

ATTACHMENT 3



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



Quality Assurance Overview

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
R. Dennis Brown
Director, Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

April 29, 2005
Las Vegas, Nevada

Quality Assurance Overview

- **Quality Assurance Program Improvements**
 - **BSC Management Changes**
 - **Quality Assurance Requirements and Description (QARD) Independent Review Issue**
 - **Anticipate Closing CAR-001 on Models Eight (8) Months Early**
 - **Increased Line Management Involvement in Quality Assurance Program**
 - ♦ **Quality Focus Stand Down**
 - ♦ **Corrective Action Program**
 - ♦ **Monthly Operating Review**
 - ♦ **Technical Direction Letter on Procedures**

Quality Assurance Overview

(Continued)

- **Simplified Corrective Action Process**
- **Performance-based Audits**
 - ♦ **Data**
 - ♦ **Models**
 - ♦ **Software**
- **DOE Quality Engineers Integrated with DOE Line Staff**
- **Project Position on Graded Approach**

Quality Assurance Overview

(Continued)

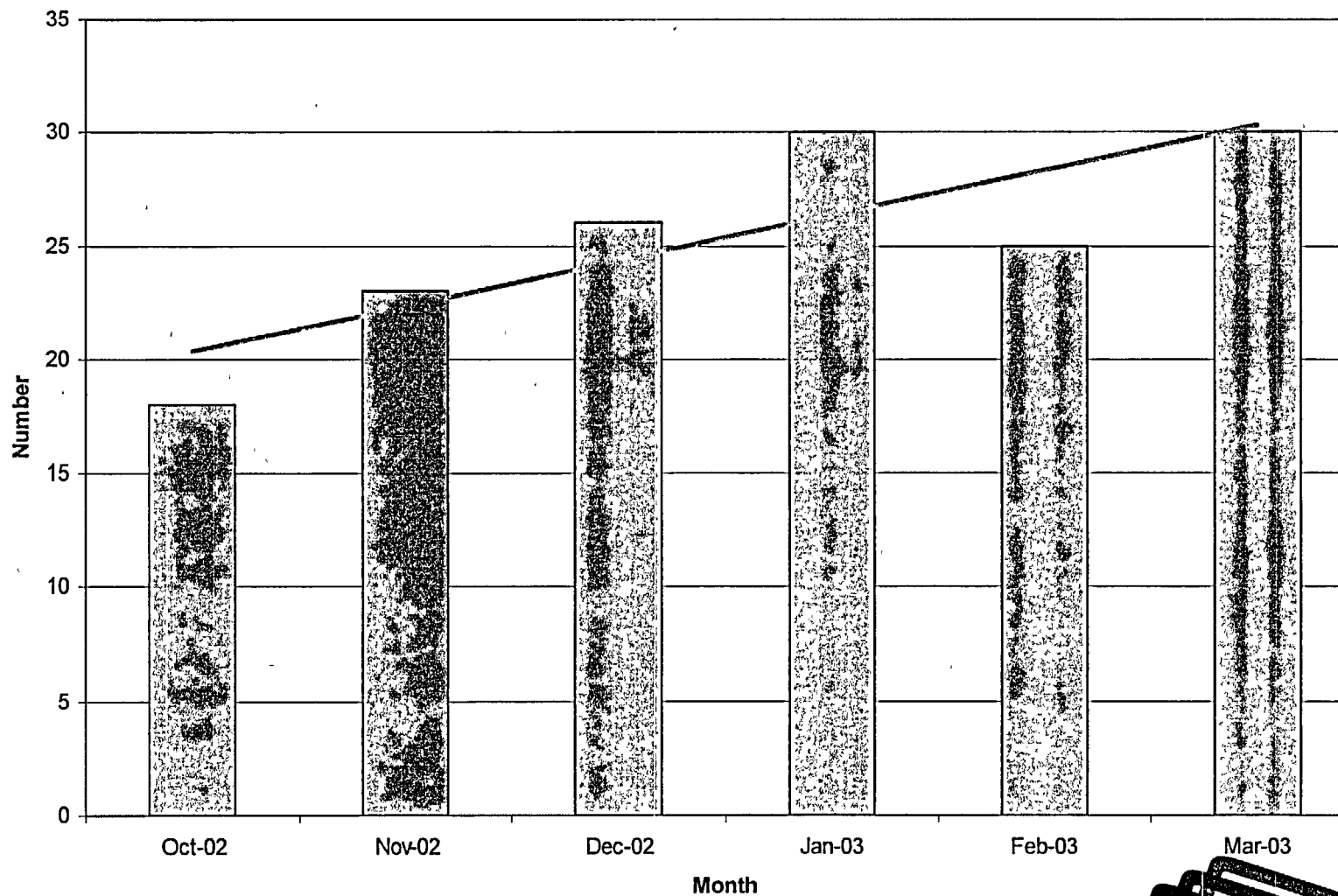
- **Procedure Transition**
 - Retain existing procedure structure
 - Streamline AP-5.1Q
 - DOE Line Management will concur on applicable BSC Line Procedures
 - BSC/DOE Quality Assurance (QA) will concur on procedures that implement QARD requirements



Quality Assurance Overview

(Continued)

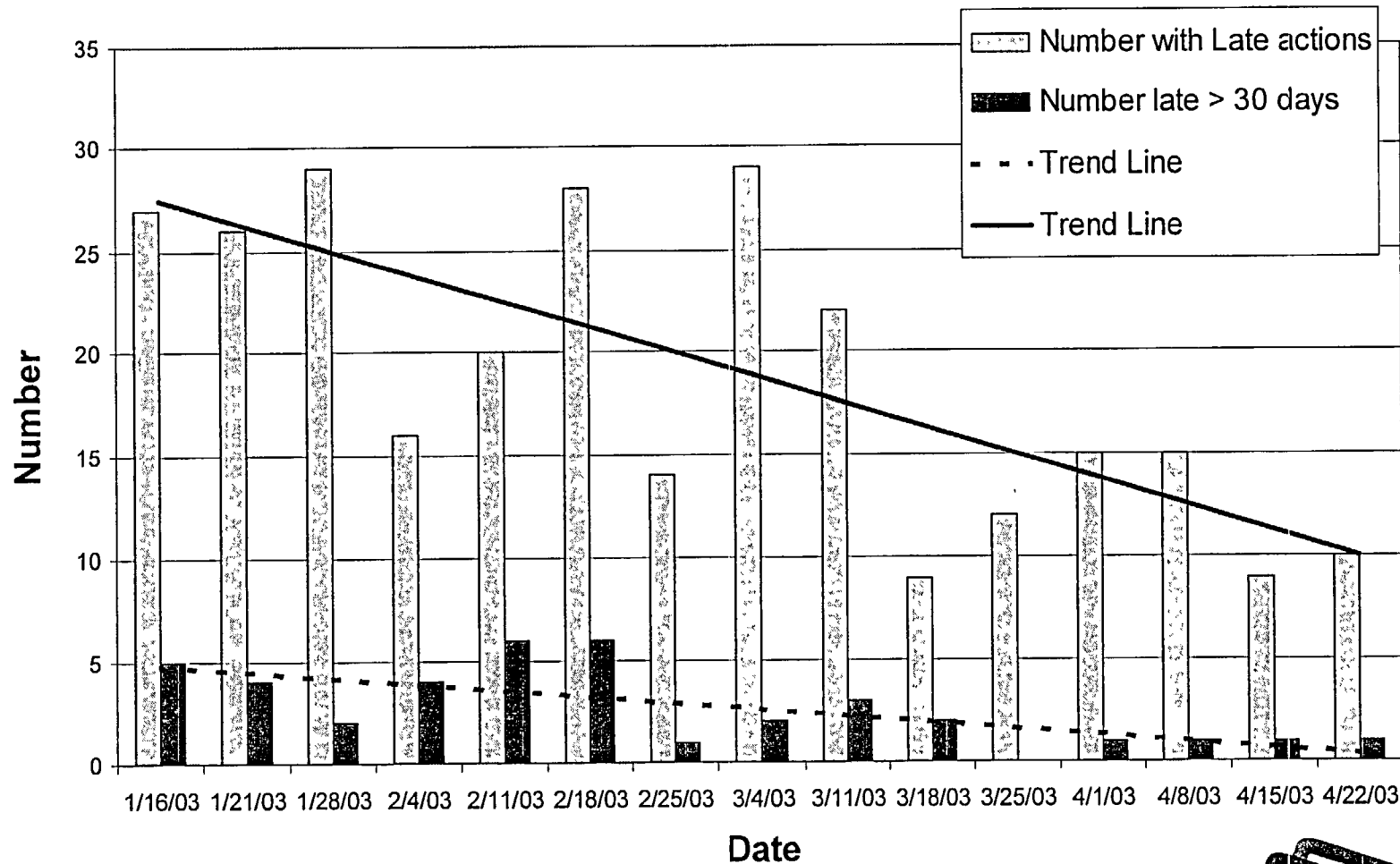
Deficiency Report Closures



Quality Assurance Overview

(Continued)

DR/CAR Weekly Late Actions



Quality Assurance Overview

(Continued)

- **DOE Office of Quality Assurance Oversight**
 - **Audit BSCP 03-05 of Data Management**
 - ♦ **Performance-based audit**
 - ♦ **Limited number of completed model reports**
 - ♦ **Five (5) Deficiency Reports (DRs) initiated**
 - ♦ **Conclusion indeterminate due to model report sample size/distribution**
 - ♦ **Second performance-based audit in 60-90 days**

Quality Assurance Overview

(Continued)

- **Audit EMC 03-01 of West Valley**
 - ♦ Compliance audit
 - ♦ One (1) DR initiated
 - ♦ Program in compliance with QARD requirements
- **Audit BSC 03-04 of Yucca Mountain Site Activities**
 - ♦ Compliance audit
 - ♦ Two (2) DRs initiated
 - ♦ Activities in compliance with program requirements



Quality Assurance Overview

(Continued)

- **OQA and BSC to combine/coordinate audits**
 - ♦ **Redundancy of audits eliminated**
 - ♦ **Increased number of audits in other areas**
 - ♦ **Joint memberships on audits**
 - » **Audit Team Leader appropriate for audit scope**
 - » **Team membership tailored to subject**

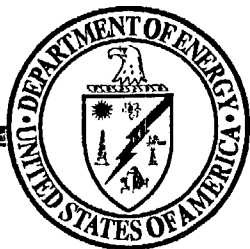


Quality Assurance Overview

(Continued)

- **New BSC QA Manager - Mike Mason**
 - Over 25 years of management and quality assurance experience
 - Design, construction, start-up, operations of nuclear and commercial facilities
 - Extensive knowledge of 10CFR50, Appendix B, ASME-NQA-1, 10CFR830, Subpart A, and DOE Order 414.1A
 - Specific experience:
 - ♦ QA Manager
 - ♦ Procedures Manager
 - ♦ Project Quality Engineer
 - ♦ Training and Audit Coordinator
 - ♦ Quality Control





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



BSC Quality Assurance Overview

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DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

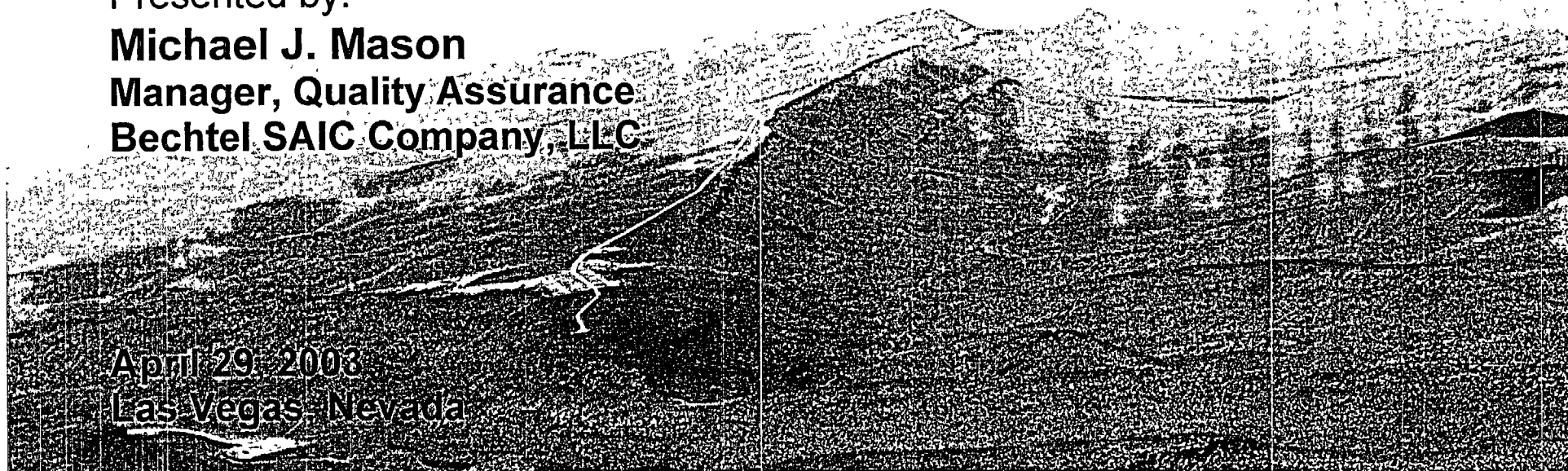
Michael J. Mason

Manager, Quality Assurance

Bechtel SAIC Company, LLC

April 29, 2003

Las Vegas, Nevada



BSC Quality Assurance Overview

- **BSC Completed Internal Audits - 2nd Quarter FY 2003**
 - **Unsaturated Zone (UZ) Transport Test at Busted Butte**
 - ♦ **Performance-Based**
 - ♦ **Evaluated scientific investigations supporting UZ Models**
 - ♦ **One (1) Deficiency Report**
 - ♦ **One (1) Technical Error Report**
 - ♦ **Concluded effective implementation of critical processes**
 - **Lawrence Livermore National Laboratory**
 - ♦ **Compliance audit**
 - ♦ **One (1) Deficiency Report**
 - ♦ **Activities in compliance with program requirements**



BSC Quality Assurance Overview

(Continued)

- **BSC Scheduled Internal Audits**
 - **3rd Quarter FY 2003**
 - ♦ **Engineered Barrier System Analysis/Model Reports (Performance-Based) - June**
 - ♦ **Design Process Activities (Performance-Based) - June**
 - ♦ **Compliance Audits**
 - » **United States Geological Survey - May**
 - » **Los Alamos National Laboratory - May**
 - » **Lawrence Berkeley National Laboratory - June**
 - ♦ **Audits to be joint audits with Office of Quality Assurance**



BSC Quality Assurance Overview

(Continued)

– BSC Supplier Audits

- ♦ **Completed 8 Audits in 2nd Quarter FY 2003**
 - » **Issued One (1) Corrective Action Report for Westbay Instruments for ineffective QA Program - perform calibration services**
 - » **Issued eight (8) Deficiency Reports**
- ♦ **Removed three calibration suppliers from Qualified Suppliers List for ineffective Quality Assurance (QA) Programs - no impact**



BSC Quality Assurance Overview

(Continued)

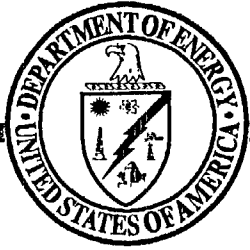
- **BSC Surveillances 2nd Quarter FY 2003**
 - ♦ **Internal surveillances**
 - » **Completed 23 surveillances**
 - » **Issued 10 Deficiency Reports**
 - ♦ **Supplier surveillances**
 - » **Completed 5 surveillances**
 - » **Issued 1 Deficiency Report**
- **Improvement Actions**
 - ♦ **Implemented Supplier Quality Improvement Plan**
 - ♦ **Supplier oversight results to be analyzed to determine improvement**



BSC Quality Engineering – Documents Reviewed by Organization

- **Performance Assessment Project**
 - Model Reports and Scientific Analyses
 - Technical Work Plans
 - Technical Error Reports
 - Technical Documents
- **Repository Design Project**
 - Design Calculations and Analyses
 - Design Criteria and System Description Documents
 - Specifications and Drawings
- **License Application Project**
 - LA Chapters and Classification Analyses
- **Procurement**
 - Procurement Documents





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



Model Validation Corrective Action Report

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Robert W. Andrews
Performance Assessment Project Manager
Bechtel SAIC Company LLC

April 29, 2003
Las Vegas, Nevada

Outline

- **Status of model validation for License Application (LA)**
- **Status of model validation Corrective Action Report (CAR) actions**
- **Summary**

Model Validation Corrective Action Report Actions

- **8 of 11 actions identified in September 24, 2002 response (as modified by amended response) are complete**
- **3 actions remain**
 - **Self assessments during the development and documentation of models supporting the LA**
 - **Self-identification of issues through in-process reviews of model development**
 - **Development of performance indicators to assess the effectiveness of the self-identification process**

Model Validation Corrective Action Report Actions

Status of Self Assessments

- **3 Self Assessments completed**
 - **SA-ENG-2002-006**
 - ◆ No deficiencies or non-conformances identified
 - ◆ 5 opportunities for improvement were noted
 - **SA-CSO-2003-001**
 - ◆ No deficiencies or non-conformances identified
 - ◆ In-process reviews of Technical Work Plans and Model Validation sections of Model Reports are providing early detection and resolution of model validation issues
 - ◆ 3 opportunities for improvement were noted
 - » all related to the Chief Science Office review tracking system

Status of odel Validation Corrective Action Report Actions

Status of Self Assessments

(Continued)

— SA-CSO-2003-004.

- ♦ **Performance indicators suggest the model validation process is stable**
- ♦ **Reviews of Technical Work Plans and Model Validation sections of Model Reports indicate a decreasing trend of comments**
- ♦ **4 opportunities for improvement were noted**
 - » **3 related to the Chief Science Office review tracking system**
 - » **1 relates to providing performance indicator metrics to Performance Assessment managers on a routine basis**

Model Validation Corrective Action Report Actions - Status of In-Process Reviews (as of April 14, 2003)

- **64 Model Reports are being developed under the revised procedure to support the LA**
 - **This includes those models which support Features, Events and Processes screening as well as the implementation of the criticality methodology**
 - **Technical Work Plans for each model, which include the model validation criteria, have been reviewed and approved by the Chief Science Office**
 - **34 model validation sections of in-process Model Reports have been reviewed and approved by the Chief Science Office**
 - **13 Model Reports have completed Chief Science Office technical review and concurrence**

Model Validation Corrective Action Report Actions

Status of Development of Performance Indicators

- **Performance indicators have been developed**
- **Performance indicators are based on reviews of Technical Work Plans and in-process model validation documentation**
- **These indicators (identified through the self assessments) include**
 - **Number of comment cycles with mandatory comments during each of the three in-process reviews**
 - **Number of mandatory comments during each of the three in-process reviews**
 - **Number of in-process reviews that require escalation to the BSC Natural System or Engineered System Performance Assessment Subproject Manager**
 - **Number of in-process reviews that require escalation to the BSC Performance Assessment Project Manager and Chief Science Officer**



Summary of Model Validation Corrective Action Report

- **Revised model validation process is effective**
 - Includes three levels of in-process reviews
 - ♦ Review of model validation criteria during planning
 - ♦ In-process reviews of model validation sections of Model Reports
 - ♦ Technical review of Model Reports
- **Chief Science Office in-process reviews are identifying any issues**
- **Office of Quality Assurance audit expected in July 2003**
- **Forecast completion of corrective actions by August 2003**





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Office of Civilian Radioactive Waste Management



Software Corrective Action Report

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

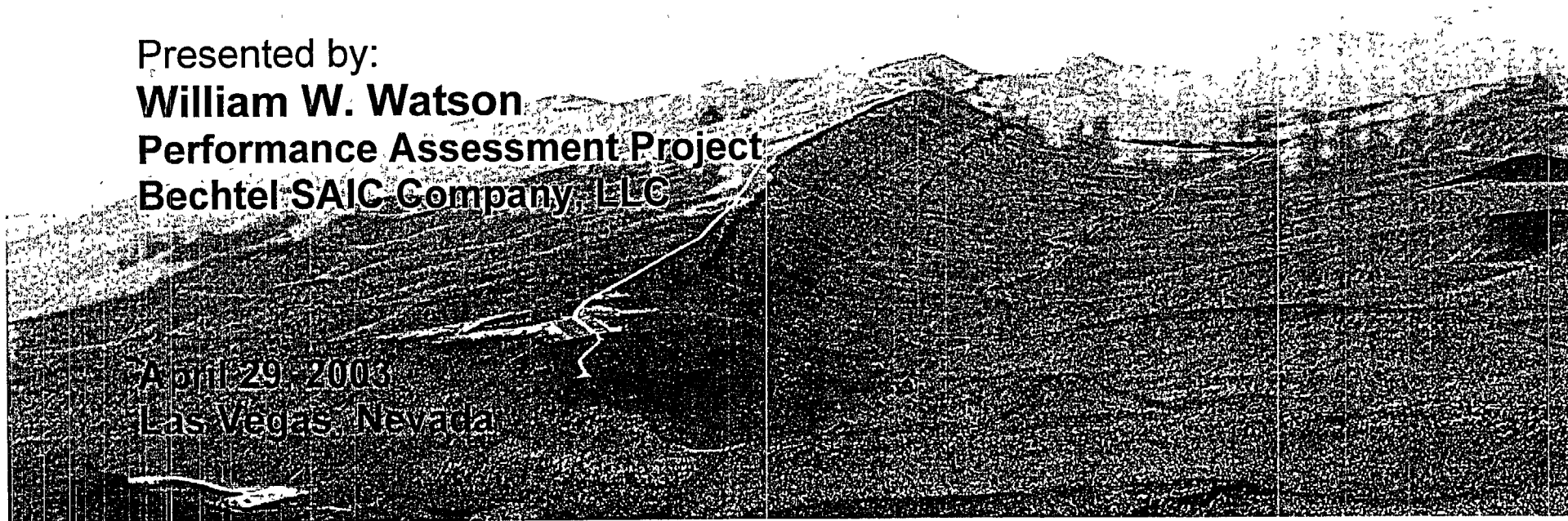
William W. Watson

Performance Assessment Project

Bechtel SAIC Company, LLC

April 29, 2003

Las Vegas, Nevada



Software Corrective Action Report

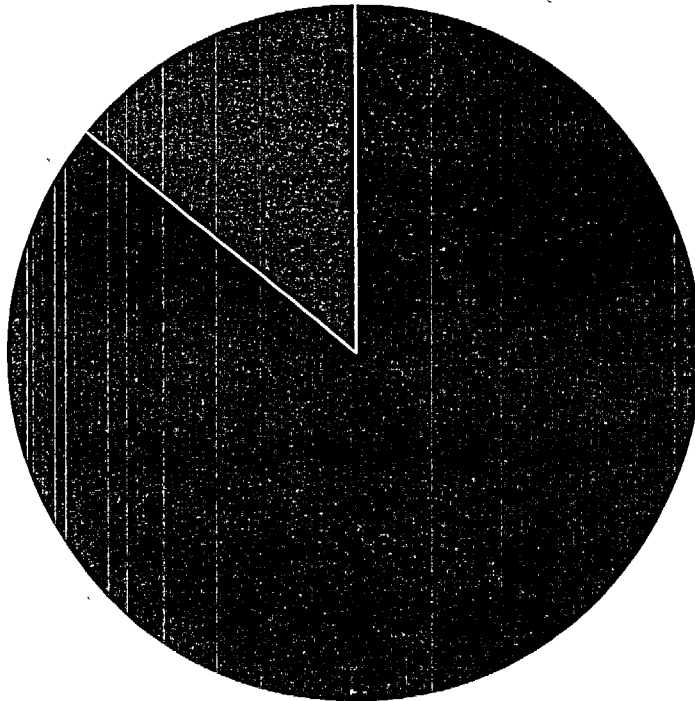
(Counts as of April 11, 2003)

- **648 codes* qualified for use under previous software development processes (i.e., are on software configuration management baseline)**
 - Includes 6 codes qualified after January 13, 2003
 - **~ 100* additional codes under development and will be qualified under processes effective January 13, 2003**
 - 28 codes have been submitted to Independent Verification and Validation (IV&V)
 - ♦ 6 codes - comments resolved and passed IV&V, i.e., are on baseline
 - ♦ 22 codes in IV&V review
- * ~ 400 codes are expected to be used to support License Application (LA)**



Software Code Status

(Counts as of April 11, 2003)



- Qualified Codes on Baseline: 648
- Codes to be Qualified and added to Baseline: ~ 100

Software Corrective Action Report

(Continued)

- **Procedure adequacy evaluated by line in self-assessments and by BSC QA in a surveillance**
 - **Deficiency identified with respect to development process sequence**
 - **Deficiency identified with respect to sequence of Software Configuration Control Request**
 - **Deficiency Report initiated - BSC(B)-03-D-114**
- **Additional enhancements identified during pilot testing of procedure**
- **Enhanced procedure revised and issued in April 2003**

Software Corrective Action Report

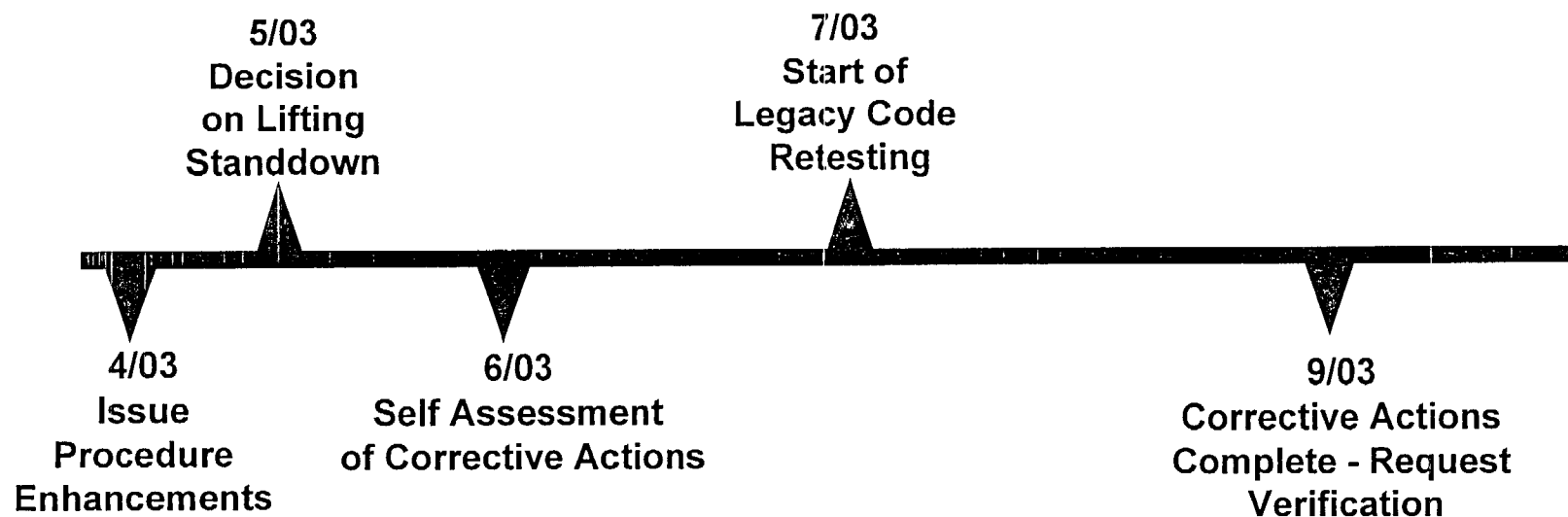
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- **Legacy Code Retesting**

- Qualified software used to support the LA that was developed using a process other than software IV&V (i.e., procedures prior to January 13, 2003) will undergo a retest
- Retest will consist of installation and validation tests
- Retest will be governed by a new procedure
 - ♦ **AP-SI.4Q - *Independent Verification and Validation of Legacy Code***
- New procedure is under development



Timeline for Completion



Summary

- **Independent Verification and Validation process improved and implemented**
- **Line assessments of process adequacy and implementation have identified issues**
- **Procedure revised to address deficiencies and process enhancements**
- **Additional procedure to retest codes baselined prior to January 13, 2003 is being developed**
- **Corrective actions to be complete by September 2003**





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Office of Civilian Radioactive Waste Management



Preservation of Electronic Media Corrective Action Report 129

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by
James L. Harding
Manager, Records Management and Document Control
Bechtel SAIC Company, LLC

April 29, 2003
Las Vegas, Nevada

Preservation of Electronic Media

- **BSC(B)-02-C-129, issued July 19, 2002 - Failure to Preserve Records on Electronic Media**
 - Identified during Self Assessment SA-CIO-IRM-2002-001
 - **Corrective Actions:**
 - ♦ **Defining of procedural process**
 - » Issuance of AP-IM-016Q, Electronic Records Migration
 - » Revision of LP-17.1Q-BSC, Processing Inclusionary Records
 - ♦ **Awarding of contracts**
 - » National Data Conversion Institute (NDCI)
 - » University of Nevada Reno



Preservation of Electronic Media

(Continued)

- National Data Conversion Institute**
 - ♦ **First shipment of 20 boxes currently in process**
 - ♦ **Surveillance results indicate positive control process in place**
 - ♦ **Timeline for completion of records migration**
 - » **July 2003 - Initial shipment complete**
 - » **March 2004 - Migration complete**



Preservation of Electronic Media

(Continued)

- **University of Nevada Reno**
 - ♦ 60% of seismic data has been transferred with no loss of data
 - ♦ Completion of seismic migration - August 2003
- **Needed for Completion of Corrective Action**
 - ♦ All corrective actions have been implemented
 - ♦ Successful verification of corrective action anticipated by July 2003





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Office of Civilian Radioactive Waste Management



Procedure AP-5.1Q Implementation

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

John T. Mitchell, Jr.

General Manager

Bechtel SAIC Company LLC

April 29, 2003

Las Vegas, NV

Procedure AP-5.1Q Implementation

- Procedure BSC-AP-ATS-0001 Procedure Development and Use Effective February 10, 2003
- Stop Work Order for use of BSC-AP-ATS-0001 issued March 4, 2003
- Corrective Action Report (CAR) BSC(O)-03-C-097 issued March 6, 2003



Corrective Action Report - 097

- **Development of BSC-AP-ATS-0001 did not comply with requirements of AP-5.1Q**
- **Re-numbering procedures in transition**
 - Failed to comply with BSC-AP-ATS-0001
 - Did not have proper delegation of authority
 - Signature handled improperly
- **Quality Assurance Requirements and Description Requirements not implemented in BSC-AP-ATS-0001**
 - Issue being clarified by Office of Quality Assurance and BSC Quality Assurance

Root Cause Determination

- **Root Causes**
 - Lack of accountability for procedure compliance
 - Inadequate supervision
 - Failure of recent related Deficiency Reports to identify behavior based problems
 - Lack of signature accountability and integrity
- **Contributing Causes**
 - Personnel chose not to comply with procedures
 - Inadequate definition of roles and responsibilities

Root Cause Team Recommendations

- **Enforce procedure compliance**
- **Revise review and comment process**
- **Establish and enforce policy on signatures**
- **Hold management and supervision accountable for performance of subordinates**
- **Assure corrective action program addresses behavior based issues as well as process issues**





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Office of Civilian Radioactive Waste Management

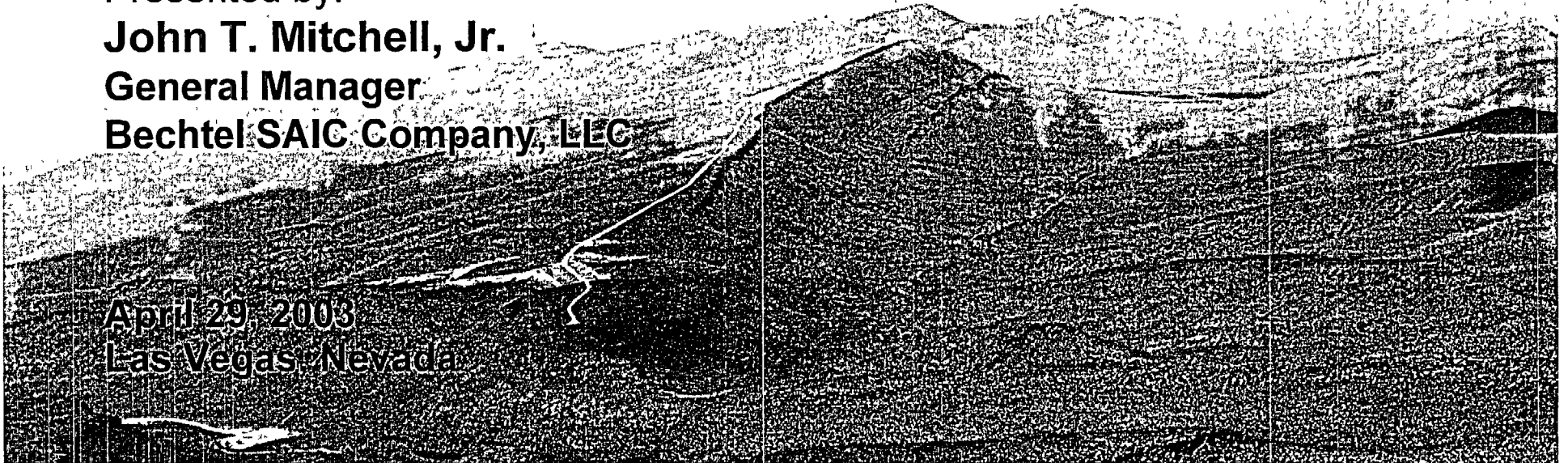


Data Management Deficiency Corrective Action Report

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
John T. Mitchell, Jr.
General Manager
Bechtel SAIC Company, LLC

April 29, 2003
Las Vegas, Nevada

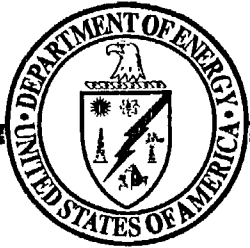


Data Corrective Action Report

SSC(B)-03-C-107

- **BSC Management initiated a review of historical data issues in January 2003**
- **Review of historical deficiencies identified reoccurring data issues of various types**
- **Corrective Action Report (CAR)-107 issued April 17, 2003**
- **Initial response submitted April 24, 2003**
- **Route cause determination began April 28, 2003**





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



Corrective Action Program

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
R. Dennis Brown
Director, Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

April 29, 2004
Las Vegas, Nevada

Corrective Action Program

- **Management Improvement Initiative - Corrective Action Program Plan Status**
 - **BSC will implement a single Office of Civilian Radioactive Waste Management (OCRWM) Corrective Action Program consistent with nuclear industry practices, including tracking, trending, reporting, and closure verification processes - ON HOLD**
 - ♦ **Allows reevaluation of the path forward**
 - ♦ **Will determine the necessity of continuing implementation of the new Corrective Action Plan (CAP) or modification of the existing CAP**

Corrective Action Program

(Continued)

- **Actions Taken/In progress**

- **Increased management accountability for Deficiency Report/Corrective Action Report (DR/CARs)**
 - ♦ **DOE management assigned as responsible individual for each DR/CAR**
 - ♦ **Status frequently reviewed by DOE and BSC leadership team**
 - » **Reported to DOE line management and BSC project management weekly**
 - » **Reviewed at DOE Monthly Operating Review**
 - » **BSC Projects review late actions weekly**



Corrective Action Program

(Continued)

- **Actions Taken/In progress**
 - Increased line and project management involvement in DR/CARs process
 - ♦ DOE line and BSC project management inserted into DR/CAR process
 - » Reviews (and can reject) corrective action plan before Quality Assurance (QA)
 - » Verifies corrective action completion (and can reject) before QA



Corrective Action Program

(Continued)

- **Revising AP-16.1Q, CAP procedure**
 - **Formally insert line/project management into DR/CAR process**
 - **Line/project managers may issue DR/CAR**
 - ♦ **QA will still review**
 - **Simplified process**
 - **No extensions to develop corrective action plan (30 days)**
 - **No extensions of corrective action due dates**

Corrective Action Program

(Continued)

- **Quality Assurance involvement in CAP**
 - **Quality Assurance still issues DR/CARs, no loss of independence**
 - **Quality Assurance Representative:**
 - ♦ **Reviews each DR/CAR before issuance**
 - » **Determines significance**
 - » **Determines if Stop Work Order needed**
 - ♦ **Approves corrective action plan**
 - ♦ **Verifies corrective actions complete**



Corrective Action Program

(Continued)

- **Corrective Action Program Metrics**
 - **BSC DR/CAR Corrective Action Effectiveness**
 - **Timeliness of Closure**
 - **QA Verification Success**
 - **Self-identification of Issues**

Corrective Action Program

(Continued)

- **Path Forward**
 - Implement revised procedure
 - Monitor effectiveness
 - Continue to improve process
 - ♦ Continued emphasis on management involvement
 - ♦ INPO's *Principles for Effective Self-assessment and Corrective Action Programs*





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Office of Civilian Radioactive Waste Management

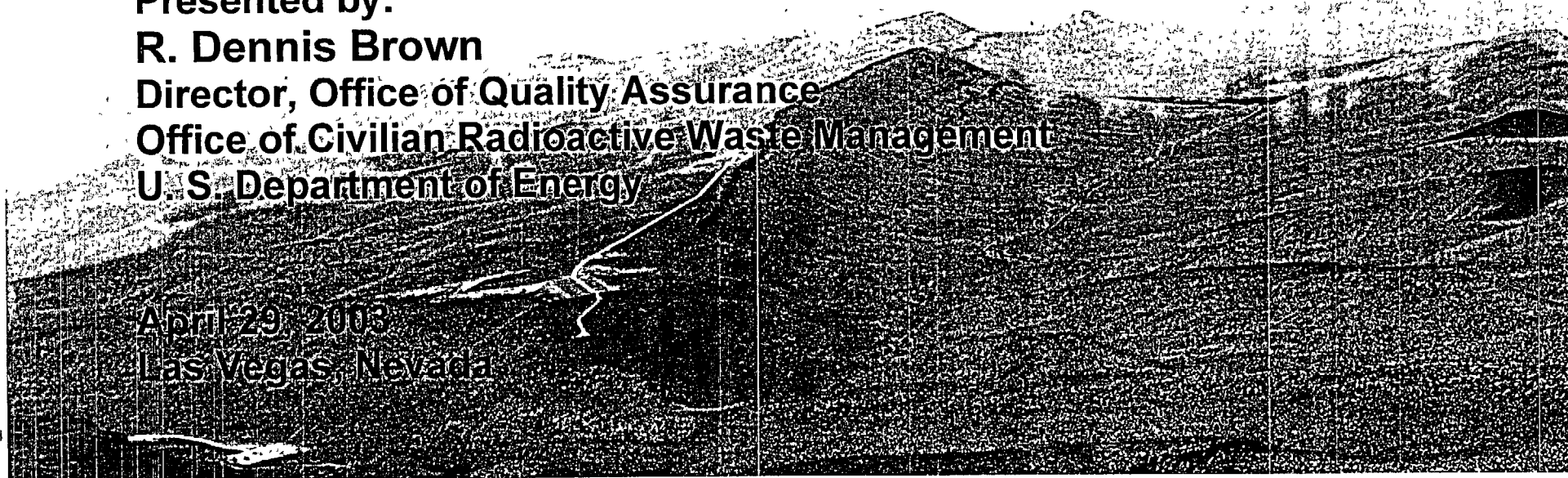


Revisions to the Quality Assurance Requirements and Description Document

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
R. Dennis Brown
Director, Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U. S. Department of Energy

April 29, 2003
Las Vegas, Nevada



Revisions to the Quality Assurance Requirements and Description Document

- **Management Improvement Initiatives (MII) Commitment:**
 - The Quality Assurance Requirements and Description (QARD) will be reviewed and revised as necessary to ensure that applicable requirements are identified, documented, and traceable to regulatory drivers
- **QARD, Revision 13, was revised and approved**
 - Formal review and acceptance requested from the NRC on April 2, 2003

Revisions to the Quality Assurance Requirements and Description Document

(Continued)

- **QARD, Revision 14, will be a more comprehensive revision and addresses:**
 - **Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada, 10 CFR Part 63**
 - **The Yucca Mountain Review Plan, NUREG 1804, Draft Final Revision 2**
- **QARD, Revision 14, Review Process**
 - **DOE/BSC Reviews**
 - **NRC Technical Exchange**





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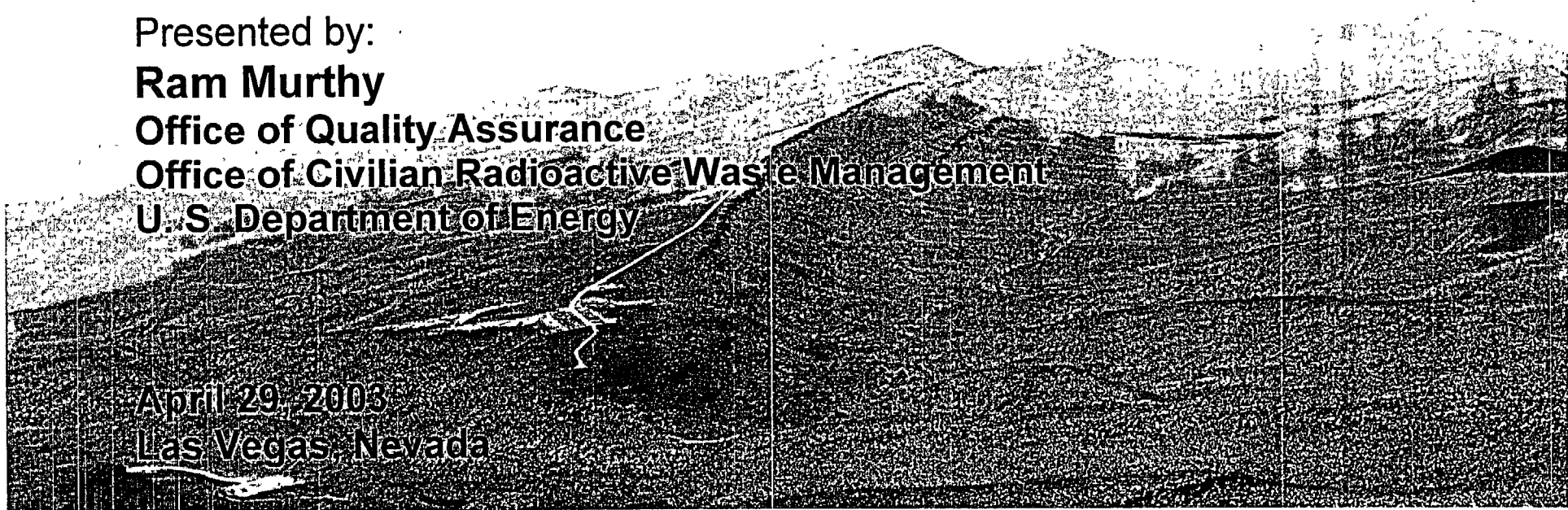


Quality Assurance Graded Approach

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Ram Murthy
Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

April 29, 2003
Las Vegas, Nevada



Objectives

- **Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Grading Process**
- **Review QA grading processes:**
 - The NRC approach (Reg. Guide 1.176)
 - South Texas Project approach
- **Make recommendations to OCRWM management**



Team Members

- Ram Murthy, DOE-OQA,
Team Leader
- Kerry Grooms, DOE-OQA
- Robb Keele, BSC-QA
- Dennis Richardson, BSC/LAP
- Don Beckman, BSC/B&A
- Paul Harrington, DOE-ORD
- Marlin Horseman, NQS QA
- Tom Dunn, BSC/LAP
- Preston McDaniel, BSC/RDP
- Andrew Orrell, BSC/CSO/SNL



Approach

- **Terminology:**
 - Grading
 - QA Grading
 - Requirements
 - Classification
 - Applicability



YUCCA MOUNTAIN PROJECT

Quality Assurance Grading Task Process

- **Reg. Guide 1.176 requirements**
- **Team agreement on terminology**
- **PROs and CONs**
- **Prepare position paper of team recommendations**
- **Brief OCRWM management**



Pictorial Results of the Forces

Force Field Analysis – Impact of Grading						
	Negative Impact on OCRWM			Positive Impact on OCRWM		
	High	Medium	Low	Low	Medium	High
COSTS						
FOCUS						
PROGRAM FLUX						
PERCEPTIONS						
OVERALL IMPACT OF GRADING						

Notes:

The measurements illustrated are qualitative in nature and represent a detailed evaluation of the PROs and CONs identified by the team

1. **Costs** considers those resources required to develop, obtain approval, implement, maintain, and defend the QA Grading process. On the positive side, the costs are resources and dollars that could be saved by doing fewer inspections, reviews, audits, and other QA controls.
2. **Focus** is primarily a benefit and represents the positive planning and implementation based upon knowing the safety and waste isolation importance. Also included is the benefit derived from Program and regulatory personnel being able to focus on the important SSCs.
3. **Program Flux** refers to the change of Program documents and requirements. If QA Grading is adopted, fairly extensive changes would be required to the QARD and implementing procedures. Changes will affect costs and the confusion index.
4. **Perceptions** of the various stakeholders may be negative if they perceive that not all SSCs and their related activities will receive all of the QA controls as directed by the Grading process. Additionally, if the process is not effective or if some serious incident occurs that can be traced to the QA Grading process, perceptions will more than likely be negative. Included in this category are the perceptions of the NRC, the State, other regulators, and the public.



Conclusions

- **The QA Grading process is not well established throughout industry**
- **OCRWM uses a Risk-Informed Performance-Based Classification process**
- **The Team recommended that an OCRWM QA Grading process not be implemented**
- **OCRWM management unanimously agreed with the Team's recommendation**





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



Trending Deficiencies

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Kerry Grooms
Acting Team Leader, Assessments
Office of Civilian Radioactive Waste Management
Office of Repository Development
U.S. Department of Energy

April 29, 2003
Las Vegas, Nevada

Trending Deficiencies

- **Requirements**

- **Quality Assurance Requirements and Description (QARD) - Reports of nonconformances and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes**
- **QARD - Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends**

Trending Deficiencies

(Continued)

- **Deficiency Documents Trended**
 - **CAR** - Corrective Action Report
 - **DR** - Deficiency Report
 - **QO** - Quality Observation
 - **CDA** - Corrected during Audit
 - **DIR** - Deficiency Identification and Referral
 - **NCR** - Nonconformance Report
 - **TER** - Technical Error Report



Trending Deficiencies

(Continued)

- **Trending Program is being reviewed**
 - **Questions raised by DOE management and NRC Onsite Representative**
 - ♦ **Is the process telling management what it needs to know**
 - ♦ **Are emerging issues being identified**
 - ♦ **Is the threshold for trends appropriate**

Trending Deficiencies

(Continued)

- **Software Defect Notices (SDNs)**
 - SDNs are initiated upon discovery of a defect in a controlled software item
 - All SDNs are evaluated to determine if they are a Condition Adverse to Quality (CAQ)
 - Evaluation of the SDN is done by organization responsible for the software

Trending Deficiencies

(Continued)

- **In two year period (2001 and 2002)**
 - **24 SDNs written**
 - **Four of the 24 SDNs were evaluated as CAQ**
 - ♦ **None identified impacts on previous applications**
 - ♦ **All were procedure non-compliances**
 - **Those four trended with other CAQ**

Trending Deficiencies

(Continued)

- **Examples of SDNs**

- **An error was received when attempting to run the executable as a stand-alone or by running a provided script file**
- **Code could not be successfully compiled or executed**
- **Code could not be run without the assistance of a readme file provided by the developing organization**
- **Supplied executable would not run**



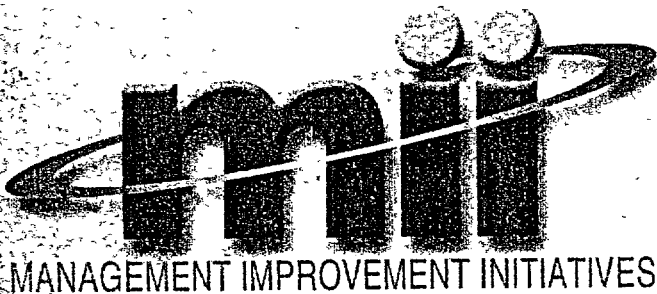
YUCCA MOUNTAIN PROJECT

Consolidated Action Items
From The
NRC/DOE Quarterly QA Meetings
(April 29, 2003)

Item No.	Description	Status
QA 0210-01	DOE review the reasons for OQA delaying their audit of YMSCO, and whether a DR should be issued on that issue.	Completed DR No. OQA (0)-03-D-012, issued on 10/16/02, was closed on 1/9/03. A copy of the DR has been provided to the NRC On-Site Representative (OR).
QA 0210-02	DOE is to consider the State of Nevada's request for copies of all self-assessment reports.	Completed 01/22/02 status: DOE has decided it is not in the best interest of the Self-Assessment Program to publicly release the reports generated from the performance of Self-Assessments. Self-Assessments are most valuable when the author of the report can be openly self critical about the area being assessed.
QA 0210-03	DOE to assess the frequency and team makeup for performance-based QA audits.	Completed 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. This action item was further discussed during the January 22, 2003 Quarterly QA Meeting and has been adequately addressed.

		Recommendation: Action Item is complete
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.	<p>Completed</p> <p>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.</p> <p>This action item was further discussed during the January 22, 2003 Quarterly QA Meeting, and a detailed response was included in the meeting summary.</p>
QA 0301-01	DOE will provide NRC the result of the independent review of the QARD	<p>Completed.</p> <p>Information was provided to the NRC Onsite Representative.</p>
QA 0301-02	DOE will evaluate the applicability of Software Deficiency Notices to the trending program.	<p>Open.</p> <p>Results of evaluation will be presented at the April 2003 Quarterly QA Meeting.</p>
QA 0301-03	DOE will provide the status of migration of electronic media at the next Quarterly QA Meeting	<p>Open.</p> <p>Is on the agenda for the April 2003 Quarterly QA Meeting.</p>
QA-0301-04	DOE will provide a timeline and schedule for the migration of electronic media	<p>Open.</p> <p>Will be provided as part of planned status information at the April 2003 Quarterly QA Meeting.</p>
QA-0301-05	DOE will provide an update on the task force for QA grading at the next Quarterly QA Meeting	<p>Open.</p> <p>Is on the agenda for the April 2003 Quarterly QA Meeting.</p>
QA-0301-06	NRC will provide examples / references to what NRC considers to be good examples of QA programs which differentiate separate regulatory requirements.	<p>Open</p>

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.



Program Level Effectiveness Indicators

Reporting Period: *March 31, 2003*

GENERAL SUMMARY

Following the July submission of the MII to the NRC, a joint DOE / BSC team was established to enhance the Management Improvement Initiatives (MII) effectiveness indicators. During the development of the indicators, the team recognized that a cornerstone of an effective quality assurance (QA) program is the self-identification and resolution of issues by the responsible line organization. Thus, many of the indicators are developed to encourage self-identification of issues so that corrective actions are taken before issues cause significant quality problems. The MII effectiveness indicators focus on the important elements of our performance, such as breakdowns in our QA program implementation, performance-based violations of regulatory requirements, and issues that result or could result in significant NRC enforcement actions.

The team realized that a single indicator for any of the MII key areas was not sufficient. For example, the inherent cross-functional nature of R2A2s means that the effective implementation of the revised R2A2s will affect many if not all of the complex processes on the Program. Therefore, the effectiveness of the revised R2A2s is measured by the success of meeting goals that were not achievable before the MII was implemented, for example, the goals established for CAR closure (EI-6) will not be achieved unless the revised R2A2s are effectively implemented. The team concluded the processes monitored by the effectiveness indicators will not produce the desired goals without an improvement of the R2A2s. It should be noted that a single indicator alone will not measure the effectiveness of R2A2 actions, but taken as a whole, these indicators assess the successful achievement of the MII.

The team assigned effectiveness indicators to the five key areas of MII to assess indicator completeness. The interdependent nature of the MII key areas is demonstrated by the use of an indicator for more than one key area. The following effectiveness indicators were assigned to MII key areas.

A high-quality Program with clear R2A2s will efficiently and effectively resolve cross-functional issues. This means the organization will self-identify and resolve issues before they become major issues. EI-1 measures the success of the Program in preventing major issues from occurring. The Program must find and fix quality issues at the earliest opportunity to successfully meet the goals of EI-1. The success of the organization in finding and fixing issues before they become major issues is monitored by meeting MII closure goals EI-3, -5, -6, and -9. These indicators require R2A2s to be well-defined to accomplish the desired self-identification and timely closure of issues. Change Control Board is a cross-functional activity that will have timeliness issues if the R2A2 are not clearly defined and followed. EI-7 will monitor this process for effective R2A2 implementation. EI-12 will measure the effectiveness of the communication and implementation of the MII R2A2s by conducting a survey of employee attitude and opinion of the success of R2A2 implementation.

Therefore, the effective implementation of the R2A2s will be accomplished if major issues are prevented, the organization identifies and corrects issues in a timely and effective manner, and the organization embraces the changes implemented in the R2A2s.

The effective implementation of the QPP portion of the MII can be demonstrated by the prevention of major issues as measured by EI-1. Fundamental to an effective QA program is the ability of the organization to self-identify and correct issues before the issues adversely affects the Program. Additional indicators become necessary to determine whether the Project is self-identifying and closing important issues in a timely manner. EI-2, -3, -4, -5, -6, and -9 have been chosen as additional effectiveness indicators to monitor this area. These indicators measure the effectiveness of the CAR closure process, the ability of BSC to self-identify issues, the effectiveness of OQA audit process, the performance of department-level self-identification of issues, and the timely closeout of CAR and DR actions.

An effective procedure program has several attributes that indicate successful implementation. The procedures should prevent major issues (EI-1). If there are issues with the procedures, they are identified and resolved in an effective and timely manner (EI-3, -5, -6, -9, and -10). As with any project, the procedure program should meet established schedules (EI-8). Finally, the procedure program should be viewed by the affected workers as usable, responsive to their needs, and effective at revising procedures in a timely manner (EI-12).

The effective implementation of the PRO section of the MII will establish procedures that prevent major issues from occurring, establish a process for the resolution of procedure issues in a timely and effective manner, and be recognized as a process that is responsive and effective in meeting procedural needs of employees. These attributes will be accomplished by meeting the MII closure goals established in EI-1, -3, -5, -6, -8, -9, -10, and -12.

The CAP is an important process in any effective QA program. Because of the close relationship between QPP and CAP, many of the effectiveness indicators for the successful implementation of the CAP will be the same as those selected for the QPP area.

An effective CAP will prevent major issues from occurring (EI-1). It will allow issues to be identified and corrected effectively in a timely manner (EI-2, -3, -5, -6, and -9). The program should be viewed as an effective way for employees to identify and get issues resolved in a non-threatening manner (EI-12).

It is important to provide an environment that encourages the work force to self-identify problems and for those problems to be resolved. By measuring the employee's willingness to raise concerns, OCRWM management is made aware of line management's ability to effectively address issues.

In conclusion, the team obtained information to assess the Program's current performance relative to each indicator MII closure goal. It was concluded that incremental improvement goals were needed for several of the indicators. If at any time the progress is less than desired, the

**Roles, Responsibilities,
Authorities, and
Accountability (R2A2)**
EI-1, -3, -5, -6, -7, -9, -12

**Quality Assurance
Programs and
Processes (QPP)**
EI-1, -2, -3, -4, -5, -6, -9

**Program Procedures
(PRO)**
EI-1, -3, -5, -6, -8, -9, -10, -12

**Corrective Action
Program (CAP)**
EI-1, -2, -3, -5, -6, -9, -12

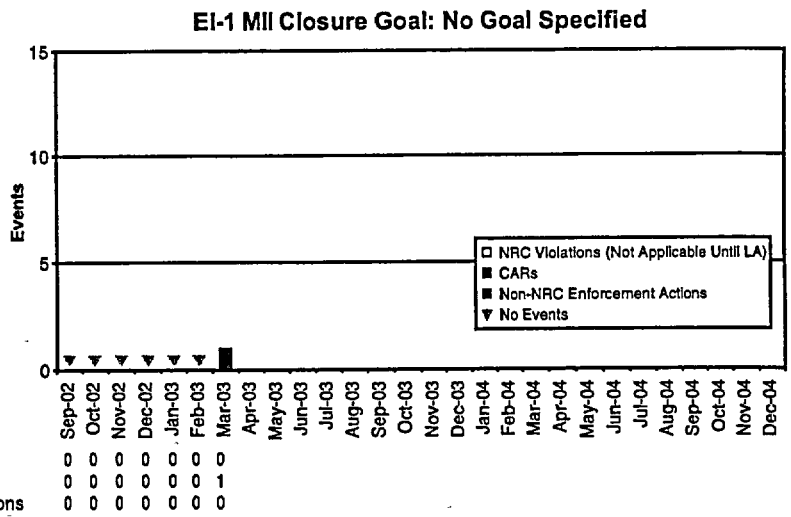
**Safety Conscious
Work Environment
(SCWE)**
EI-3, -4, -5, -11, -12

EI-1 Events Per Month

EI-1 NRC Level 1, 2, or 3 Violations, Enforcement Actions, and CARs

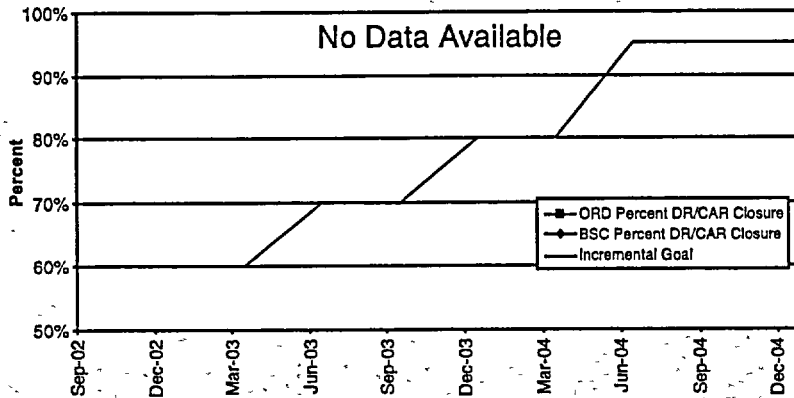
Responsible Manager: **Russ Fray**

Data Point of Contact: **Len Skoblar**



NRC Violation	0	0	0	0	0	0
CARs	0	0	0	0	0	1
Non NRC Actions	0	0	0	0	0	0

EI-2 MII Closure Goal: 95%



EI-2 Quarterly DR/CAR Closure Effectiveness

EI-2 Number of DR/CAR Corrective Actions Determined Effective by External Review
Number of DR/CAR Corrective Actions Reviewed by External Review

Responsible Manager: **Russ Fray**
Data Point of Contact: **Len Skoblar**

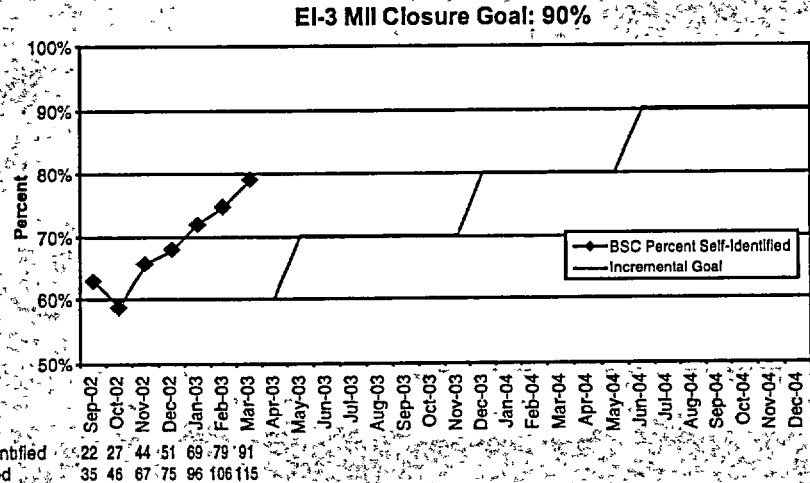
NO DATA AVAILABLE

EI-3 BSC Self-Identification

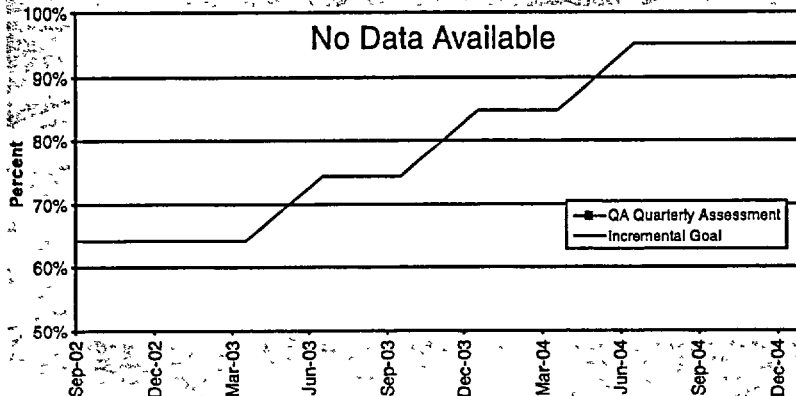
EI-3 Six-Month Cumulative Number of BSC (Contractor) Self-Identified Issues (DRs/CARs)
Six-Month Cumulative Number of Total Identified Issues Assigned to BSC (DRs/CARs)

Responsible Manager: **Michael Mason**
Data Point of Contact: **Pam West-Thompson**

GREEN **BSC**



EI-4 MII Closure Goal: 95%



EI-4 Quarterly Effectiveness Assessment

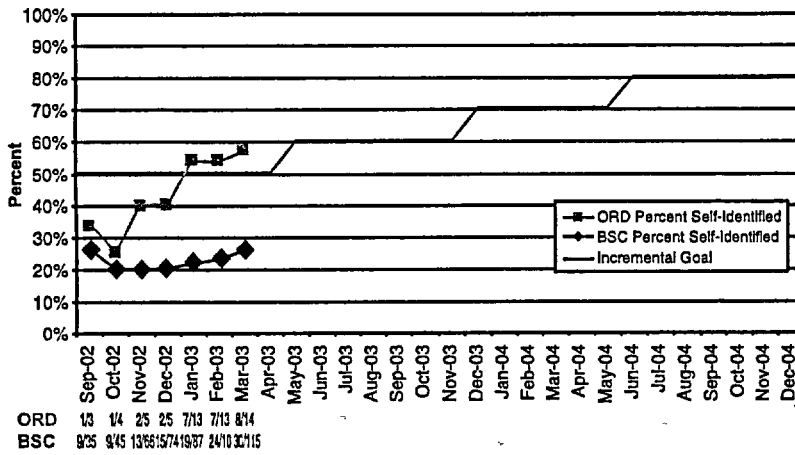
EI-4 Number of Project Identified DRs/CARs
Total Number of Project and Externally Identified DRs/CARs
*DRs are temporarily included

Responsible Manager: **Russ Fray**
Data Point of Contact: **Len Skoblar**

NO DATA AVAILABLE

BLUE ■ Significantly exceeds expectations
■ Meets or exceeds expectations
--- Borderline or declining performance

El-5 MII Closure Goal: 80%



El-5 Self-Identified Department Issues (DRs/CARs)

El-5 Six-Month Cumulative Number of Department Issues Self-Identified (DRs/CARs)
Six-Month Cumulative Number of Department Issues (DRs/CARs)

Responsible Manager: Russ Fray
Data Point of Contact: Len Skoblar

GREEN ORD
RED BSC

El-6 Timely CAR Closure

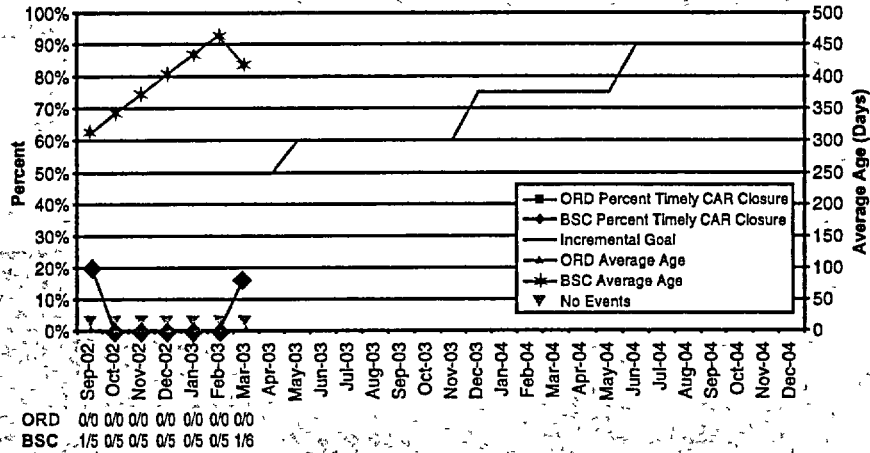
El-6A Six-Month Cumulative Number of CARs (< 100 Days)
Six-Month Cumulative Number Total Number of CARs

El-6B Six-Month Cumulative Days Open for All CARs
Six-Month Cumulative Number of CARs

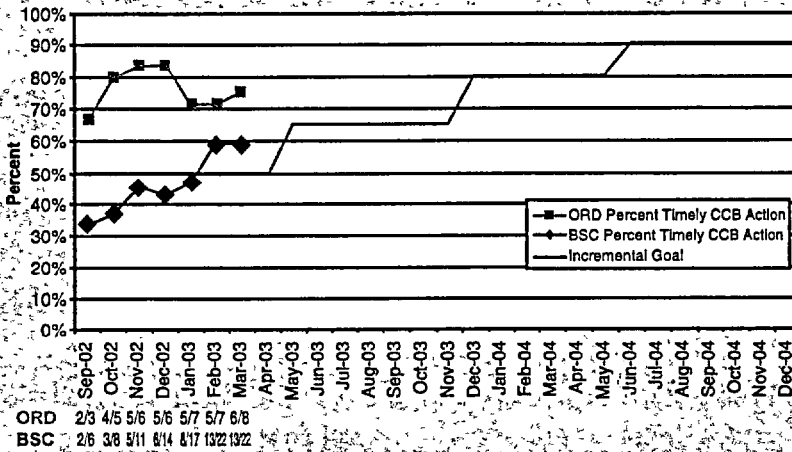
Responsible Manager: Russ Fray
Data Point of Contact: Len Skoblar

GREEN ORD
RED BSC

El-6 MII Closure Goal: 90%



El-7 MII Closure Goal: ORD - 90%, BSC - 90%



El-7 Timely Change Control Board (CCB) Action

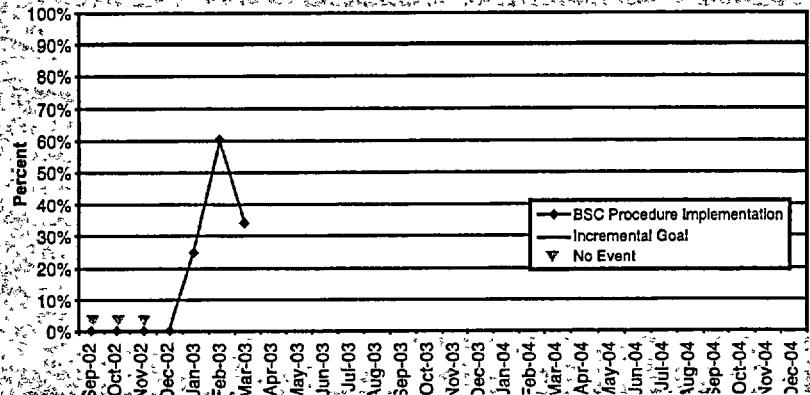
El-7A Six-Month Cumulative ORD Actions (< 7 Days after Level 3 Disposition)
Total ORD Actions

El-7B Six-Month Cumulative BSC Actions (< 21 Days)
Total BSC Actions

Responsible Manager: Scott Hajner
Data Point of Contact: Bill Sutfin

GREEN ORD
GREEN BSC

El-8 MII Closure Goal: 90%



El-8 BSC Procedure Implementation Schedule

El-8 Six-Month Cumulative Number of MII Procedures Issued within Schedule
Six-Month Cumulative Number of MII Procedures Issued

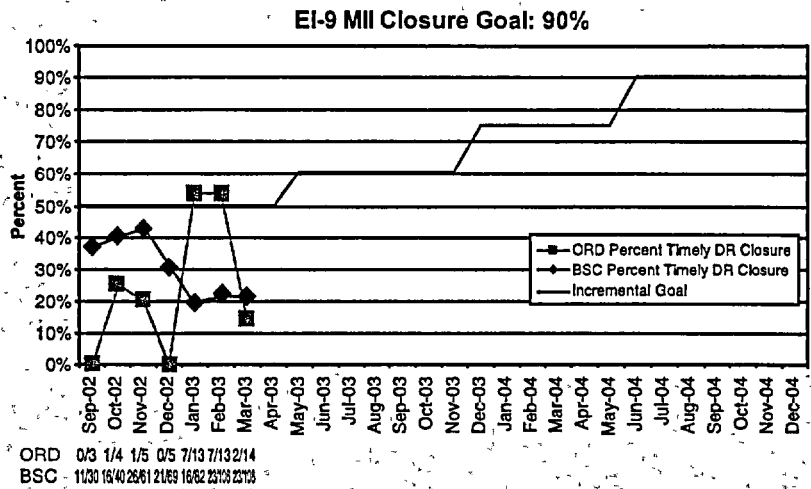
Responsible Manager: Melinda d'Ouville
Data Point of Contact: Jim King

RED

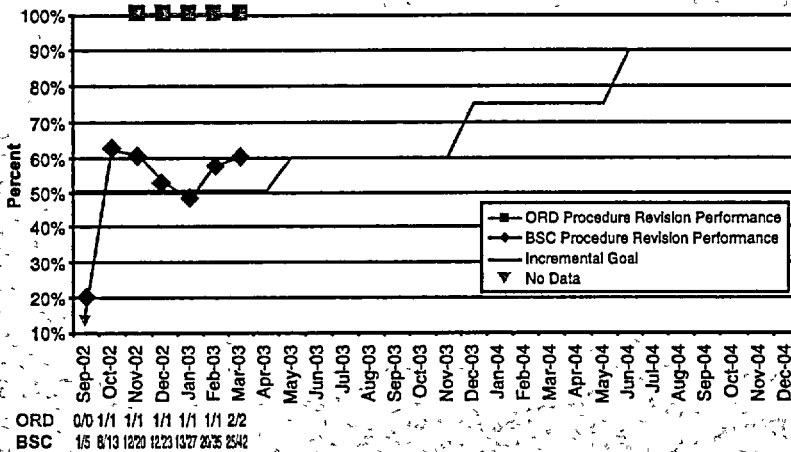
● EI-9 Timely DR Closure

EI-9 Six-Month Cumulative Number of DRs (< 45 Days)
Six-Month Cumulative Total Number of DRs

Responsible Manager: Russ Fray
Data Point of Contact: Len Skoblar



EI-10 MII Closure Goal: 90%



● EI-10 Procedure Revisions Performance

EI-10 Six-Month Cumulative Number of Procedure Revisions Based on Initiation (< 45 Days)
Six-Month Cumulative Number of Procedure Revisions Based on Initiation

Responsible Manager: Melinda d'Ouille
Data Point of Contact: Melinda d'Ouille

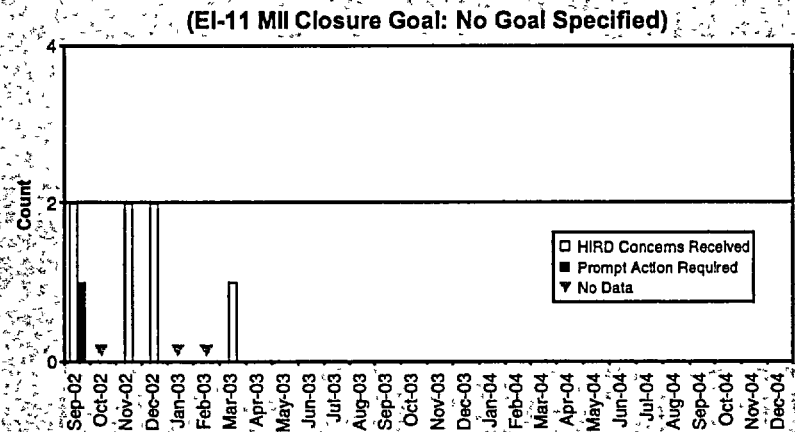


● EI-11 Monthly HIRD Concerns Received

EI-11 Number of HIRD Concerns Received

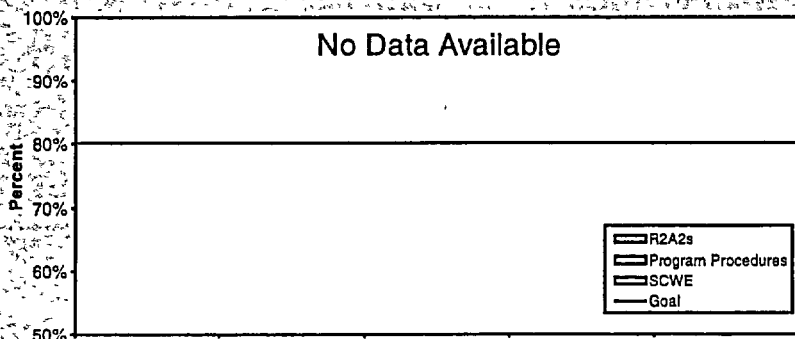
Responsible Manager: Dick Phares
Data Point of Contact: Dick Phares

Concerns Received
Prompt Action Required



EI-12 MII Closure Goal: 80%

No Data Available



● EI-12 BSC Surveys - MII Procedures, R2A2, SCWE

EI-12 General Project Population Understands and Properly Implements the Revised R2A2s
Program Procedure
Safety Conscious Work Environment

Responsible Manager: Melinda d'Ouille
Data Point of Contact: Russ Riding