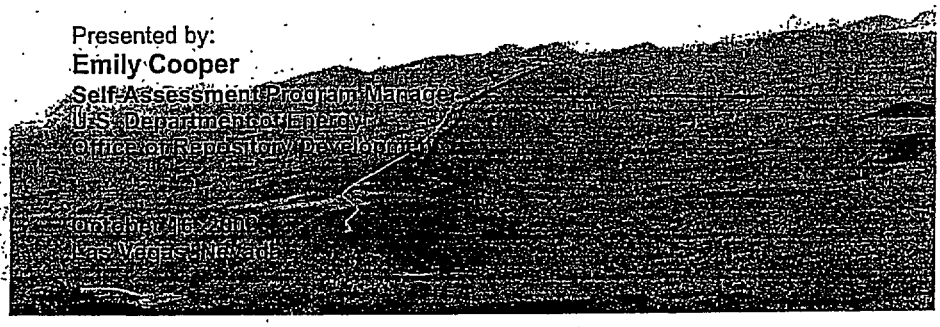
- CAR BSC-01-C-002 (Software)
  - Nine (9) actions completed and verified, for example:
    - Software stand down issued
    - Root Cause Analysis
    - Submittal of Software User Requests
    - Transfer of ownership of software procedure
    - (AP-SI.1Q)
  - Verification to date is satisfactory

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

YUCCA MOUNTAIN PROJECT

Self-Assessment Program Status

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting



Presented by:
Emily Cooper
Self-Assessment Program Manager
U.S. Department of Energy
Office of Repository Development

October 17, 2006
Las Vegas, Nevada

History and Background

- The Self-Assessment Program was originally one of the six initiatives of Nuclear Culture (1999)
- The Self-Assessment Program was proceduralized in June 2000 to implement DOE Order 414.1A and "Integrated Safety Management Quality Assurance Program" (ISMQAP)
- The first evaluation of the Self-Assessment Program was performed approximately one year later, resulting in the self-identification of the program issues leading to the following program improvements:

Self-Assessment Program Progress

- Revised Procedure/Established Management Expectations
- Designated Organizational Point of Contacts (POCs) and Initiated Routine POC Meetings
- Developed Self-Assessment (SA) Handbook
- Developed New/Improved SA Training
- Perform Screening of SA Reports
- Providing SA Mentoring
- Developed SA Performance Indicators

Results of Self-Assessments

- Every organization schedules and performs regular self-assessment of activities
- Issues are self-identified and resolved
- Program effectiveness is routinely evaluated
- Examples of Significant Findings:
  - BSC(B)-02-C-129, RPC Failure to Preserve Records on Electronic Media
  - YMSCO-02-D-083, Self-Assessment Conditions not Entered in CIRS by the Self-Assessment Team Lead
  - LBNL(B)-02-D-155, Use of Required Criteria in Scientific Notebook Review

Continuous Improvement Process Enhancements

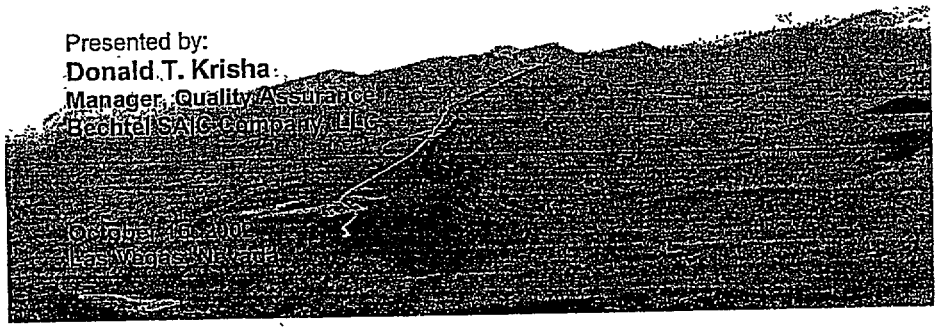
- As we move forward in the Self-Assessment Program, we strive for continuous improvement. We look forward to incorporating a number of Program enhancements, such as:
  - Incorporate commercial nuclear guidance and clarify roles and responsibilities
  - Develop electronic SA format
  - Develop Computer Based Training for SA
  - Improve SA metrics

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

YUCCA MOUNTAIN PROJECT

Status of BSC Quality Assurance Program

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting



Presented by:
Donald T. Krisha
Manager, Quality Assurance
Bechtel SAIC Company, LLC

October 16, 2002
Las Vegas, Nevada

Status of BSC Quality Assurance Program

- BSC QA surveillances
- Approval to perform QA surveillances - March 25, 2002
  - FY02 - 44 completed
  - FY03 - 1st quarter schedule has been issued
- Surveillance focus
  - Repetitive past problems
  - Real-time critical activities
  - Upon request

Status of BSC Quality Assurance Program

- Update on BSC audits
  - External audits
    - 36 audits completed for FY02
    - FY03 audit schedule has been issued
  - Internal audits
    - Approval to perform internal audits received July 2002
    - First BSC internal audit conducted October 7-11, 2002 on Records Management and Document Control
    - FY 03 audit schedule has been issued

Consolidated Action Items
From The
NRC/DOE Quarterly QA Meetings

Item No.	Description	Status
QA 0112-05	DOE agreed to inform NRC of any changes in OQA/BSC QA responsibilities prior to their implementation.	Completed. On March 19, 2002, the NRC was informed by letter of the first step in changing QA responsibilities: BSC's assumption of internal surveillances and internal corrective action activities(with some limitations). These changes were effective on March 25, 2002. It is anticipated that this action item will be completed with the issuance of QARD Rev. 12 prior to implementing further changes; however, if such changes are implemented prior to issuance of QARD Rev. 12, the NRC will be informed prior to implementation. This item was closed as agreed during the July 30, 2002 Quarterly QA Meeting.
QA 0204-01	Provide the State of Nevada a list of the external (independent) software experts, where they are from and where they are assigned on the project.	Open. State of Nevada has been informed verbally of delays in providing this response. The original planned vendor is not being used. A new contract is being put in place. In the interim, IT staff are on loan to work the issues.
QA 0204-04	DOE will provide the NRC with an audit schedule (to enable the NRC to facilitate their planning) for Analysis Model Reports when available.	Completed. A schedule of performance based audits to facilitate NRC planning of audit oversight will be developed based on plans for the next phase of model development and will be provided to the NRC when available. A current audit schedule has been provided to the NRC.
QA 0207-01	DOE will provide additional information regarding capturing conditions adverse to quality in the trend program.	Open.
QA 0207-02	DOE to provide date for the upcoming software audit and surveillance.	Completed. Information provided to the NRC OR on August 8, 2002.

Note: The Quarterly QA Meeting action items are designated as "QA yymm-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.

Enclosure 10

Consolidated Action Items From The NRC/DOE Quarterly QA Meetings

Item No.	Description	Status
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QA 0204-01	Provide the State of Nevada a list of the external (independent) software experts, where they are from and where they are assigned on the project.	Open. State of Nevada has been informed verbally of delays in providing this response. The original planned vendor is not being used. DOE will no longer use external experts and internal staffing independent of software developers will be provided to perform the reviews. DOE will provide position qualification requirements for the reviewers to the State of Nevada.
QA 0204-04	DOE will provide the NRC with an audit schedule (to enable the NRC to facilitate their planning) for Analysis Model Reports when available.	Complete. A schedule of performance based audits to facilitate NRC planning of audit oversight will be developed based on plans for the next phase of model development and will be provided to the NRC when available. A current audit schedule has been provided to the NRC.
QA 0207-01	DOE will provide additional information regarding capturing conditions adverse to quality in the trend program.	Complete. Information on trending program provided during the July and October 2002 meetings and trending of TERs have been proceduralized.
QA 0207-02	DOE to provide date for the upcoming software audit and surveillance.	Complete. Information provided to the NRC OR on August 8, 2002.

QA 0210-01	DOE review the reasons for OQA delaying their audit of YMSCO, and whether a DR should be issued on that issue.	Open.
QA 0210-02	DOE is to consider the State of Nevada's request for copies of all self-assessment reports.	Open.
QA 0210-03	DOE to assess the frequency and team makeup for performance-based QA audits.	Open. This QA related item from the Quarterly Management Meeting action item list (MM 0207-02) has been transferred to this list for tracking purposes. The status of this item on MM Action Item list is indicated as "Complete." However, it will remain open on this list as QA 0210-03 until completed. Concern regarded whether appropriate technical specialists (specifically regarding welding) were included in the audit team for a particular audit. Evaluation indicated that appropriate expertise was available. This item was discussed to some extent during the July and October 2002 MM.

Note: The Quarterly QA Meeting action items are designated as "QA yymm-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.