

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 Schl	ueter dated <u>November 8, 2002</u>
cc: R. Loux, State of Nevada	R. Massey, Lander County, NV
S. Frishman, State of Nevada	L. Stark, Lincoln County, NV
M. Chu, DOE/Washington, DC	M. Baughman, Lincoln County, NV
C. Einberg, DOE/Washington, DC	A. Funk, Mineral County, NV
S. Gomberg, DOE/Washington, DC	L. Bradshaw, Nye County, NV
N. Slater-Thompson, DOE/Washington, DO	C M. Murphy, Nye County, NV
C. Newbury, YMPO	D. Chavez, Nye County, NV
W. J. Arthur III, YMPO	D. Weigel, GAO
R. Dyer, YMPO	W. Barnard, NWTRB
J. Ziegler, YMPO	R. Holden, NCAI
D. Brown, YMPO	A. Collins, NIEC
S. Mellington, YMPO	R. Arnold, Pahrump Paiute Tribe
C. Hanlon, YMPO	J. Larson, White Pine County
T. Gunter, YMPO	R. Clark, EPA
K. Hess, BSC	F. Marcinowski, EPA
D. Krisha, BSC	R. Anderson, NEI
S. Cereghino, BSC	R. McCullum, NEI
N. Williams, BSC	S. Kraft, NEI
M. Voegele, BSC/SAIC	J. Kessler, EPRI
D. Beckman, BSC/B&A	D. Duncan, USGS
B. Price, NV Legislative Committee	R. Craig, USGS
J. Meder, NV Legislative Counsel Bureau	W. Booth, Engineering Svcs, LTD
W. Briggs, Ross, Dixon & Bell	L. Lehman, T-REG, Inc
E. von Tiesenhausen, Clark County, NV	S. Echols, ECG
A. Kalt, Churchill County, NV	N. Rice, NV Congressional Delegation
G. McCorkell, Esmeralda County, NV	T. Story, NV Congressional Delegation
L. Fiorenzi, Eureka County, NV	J. Reynoldson, NV Congressional Delegation
A. Johnson, Eureka County, NV	S. Joya, NV Congressional Delegation
A. Remus, Inyo County, CA	J. Pegues, City of Las Vegas, NV
M. Yarbro, Lander County, NV	R. Bahe, Benton Paiute Indian Tribe
I. Zabarte, W.S.N.C.	C. Bradley, Kaibab Band of Southern Paiutes
C. Anderson, Las Vegas Paiute Tribe	R. Joseph, Lone Pine Paiute-Shoshone Tribe
J. Birchim, Yomba Shoshone Tribe	L. Tom, Paiute Indian Tribes of Utah

٠.

L. Jackson, Timbisha Shoshone Tribe	E. Smith, Chemehuevi Indian Tribe
C. Meyers, Moapa Paiute Indian Tribe	J. Charles, Ely Shoshone Tribe
V. Miller, Fort Independence Indian Tribe	D. Crawford, Inter-Tribal Council of Nevada

- A. Bacock, Big Pine Paiute Tribe of H. Blackeye, Jr., Duckwater Shoshone Tribe the Owens Valley
- R. Quintero, Inter-Tribal Council of Nevada D. Eddy, Jr. Colorado River Indian Tribes (Chairman, Walker River Paiute Tribe)
- M. Bengochia, Bishop Paiute Indian Tribe G. Runkle, DOE, Washington, DC
- J. Egan, Egan & Associates, PLLC
- J. Leeds, Las Vegas Indian Center H. Jackson, Public Citizen
- K. Tilges, Shundahai Network
- J. Triechel, Nuclear Waste Task Force
- W. Boyle, YMPO

- W. Briggs, Ross, Dixon & Bell
- M. Smurr, BNFL, Inc.

Citizen Alert

November 8, 2002

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/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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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	11/58/02

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

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.

danet 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

11/4/02

Joseph D. Ziegler Afting 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	<u>Description</u>
1 2	Agenda 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)

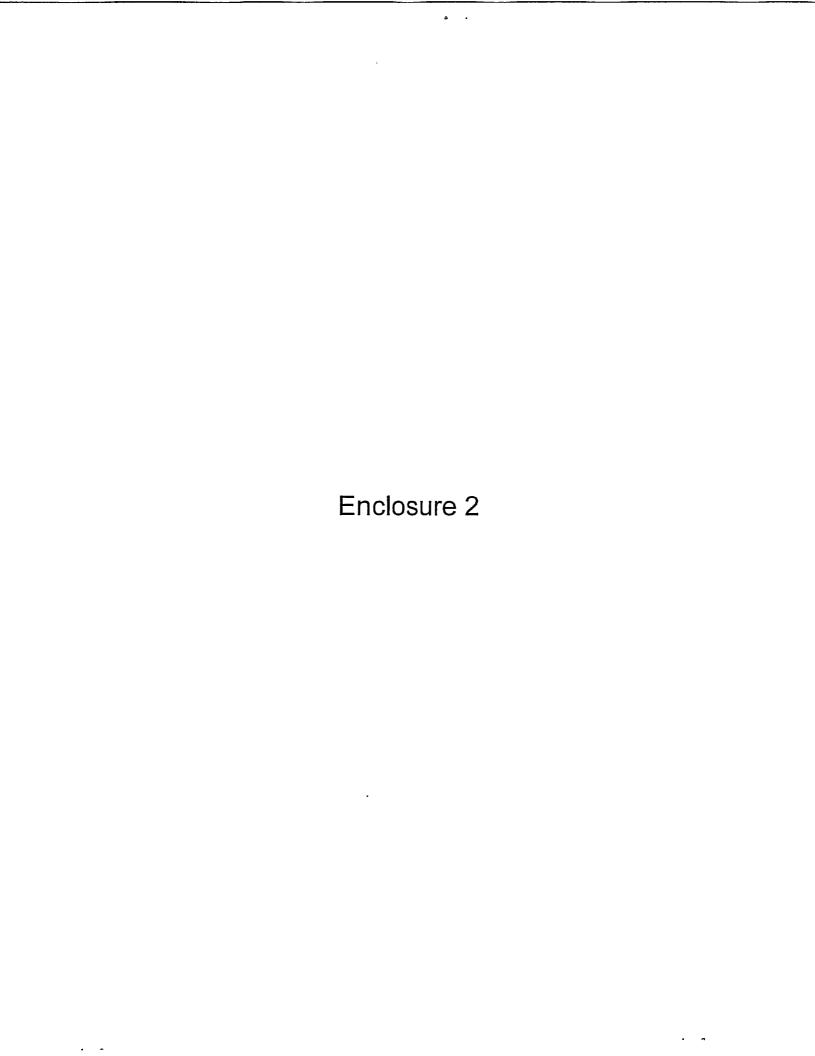
BSC Room 915 9960 Covington Cross Las Vegas, NV

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 DirectorIntroduction of New OQA DirectorApproach 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	



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

	Name	Organization	Telephone
	William J. GLASSEA	ORA/NOS	7027945014
	JIM BLAYLOCK	OGA/DOE	794-1420
-	Kristi Hodges	OQ4/NQS	794-1464
	RAM B. MUNTHY	DOE/RW-3	794-5549
	Bob Gamble.	HTS/BiozAllen	794-1440
	Nan Harris	NOS./OQA	794-1467
L	Jim Cross	BAŁA	256-459-9799
	Versnica Corne 11	MTS/Parallay	702-194-1392
2	Judy Debhart	BSC QA	295-4774
	Book Bradbum	MTS/ Shaw	794-5424
L	Tish Morgan	MTS/BOOX	794-1463
L	ROBERT SWEETLY	BSC-CT	703.624.8032
(Steve Freshman	NVWWFO	775-687-3744
	July Treichel	NAWTE	202-248-1127
_	Robert Hertstein	BSC QA	702-295-2675
_(Allian Watson	BSC Performance ASSESSIVE	- 7ciz-295-5550
1	Janet Silveter 1	NEC/HLW	301-415-7264

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

Name	Organization	Telephone
Myxle RICE	LISTERTECH/ Shinneshire County BSC/LAP	702 763 6583
ALI HAGHI	BSC/LAP	702-295.4019
SAM HORTON	BSE-QA	702-295-0304
BIII Reamy	NRC	301-415-6537
Mal Whashy	Mye Connty	360 943-560
Jim PEGUES	CITY OF LAS VEGAS	702 229-6862
Emily CONFER	DOE	702-794-5464
Mickey me Donnell	DOE	702-295-4023
George Pannell	BSC	702-295-317
Susan Lynch	State of Neurola	775-687-3744
ROBERT MURRAY	m75/B214	702-794-5566
Tim Genter	Dog	702-794-1343
Jack Parrott	NRC	702-794-5047
C. David Usborye	BSC-SHE QUALITY	702-295-5912
Frank Restrences	MTS	702-794-1369
MICHAEL JAEGER	BSC / PA	702-295-4245
PM. LATTA	NRC/ONSITE REP	702-794-5048
J.L. HARDING	BSC CTO	702-285-3840
R.W. Clark	DOE .	7027945583
George Hellstram	DOE	702-794-14/9
Don Beacons	BEC	202-295 4358

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

Name	Organization	Telephone
RUBBAT ? HASSON	OBA/NOS	(702) 794-5023
MarilynKauchak	OQA/NGS	702-794-5423
Tamila Deho	BSC	702 295-0407
Dorger T. LRISHA	BSC	702-295-6242
Russell Fray	BSC	702-295-5526
Red Marllon	Nei	202-739-8082
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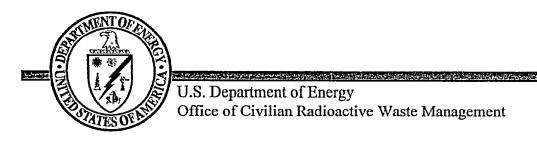
ATTENDANCE LIST NRC/DOE QUARTERLY QUALITY ASSURANCE MEETING NRC HEADQUARTERS October 16. 2002

NAME	ORGANIZATION	TELEPHONE
TED CARTER	NRC-HQ	301-415-6684
King Stablein	NRC'	301-415-7445
WACK SORENSEN	NAC	301-415-6804
Ven Chen	NRC	361-415-5615
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
MIKE LEE	NRC	361 - 415 - 6887
MITZI YOUNG	NRC	301-415-1523
Andy Comphell	NRC	301-415-6897

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES MEETING ATTENDANCE

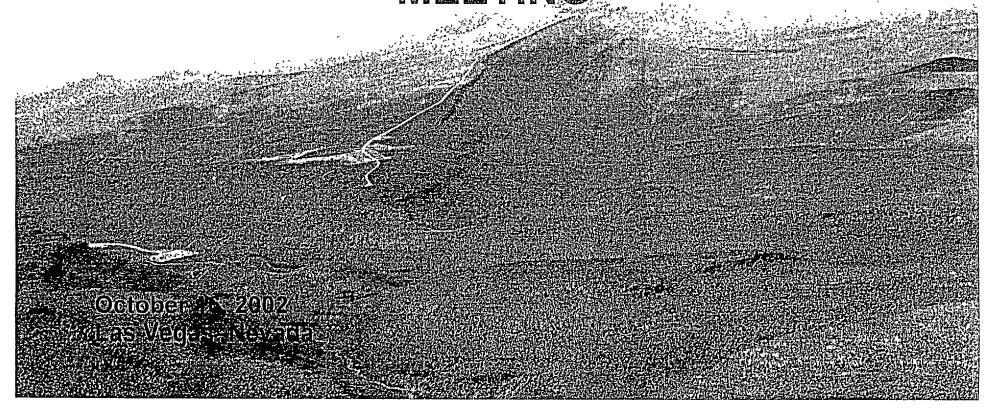
SUBJECT OF MEETING	DOE/NRC	Quarterly QA	Meeting	
DATE: 10/16/02 LOCATION: CNWRA to Las Vegas Via Telecon				
PERSON	ORGANIZATION	TITLE/FUNCTION	TELEPHONE NUMBER	
P. Weben	SWRI IPS	Manager	(210) 522-3161	
Mark M. Throstrom	SWRI IQS	Sr.QA. Yechnologis Dia QA	t(210)522-3530	
Bruce MABRITO		Dia QA	210-522-5149	
Rhut Bried	SWAT 1RS	ASSIST DT Mogra-	(210)522-7537	

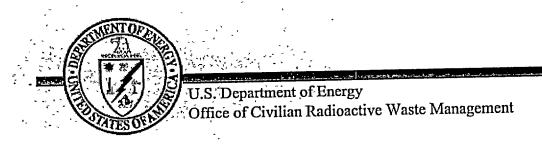
FAX To: 702-295-4545





DOE/NRC QUARTERLY QUALITY ASSURANCE MEETING



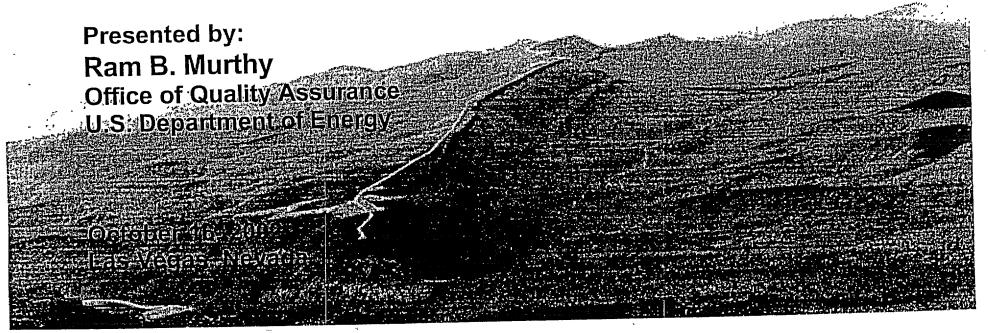




Quality Assurance Program Status

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting



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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)

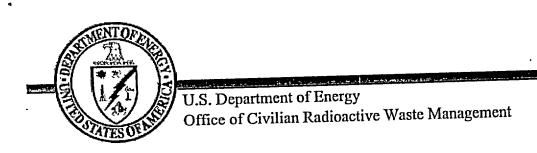
BSC Room 915 9960 Covington Cross Las Vegas, NV

And via Videoconference to:

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

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11:30 AM	Action Item Status	Gunter
11:45 AM	Closing Remarks	ALL
12:00 N	Adjourn .	

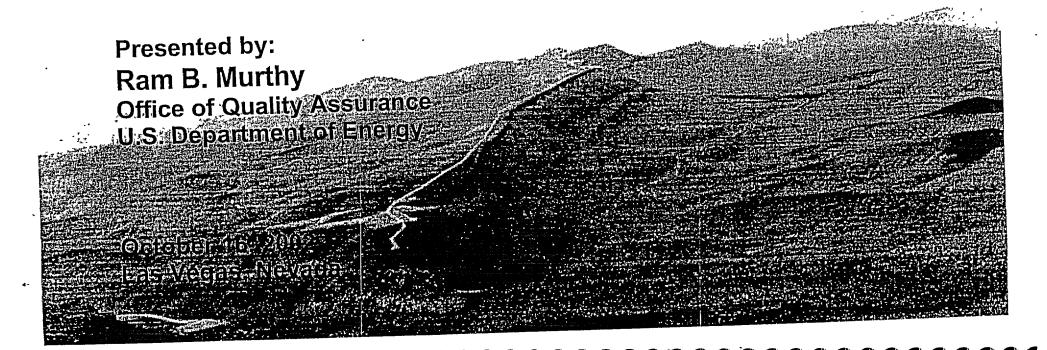




Quality Assurance Program Status

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting



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

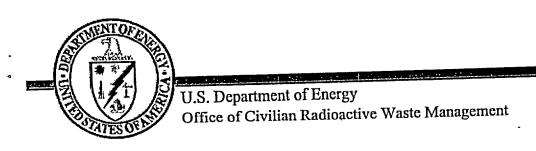
Status of the Trend Program

(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



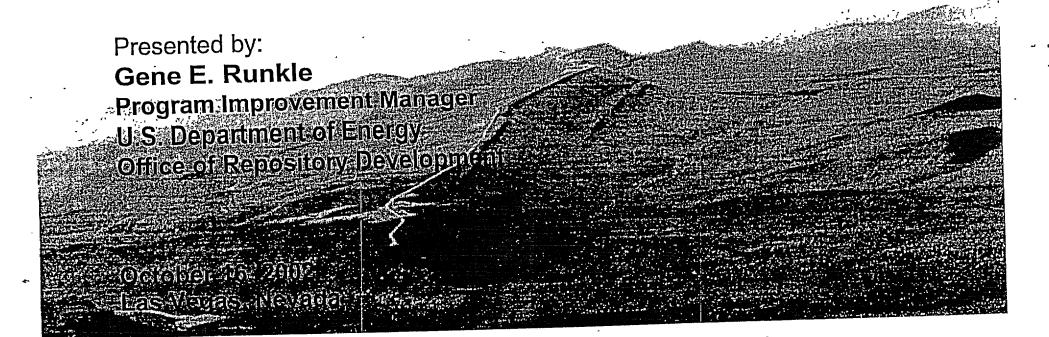




Management Improvement Initiatives Implementation

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting



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

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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

YUCCA MOUNTAIN PROJECT

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

YUCCA MOUNTAIN PROJECT

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

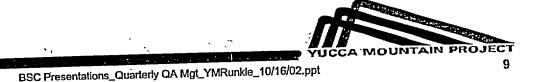
- QARD currently in review for consistency with applicable regulatory requirements and guidance
 - Including NQA-1; 10 CFR Part 63; Review Plans (1989; 2002 draft)
- Review will identify which sections would most benefit from revisions, possibly including:
 - 1.0 Organization Clarify roles and responsibilities
 - 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

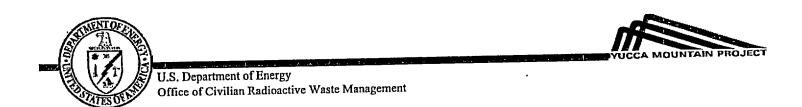
Project Procedures

- 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

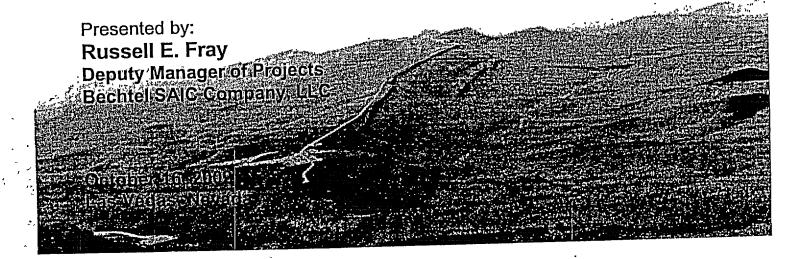
- DOE and BSC are implementing the Management Improvement Initiatives
- Completion of Action Statements on schedule in accordance with implementation plans
 - OQA Director on board
 - QA Program policies in place and R2A2 communicated
 - QARD currently in review against regulatory requirements and guidance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





BSC Procedure Action Plan

Presented to: DOE/NRC Quarterly Quality Assurance Meeting



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)



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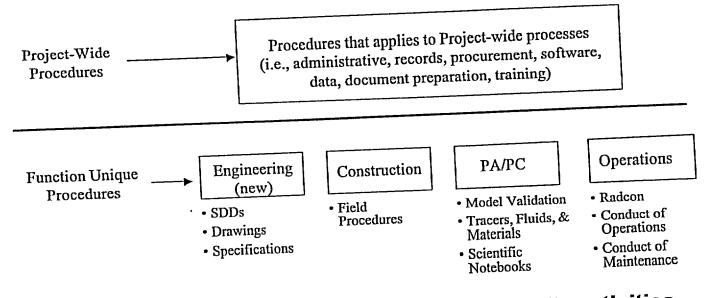
BSC Approach

- 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)



BSC Presentations_Quarterly QA Mtg2_YMFray_10/16/02 ppt

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.

BSC Presentations_Quarterly QA Mtg2_YMFray_10/16/02 ppt

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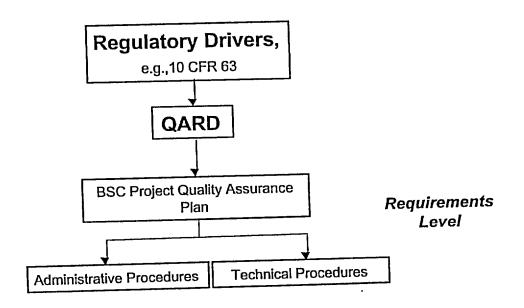
Status

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



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BSC Procedure Hierarchy





Critical Procedures Under Review for Improvement

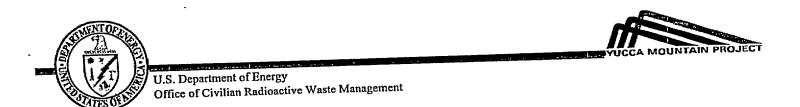
- Project Wide Procedures
 - Report Preparation, Review, and Approval
 - Software
 - Data Qualification
 - Corrective Action Program
 - Procedure Change Process
- Function Unique Procedures
 - Scientific Notebooks
 - Model Preparation and Validation
 - New Engineering Processes
 - Import industry standard

BSC Presentations_Quarterly QA Mtg2_YMFray_10/16/02 ppt

Path Forward

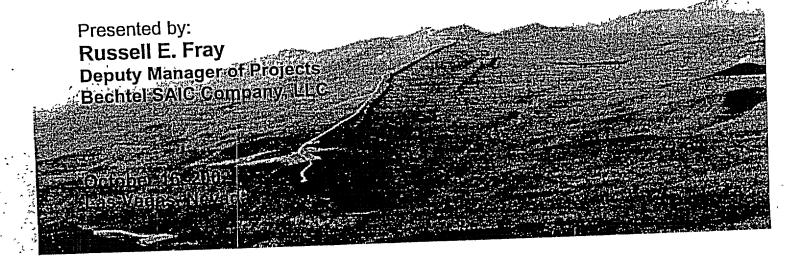
- BSC off-line team working on procedure revisions (off-project membership)
 - Conducting interviews and scoping
 - Mapping out detailed procedure revision plan
- DOE reviewing QARD for incremental changes
- Future issuance of modified procedures will be checked for compliance with current QARD revision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





Status of Corrective Action Reports and Stand-Downs

Presented to: DOE/NRC Quarterly Quality Assurance Meeting



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)



BSC Presentations_Quarterly QA Mtg_YMFray_101602.ppt

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

BSC Presentations Quarterly QA Mtg_YMFray_101602 ppt

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



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



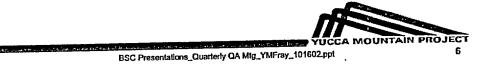
Topics

- 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**



(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



(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



BSC Presentations_Quarterly QA Mtg_YMFray_101602.ppt

(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



(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



(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



(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)



BSC Presentations_Quarterly QA Mtg_YMFray_101602.ppt

(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 Presentations_Quarterly QA Mtg_YMFray_101602 ppt

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

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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

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Site Operations Stand-Down

(Continued)

Current status

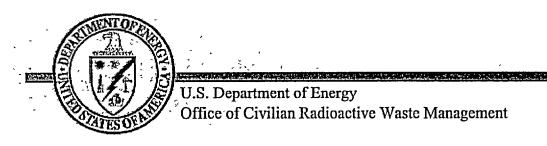
- Completed a comprehensive recovery plan based on results of the root cause investigation - August 2002
 - Recovery actions integrated into the multi-year baseline
- All work activities underway under new management approach
 - Independent oversight of work activities
 - + Operations control
 - Maintenance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



Site Operations Stand-Down

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

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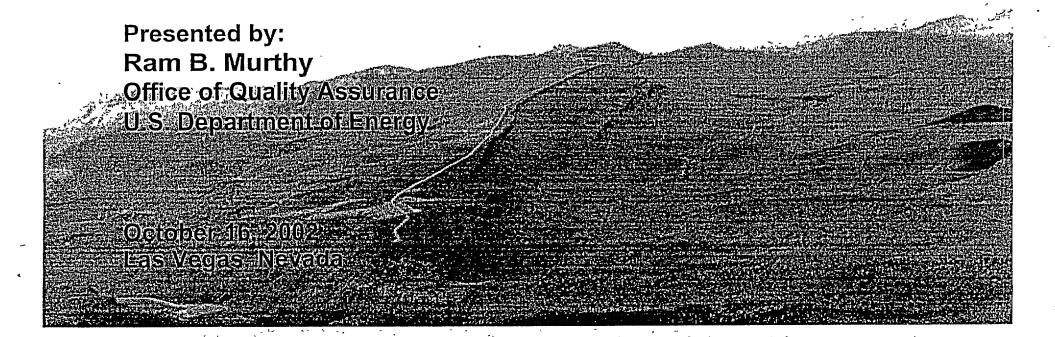




Verification of Corrective Action Reports

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting



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



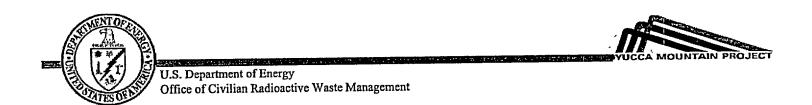
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Verification of Corrective Action Reports

- 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



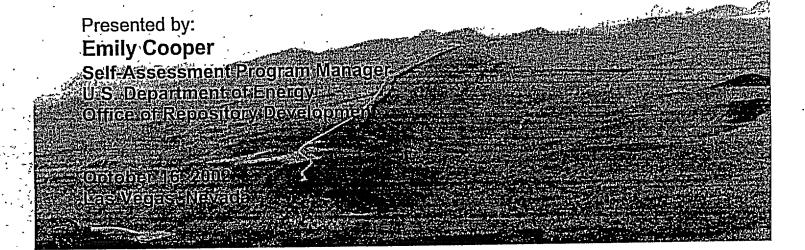
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Self-Assessment Program Status

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting



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

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BSC Presentations_Quarterly QA Meeting_YMCooper_10/16/02 ppt 3

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

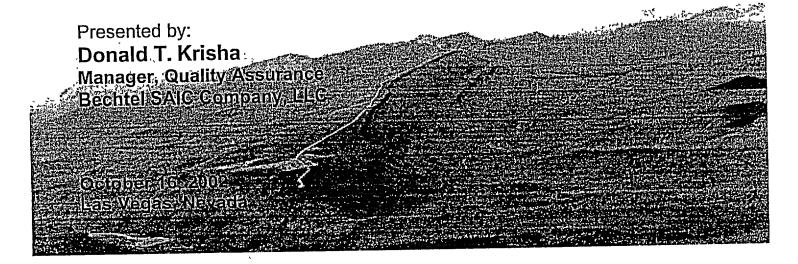
- As we move forward in the Self-Assessment Program, we strive for continuous improvement. We look forward to incorporating a number of Program enhancements, such as:
 - Incorporate commercial nuclear guidance and clarify roles and responsibilities
 - Develop electronic SA format
 - Develop Computer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





Status of BSC Quality Assurance Program

Presented to: DOE/NRC Quarterly Quality Assurance Meeting





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

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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

7. 37	Description	Status
Item No. QA 0112-05	Description 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	information regarding capturing conditions adverse to quality in the trend program.	
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

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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.