



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

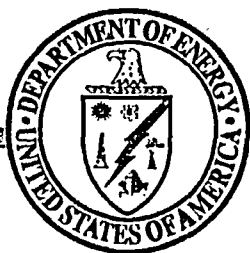


# DOE/NRC Quarterly Quality Assurance Meeting

Las Vegas, Nevada

November 12, 2003





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**

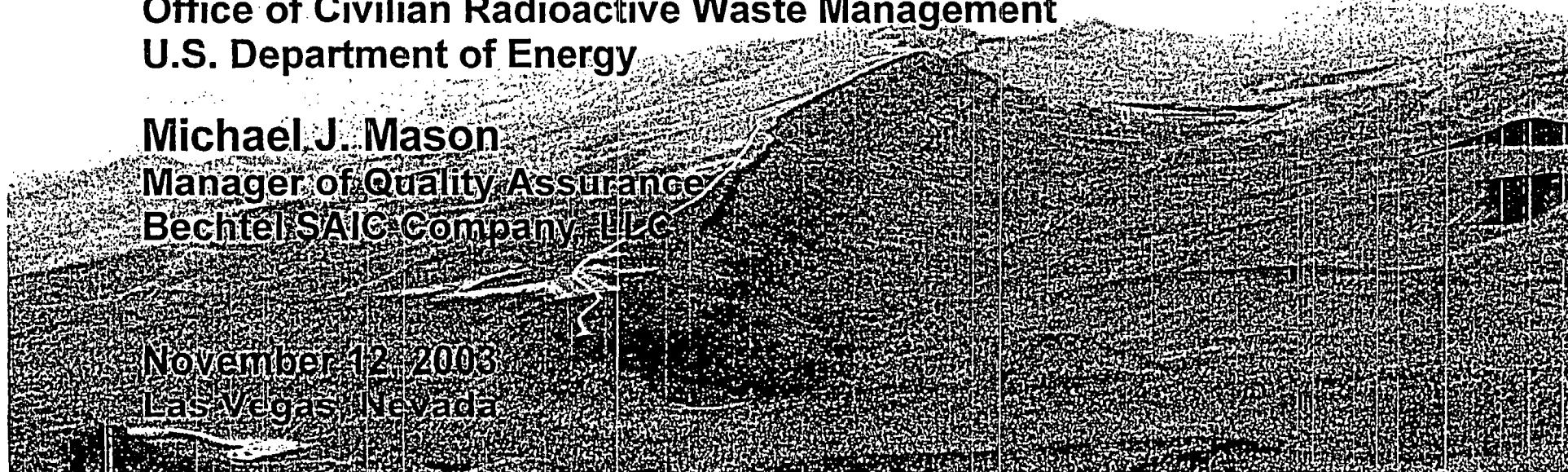
**Michael J. Mason**

**Manager of Quality Assurance**

**Bechtel SAIC Company, LLC**

**November 12, 2003**

**Las Vegas, Nevada**



# Quality Assurance Overview

- **Quality Assurance Program Improvements**
- **Assessments**
- **Surveillances**
- **Noteworthy Practices**



# Quality Assurance Program Improvements

- **Senior Management increased involvement**
  - Off site management meeting
  - Monthly operating review
- **Line Management increased involvement**
  - Percentage of self-identified Condition Reports increasing
- **Performance indicators**
  - Indicators developed
  - Data available project wide



# **Quality Assurance Program Improvements**

(Continued)

- **Corrective Action Program**
  - Single point of entry program implemented
  - Cause analysis process improved
  - Corrective action plan development process improved
  - Performance metrics developed



# Quality Assurance Program Improvements

(Continued)

- **Trending Program**
  - Uniform cause codes implemented
  - Reporting frequency quarterly
  - More rigorous process implemented
  - Integrated with Condition Reporting and Causal Analysis processes



# Assessments

- **Repository Design Project - Integrated, (BSC Audit Team Leader)**
- **Lawrence Berkeley National Laboratory - Integrated (BSC Audit Team Leader)**
- **Sandia National Laboratory - Integrated (BSC Audit Team Leader)**
- **Technical Product Inputs - Integrated, Office of Quality Assurance (OQA Audit Team Leader)**
- **Office of Repository Development - (OQA Audit Team Leader)**



# Assessments

(Continued)

- **BSC Washington D.C. - OQA only**
- **BSC Las Vegas - Integrated (OQA Audit Team Leader)**
- **Office of Quality Assurance - (DOE Idaho Audit Team Leader)**
- **All Procedures (AP-5.1Q) - Integrated, OQA Lead**
- **BSC Site Activities - Integrated, BSC Lead**





# Surveillances

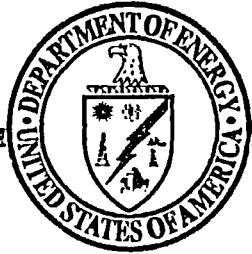
- **18 BSC Internal Surveillances**
- **7 Supplier Surveillances**
- **3 OQA Internal Surveillances**



# Noteworthy Practices

- **Causal Analysis Training**
- **Causal Analysis Handbook**
- **Quality Performance Indicators**
- **Quality Engineering Checklists (In-process reviews)**
- **Quality Engineering Handbook**
- **QA Training Needs Matrix**





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# Model Validation (CAR BSC-01-C-001)

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Jean L. Younker**  
Chief Science Officer  
Bechtel SAIC Company, LLC

November 12, 2003  
Las Vegas, Nevada



# **Model Validation (CAR BSC-01-C-001)**

## **Background**

- **Processes controlling model development and model validation were inadequate**
  - **Inconsistent model validation documentation**
  - **November 2001 independent review results categorized 87 percent of models as inadequate [60 percent documentation inadequate; 27 percent inadequate model validation]**



# **Model Validation (CAR BSC-01-C-001)**

## **Corrective Actions Taken**

- **Procedure for Modeling (AP-SIII.10Q) upgraded December 2001**
  - **Explicit methods and criteria for model validation incorporated**
  - **Independent overview function established**
  - **>500 technical staff trained to new processes in first 3 months**
  - **Metrics established to evaluate effectiveness of model development and validation processes**

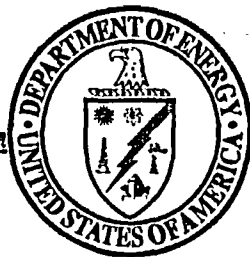


# **Model Validation (CAR BSC-01-C-001)**

## **Summary**

- **Corrective actions for CAR-001 were completed**
- **DOE/BSC Model Audit (October 21-31, 2003) and CAR-001 verification activities evaluated effectiveness of corrective actions**
  - **Implementation and effectiveness issues identified during audit are being reviewed against CAR-001 corrective actions**
- **Sample of models reviewed were substantially improved (approximately 75 percent had adequate model validation vs 13 percent in November 2001)**





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# Model Audit Results

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**R. Dennis Brown**

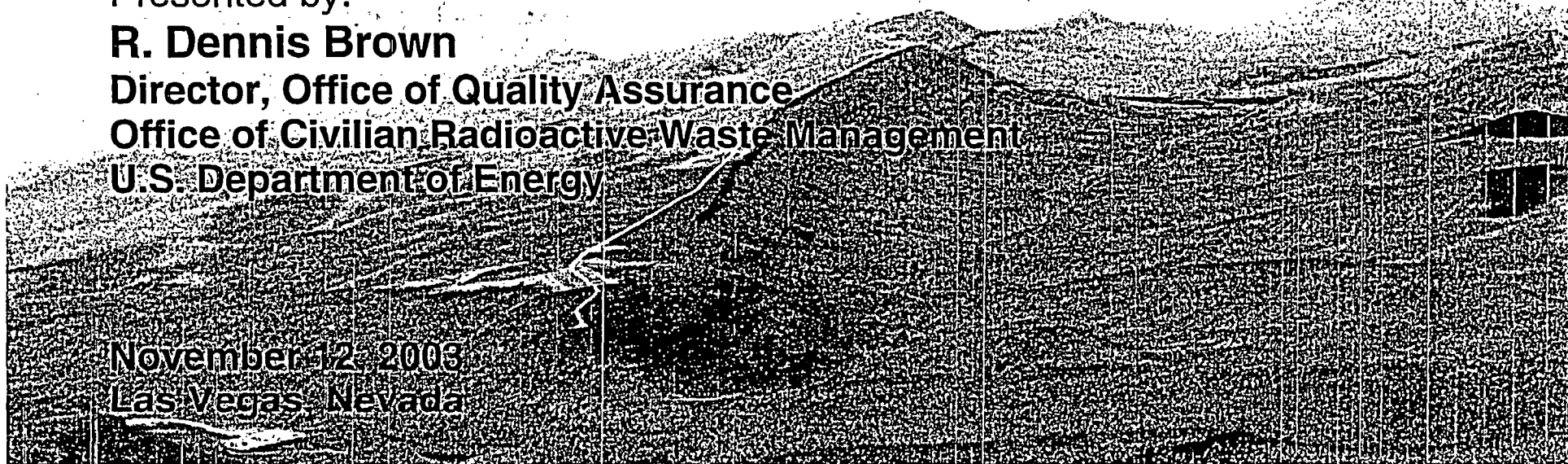
**Director, Office of Quality Assurance**

**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**November 12, 2003**

**Las Vegas, Nevada**



# Model Audit Results

- **Dates of audit - October 21- 31, 2003**
- **Integrated audit, led by the Office of Quality Assurance (OQA)**
  - Team makeup, 5 from OQA and 2 from BSC Quality Assurance (QA) and 7 technical specialists
- **Scope of audit - processes and related analysis model report products to support License Application**
- **Audit Results**







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# Management of Data (CAR BSC(B)-03-107)

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Michael A. Jaeger**  
Manager of Technical Product Input  
Bechtel SAIC Company, LLC

November 12, 2003  
Las Vegas, Nevada

# **Corrective Action Report**

## **(CAR BSC(B)-03-107)**

- **Formerly CAR BSC(B)-03-107, now CR-16**
- **Ineffective corrective actions related to data issues**
- **Data Confirmation Project addresses remedial actions for the analyses and models that support License Application (LA)**



# **Root Cause Determination**

## **(CAR BSC(B)-03-C-107)**

- **Root Cause determination completed**
- **Root Causes**
  - **Management was not held accountable for assuring effectiveness of corrective actions**
  - **Did not establish a timely and effective Corrective Action Program**
  - **Data management and usage not performed in consistent and compliant manner**
  - **Data requirements are not adequately defined**



# Summary of Corrective Actions

- **Data Confirmation Project**
  - Remedial actions for analysis model reports (AMR)
  - Phase I Review
    - ♦ Proper citation of inputs and completion of Document Input Reference System (DIRS) entries
    - ♦ Proper citation of inputs in the document
    - ♦ Content correct for cited Data Tracking Numbers (DTNs)
  - Phase II Review
    - ♦ Review of data suitability for intended use in AMRs
  - Remediation Plans/AMR revisions



# Summary of Corrective Actions

(Continued)

- **Procedure changes**
- **Management actions addressing root causes**
  - **Corrective Action Program**
  - **Accountability**



# Metrics

- **Data Confirmation Project**
  - **Approximately 130 AMRs support LA**
    - ♦ **95 (73 percent) products have completed Phase I Review**
    - ♦ **10 (8 percent) products completed Phase II Review**
    - ♦ **10 (8 percent) product remediation plans completed**



# Metrics

(Continued)

- **Approximately 1,352 data sets support LA products**
  - 689 data sets fully qualified and verified
  - 453 data sets need either qualification (88), Records Roadmap Verification (315), or further evaluation (50)
    - ♦ Have dedicated team to prepare the larger, complex data sets
    - ♦ Have more than 100 of 315 verifications in process
  - Approximately 210 additional data sets are anticipated to support LA products
    - ♦ 120 fully qualified and verified
    - ♦ 40 require qualification
    - ♦ 50 require Records Roadmap Verification



# Summary

- **Root cause complete**
- **Remedial actions in process**
- **Management leadership to establish data terminology**
- **Procedure changes being prepared**
- **Scheduled completion to support license application**







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# Data Audit Results

Presented to:

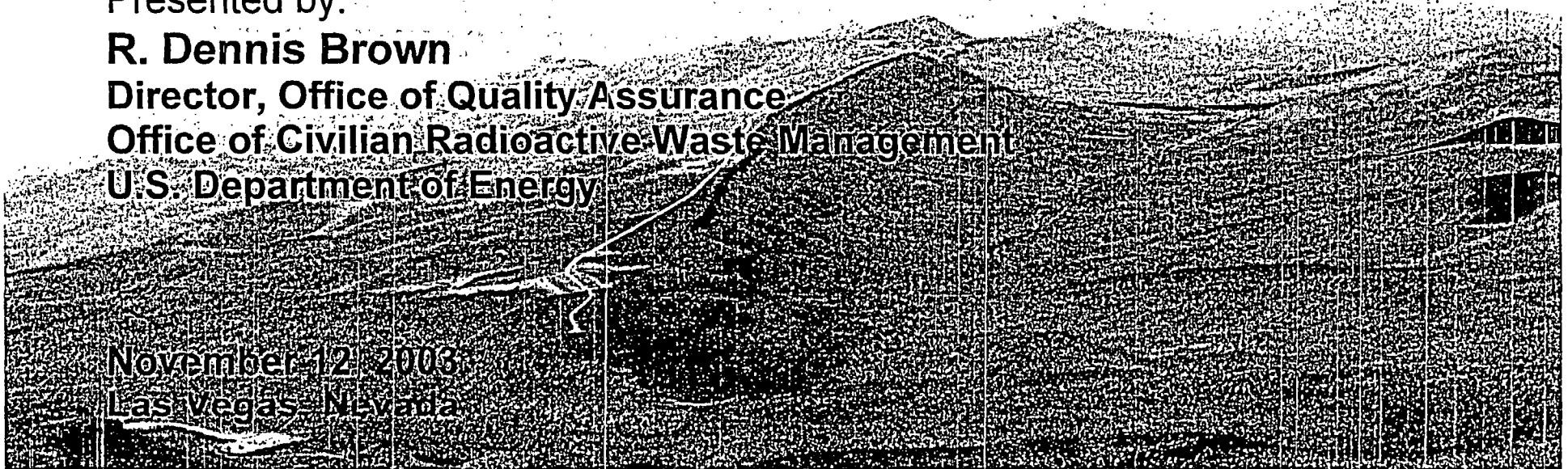
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**R. Dennis Brown**

**Director, Office of Quality Assurance  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy**

**November 12, 2003  
Las Vegas, Nevada**



# **Data Audit Results**

- **Dates of audit - September 8-19, 2003**
- **Integrated audit team led by the Office of Quality Assurance (OQA )**
  - **Team makeup, 3 from OQA and 3 from BSC Quality Assurance (QA) and 3 technical specialists**
- **Scope of audit - focused on technical product input related to License Application models and analyses**
- **Audit results**
  - **Adequacy was satisfactory**
  - **Process is effective**
  - **Procedure compliance unsatisfactory**
- **12 condition reports initiated**





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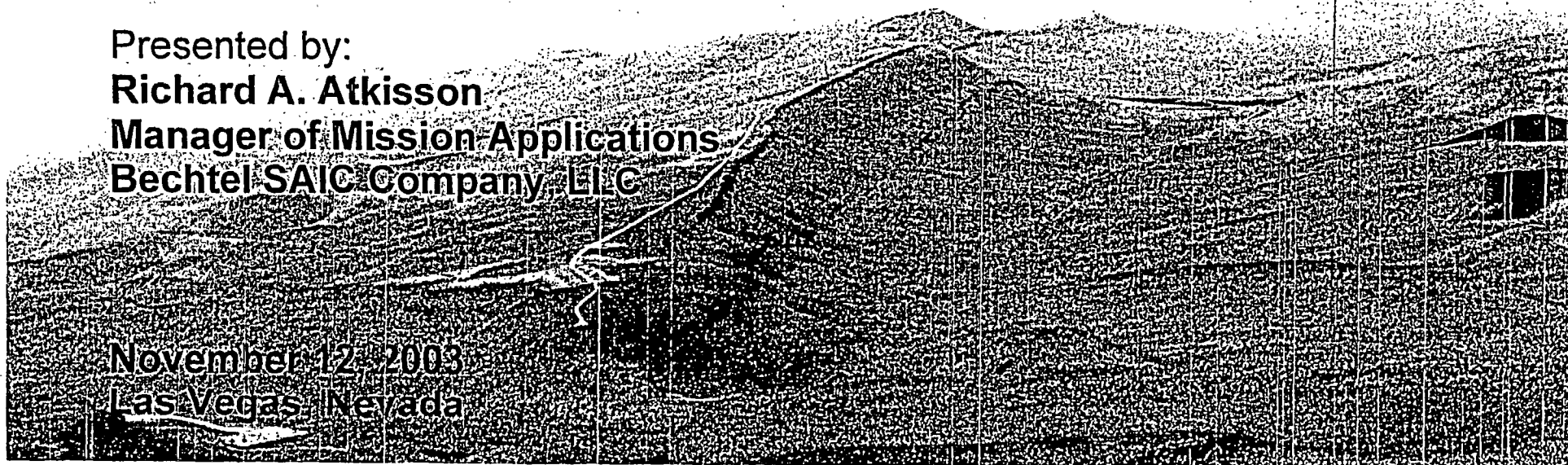


# Software Development (CAR BSC-01-C-002)

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Richard A. Atkisson**  
**Manager of Mission Applications**  
**Bechtel SAIC Company, LLC**

**November 12, 2003**  
**Las Vegas, Nevada**



# **Software Development Corrective Action Report (CAR BSC-01-C-002)**

- **Issue: Ineffective implementation of quality software management requirements**
- **Corrective actions include:**
  - **Procedure revisions/development**
  - **Training and requirements emphasis**
  - **Management improvement activities**
- **Corrective actions to be complete December 2003**

# Status of CAR-002 Actions

- Request for verification received by Office of Quality Assurance (OQA) on September 11, 2003
- 23 of 28 actions are complete and verified as satisfactory by OQA
- 5 actions judged unsatisfactory and returned for rework
  - 3 actions related to consistency/clarity in software development portion of software package - Change to procedures in progress to address Quality Assurance Requirements and Description (QARD) requirements verbatim
  - 1 action related to timeliness of software defect impact analysis - Procedure Interim Change Notice (ICN) in progress (60 day timeline)
  - 1 action related to Legacy Software Testing - Legacy Software testing procedure (AP-SI.4Q) is developed and approved. Legacy Software functionality testing is in progress



# Status of CAR-002 Actions

(Continued)

- **Software performance-based audit in June 2003 confirmed the need for software development procedure changes**
  - **Impact: To date no adverse impact on code functionality or technical products has been noted. Legacy Software testing is still in its early phase**
  - **Amended response required for 5 open actions - Due by November 15, 2003**
  - **New estimated completion date for corrective actions is December 15, 2003**



# License Application Software Categories

- The “Letter of Agreement on Documentation Requirements for Software Used in Support of License Application (LA),” dated October 24, 2003, divided software that will be used to support LA into 3 bins:
  - Legacy Software is defined as software which was baselined prior to January 13, 2003. There are 344 Legacy codes
  - Transition Software is defined as software which was baselined after January 13, 2003, but before the effective date of the next ICN to the Q Software Procedures. There are 63 Transition codes
  - QARD Rev.13 Software is defined as software which will be baselined after the effective date of the next ICN to the Q Software Procedures. There are 16 codes under development



# Legacy Software Retest

- **423 baselined software codes will be used in support of License Application (LA) (as of November 5, 2003)**
  - Those codes baselined prior to January 13, 2003 (Legacy Software) will be retested
  - Retest is for code functionality and consists of software installation and validation tests
  - Retest is governed by procedure:
    - ♦ AP-SI.4Q - Independent Verification and Validation of Legacy Code
- **60 Software codes have been qualified / completed retest (as of November 5, 2003)**
- **19 Codes are in process/undergoing Independent Verification and Validation (IV&V)**

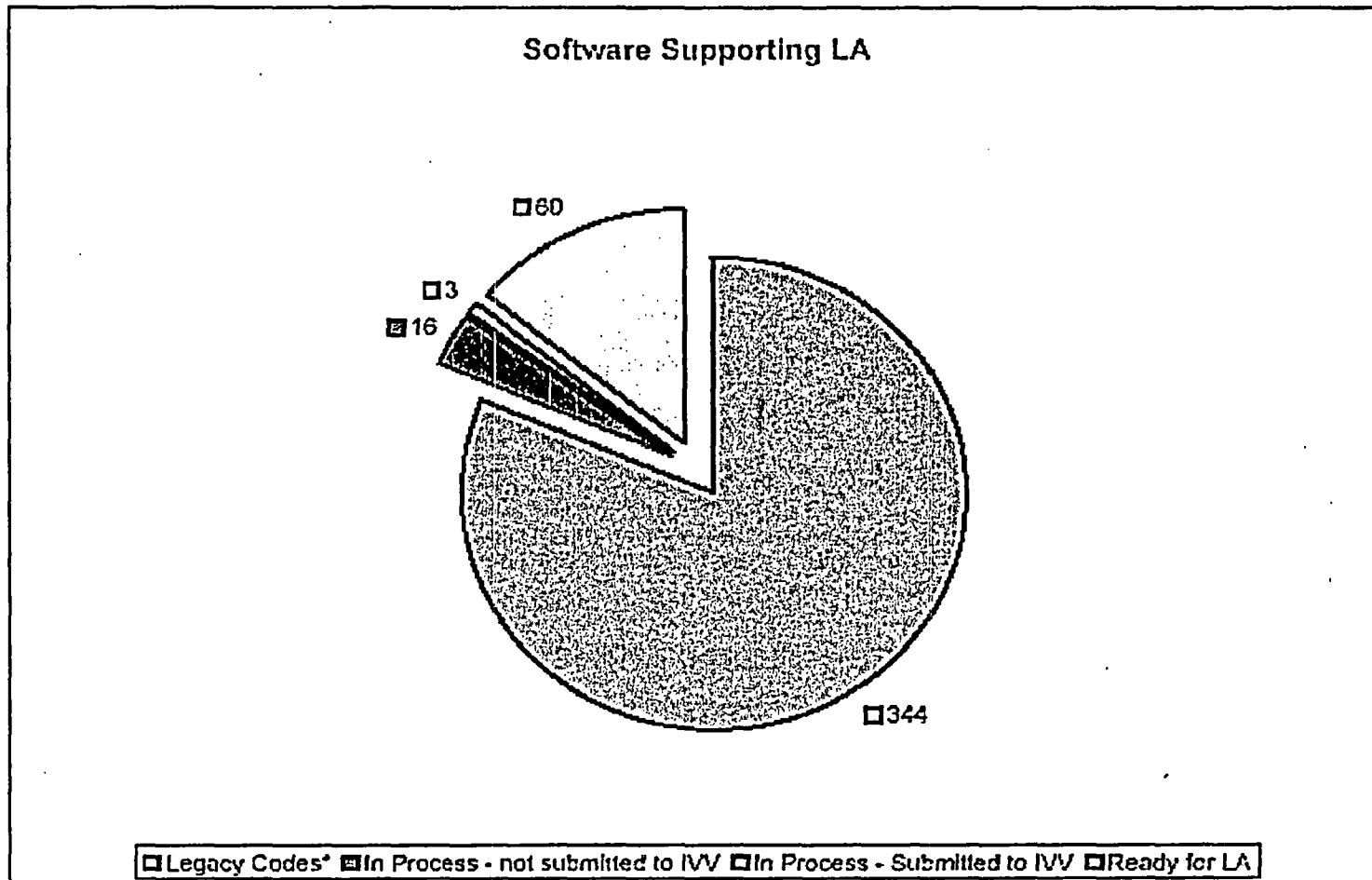




# Metrics

(Counts as of November 5, 2003)

(Continued)



\* The legacy number is subject to change based on changes to the AMR list for LA and discovery of codes qualified in technical products.  
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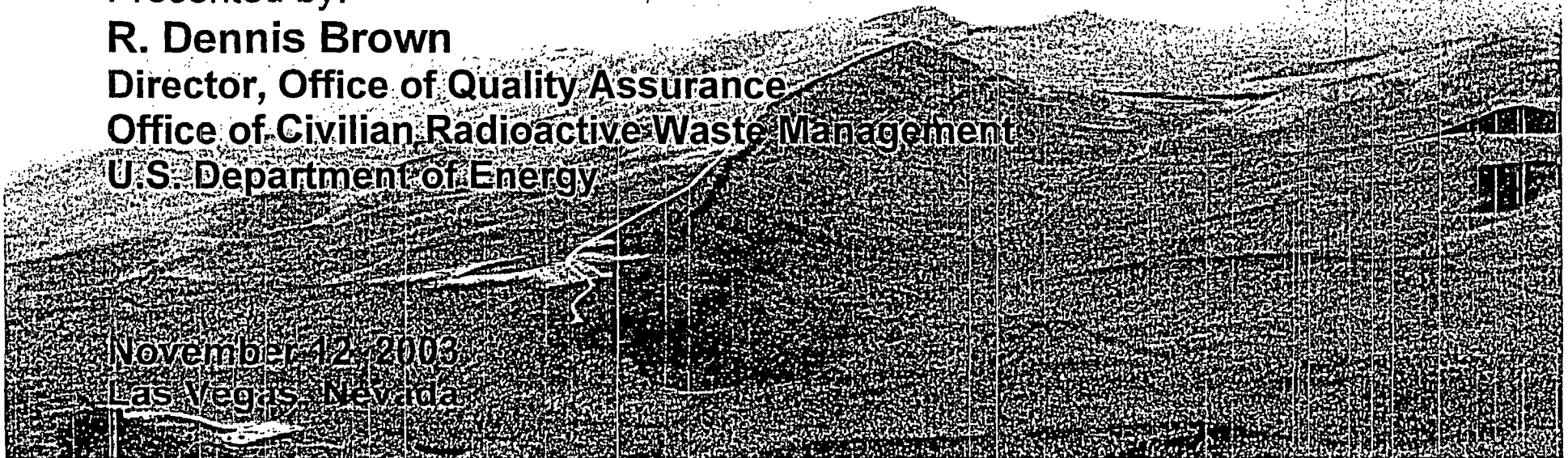


# Software Audit Results (OQAP-BSC-03-07)

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

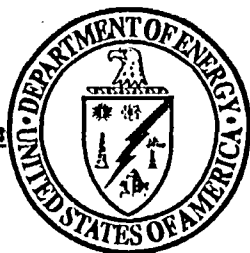
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Las Vegas, Nevada



# **Software Audit Results (OQAP-BSC-03-07)**

- **June 3-13, 2003**
- **Office of Quality Assurance (OQA) audit**
- **Synopsis of results/effectiveness**
  - **Procedures/processes are adequate**
  - **Implementation of procedures was marginally satisfactory**
  - **Processes are marginally effective**
- **Eight Conditions Adverse to Quality (CAQ)**





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# Software Use – Use of Unqualified Software to Generate Preliminary Data Feeds (BSC(B)-03-D-170)

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

November 12, 2003  
Las Vegas, Nevada

# **Use of Unqualified Software to Generate Preliminary Data Feeds (BSC(B)-03-D-170)**

- **Quality Assurance Requirements and Description (QARD) Requirement**
  - QARD, Section I.2.4, “Software shall not be used in activities identified under Section 2.2.2 or 2.2.3 (i.e., quality-affecting activities) of this document unless it is obtained, and limited to received copies, from software configuration management”



# **Use of Unqualified Software to Generate Preliminary Data Feeds (BSC(B)-03-D-170)**

(Continued)

- **Issue**
  - Unqualified software was used to generate preliminary data feeds prior to issuance of the analysis model report (AMR)
- **Path forward**





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# Procedure Implementation (CAR BSC(O)-03-C-097)

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Michael J. Mason**  
Manager of Quality Assurance  
Bechtel SAIC Company, LLC

**November 12, 2003**  
**Las Vegas, Nevada**



# **Status of Corrective Action Report**

## **BSC(O)-03-C-097**

- **Issue - BSC procedure on procedures was not developed in accordance with procedure AP-5.1Q, *Procedure Preparation, Review and Approval***
- **Corrective Actions**
  - AP-5.1Q streamlined
  - AP-5.1Q places more responsibility on line management
  - Rolling Quality Focus Meetings - help to emphasize importance of procedure compliance
  - Subject Matter Experts assigned to each procedure
  - Procedure on procedures - program wide applicability (BSC and DOE)





# **Status of Corrective Action Report**

## **BSC(O)-03-C-097**

(Continued)

- **Verification of corrective action results were satisfactory - July 31, 2003**
- **Lifted Stop Work Order - July 31, 2003**
- **Closed - August 18, 2003**





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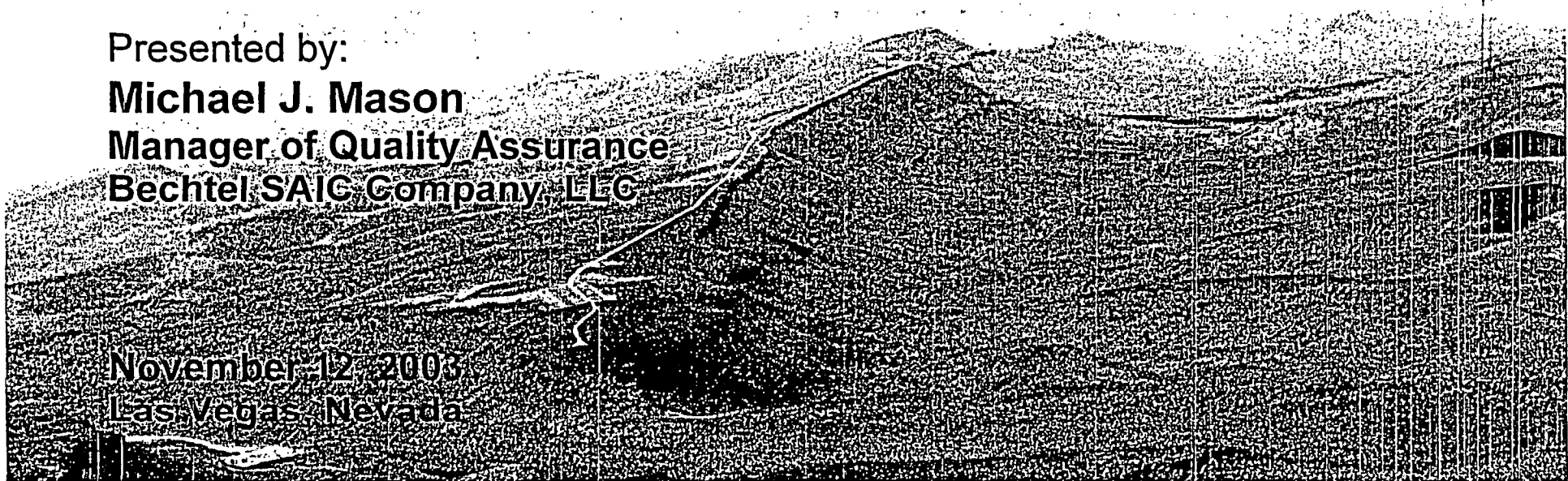


# Training and Qualification (CAR BSC-02-C-001)

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Michael J. Mason**  
Manager of Quality Assurance  
Bechtel SAIC Company, LLC

November 12, 2003  
Las Vegas, Nevada



# **Training and Qualification**

## **(CAR BSC-02-C-001)**

- **Training Requirements Matrix/Job Function not determined and not provided by Training Organization**
  - **No Verification of Education and Experience (VoEE)**
  - **Training requirements not identified to subcontractor personnel**
  - **Corrective Actions are complete**
    - ◆ **Subcontractors now have training assignments, and where needed a VoEE record has been generated**
    - ◆ **Process is in place to ensure that subcontractor personnel receive training**
    - ◆ **Process is in place to ensure documentation of VoEE**
    - ◆ **Closure of associated Deficiency Reports (DRs)**



# **Training and Qualification**

## **(CAR BSC-02-C-001)**

(Continued)

- **Actions and improvements**
  - Over 1200 VoEE record packages reviewed
  - Procedure LP-2.9Q-BSC was developed to establish process for VoEE records
  - A single database of personnel has been developed
  - All VoEE records now flow through a single group in BSC
- **Conclusion**
  - CAR BSC-02-C-001 was closed October 9, 2003





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# Requirements Flowdown (CR-756)

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Michael J. Mason**

**Manager of Quality Assurance**

**Bechtel SAIC Company, LLC**

**November 2, 2003**

**Las Vegas, Nevada**

# Requirements Flowdown (CR-756)

- Initiated October 1, 2003
- Requirement Source - AP-5.1Q, *Procedure Preparation, Review, and Approval*
- Requirement - Procedures shall implement the requirements of the *Quality Assurance Requirements and Description* (QARD) document



# Requirements Flowdown

(CR-756)

(Continued)

- **Issue** - a review of condition reports from Fiscal Years 2002 and 2003 identified a number of instances where QARD requirements did not properly flowdown to implementing documents
  - 12 condition reports
  - 20 procedures affected
- **Status**
  - The issue(s) and corrective action(s) for each Condition Report (CR) identified in CR-756 was evaluated



# **Requirements Flowdown (CR-756)**

(Continued)

- **Conclusions**

- **Does not represent a Significant Condition Adverse to Quality**
- **Flow-down issues identified represented approximately 1 percent of the QARD requirements in procedures reviewed**
- **There is no impact on quality**
- **Additional attention to detail required of reviewing organizations**







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Office of Civilian Radioactive Waste Management



# Audit of EM Sites (CR-97)

Presented to:

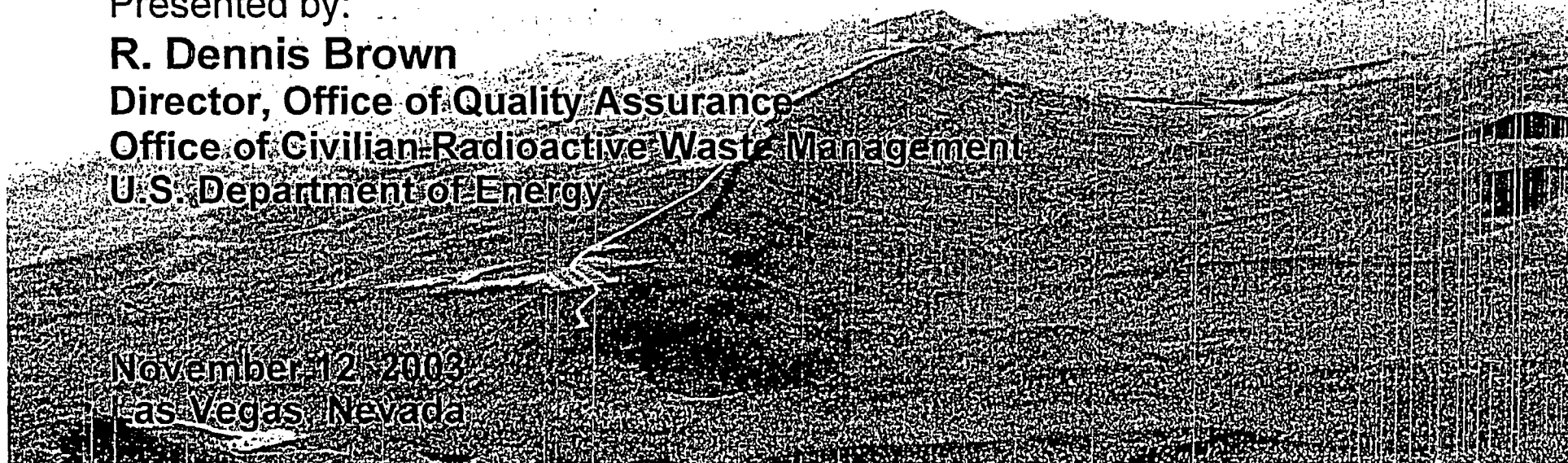
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**R. Dennis Brown**

Director, Office of Quality Assurance  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy

November 12, 2003  
Las Vegas, Nevada



# Audit of EM Sites (CR-97)

- **CR-97 Subject:**
  - Required Office of Civilian Radioactive Waste Management (OCRWM) annual audits of Office of Environmental Management (EM) High-Level Waste (HLW) Activities at Hanford and Savannah River not performed
- **CR-97 Issues:**
  - In the past, OCRWM performed audits of the EM Headquarters (HQ) Quality Assurance Requirements and Description (QARD) Oversight function and EM HQ performed direct oversight of HLW sites



# Audit of EM Sites (CR-97)

(Continued)

- **CR-97 Issues (Continued)**
  - Elimination of the EM HQ QARD Oversight function left OCRWM with no established interface to audit HLW sites
  - Issues identified in DR-EM-01-D-89 contributed to this condition



# Audit of EM Sites (CR-97)

(Continued)

- **DR-EM-01-D-89 Issues:**
  - Documented Interfaces (technical and Quality Assurance (QA)) between OCRWM and EM outdated
  - Deficiency Report (DR) originally issued to EM
  - Subsequent reorganization and policy decisions within EM resulted in the elimination of the EM Headquarters HLW QARD Oversight function



# Audit of EM Sites (CR-97)

(Continued)

- **DR-EM-01-D-89 Issues (Continued):**
  - DR responsibility re-assigned to RW-20E
- **DR-EM-01-D-89 Resolution:**
  - OCRWM and EM have reached Agreement on a path forward for resolution
  - Interfaces will be updated and documented in a joint EM/RW Memo
  - Memo will be supplemented by an oversight procedure



# Audit of EM Sites (CR-97)

(Continued)

- **CR-97 Resolution:**
  - OCRWM oversight activities will re-commence in accordance with the new oversight procedure that is being developed to resolve DR-EM-01-D-89
  - Oversight of waste sites will be performed jointly by EM HQ and OCRWM staff





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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

November 12, 2003  
Las Vegas, Nevada

# Corrective Action Program

- **Noted Improvements**
- **Levels of Significance**
- **External Teams Reviews**
- **Corrective Action Metrics**





# Noted Improvements

- **Single entry point process implemented**
- **Condition Report, Nonconformance Report, Technical Error Report, and Condition/Issue Identification and Reporting/Resolution System processes merged into one process**
- **Open items from merged databases migrated**



# **Noted Improvements**

(Continued)

- **Causal analysis process improved**
  - Procedure revised to apply more rigor to causal analysis process
  - Apparent and root cause training presented
- **Corrective action plan development process improved**
  - Procedure revised to include guidance on corrective action plan development
  - Causal training includes development of corrective action plans



# Level of Significance

- **Level A–Significant Adverse Condition:** An adverse condition involving actual or potential consequence that could have a serious impact on public or personnel health and safety, the environment, facility operations, or quality
- **Level B–Adverse Condition:** An adverse condition such as failure to comply with the technical specifications, licensing commitments, procedures, and regulations. This significance level also includes Nonconforming items and samples



# Level of Significance

(Continued)

- **Level C–Minor Adverse Condition: An adverse condition that involves lesser risk and/or significance**
- **Level D–Opportunity for Improvement: A condition that does not meet the definition of an adverse condition**

# External Teams Reviews

- Performance management assessment (Booz Allen Hamilton, Inc.)
- Quality assurance management assessment (D.L. English Consulting, Inc.)
- ORD management assessment (DOE Office of Independent Oversight and Performance Assurance)



# Corrective Action Program Metrics

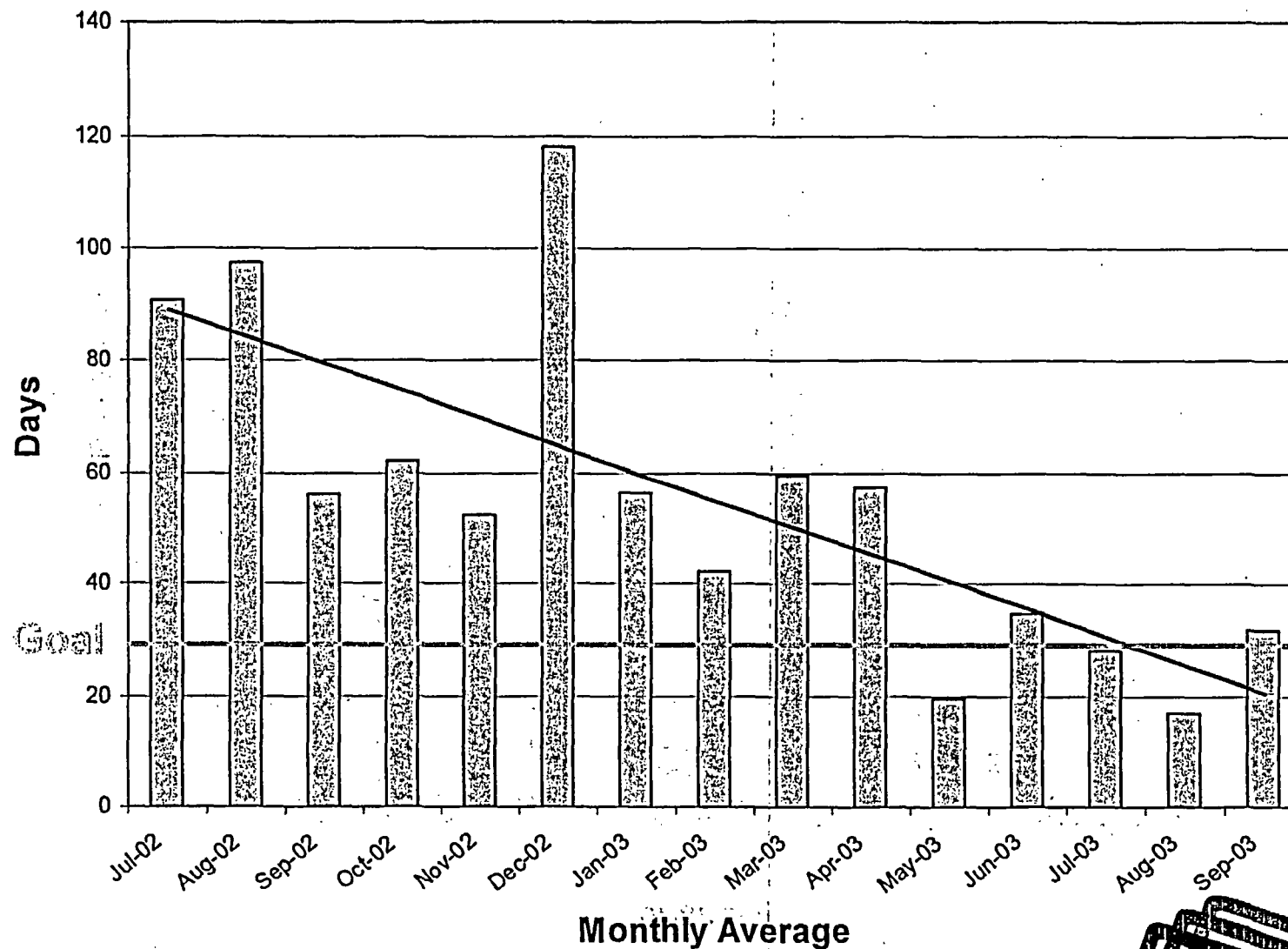
- Several performance indicators developed
- Performance indicators continue to evolve



# Corrective Action Program Metrics

(Continued)

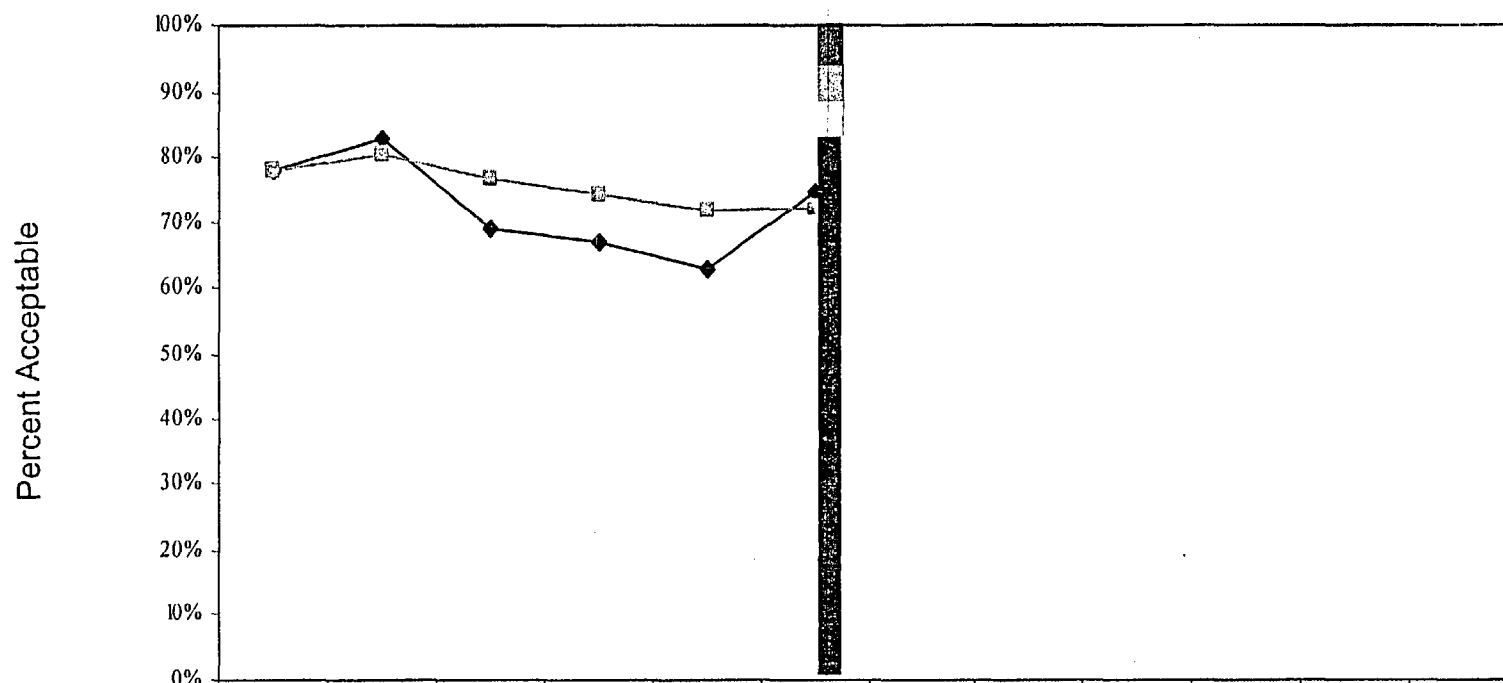
Days to Prepare Acceptable Corrective Action Plan



# Corrective Action Program Metrics

(Continued)

## Acceptable Corrective Action Plans Developed for Level A and B Condition Reports



	April	May	June	July	Aug	Sep	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
◆ Index Score	0.78	0.83	0.69	0.67	0.63	0.75						
■ Six Month Rolling Avg	78.0%	80.5%	76.7%	74.3%	72.0%	72.5%						
% initial CA plans acceptable	0.78	0.83	0.69	0.67	0.63	0.75						

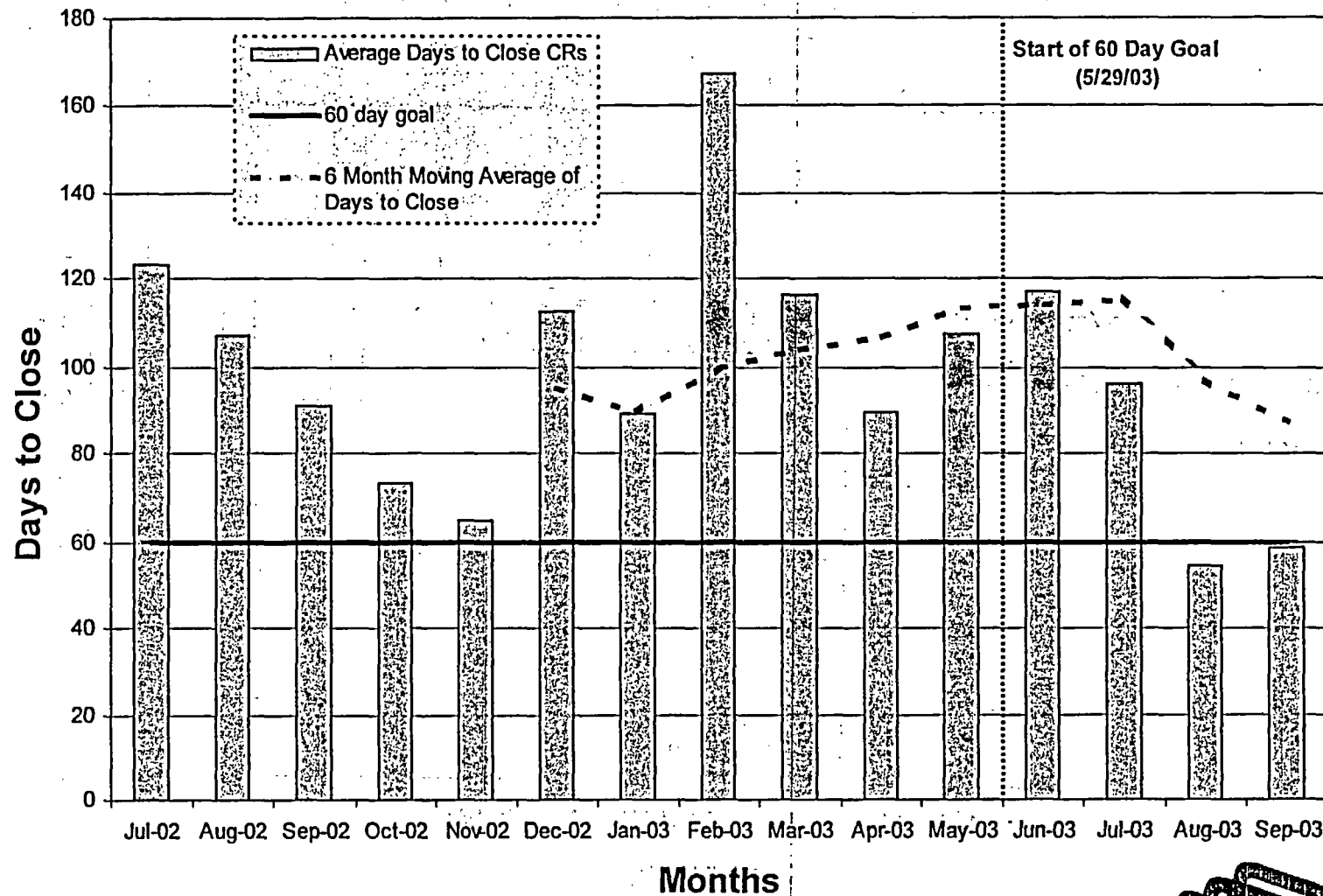




# Corrective Action Program Metrics

(Continued)

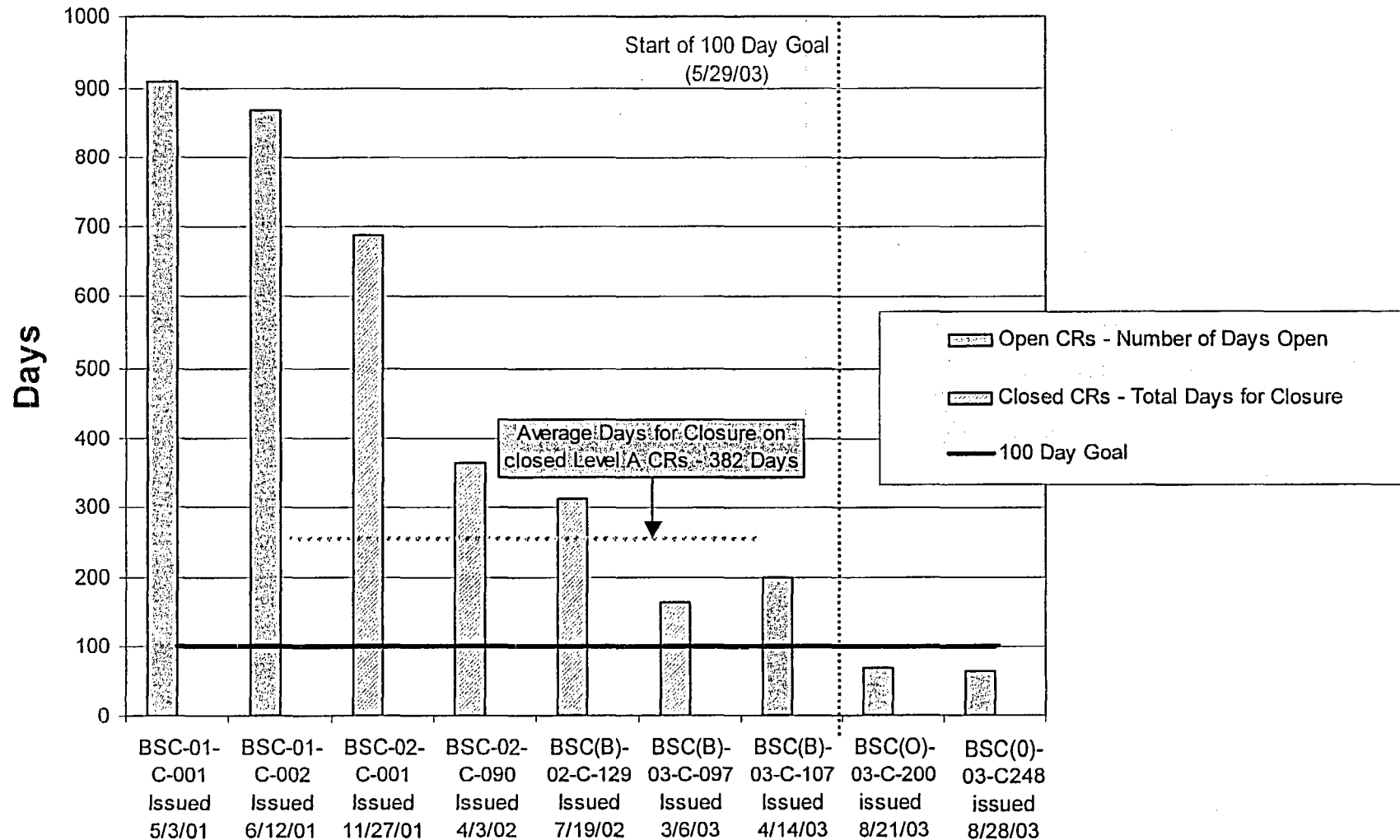
Average Days to close Level B Conditions Reports (CR)



# Corrective Action Program Metrics

(Continued)

## Level A Condition Reports as of 10/30/03



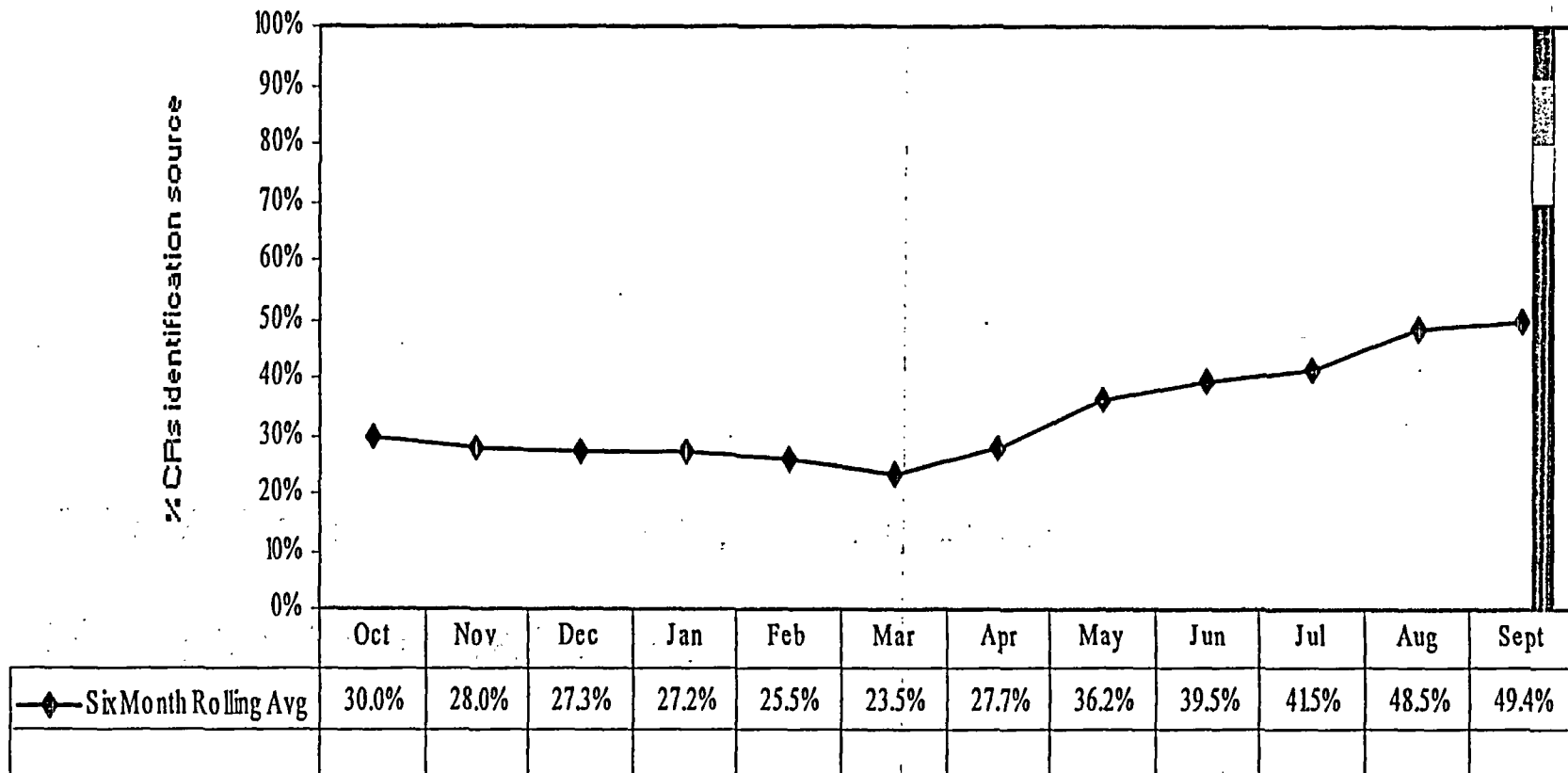
## Significant Condition Reports



# Corrective Action Program Metrics

(Continued)

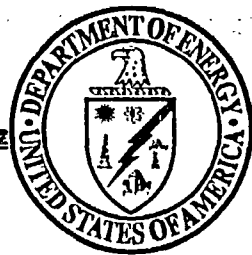
## Adverse Conditions Self-Identified by Line Organization



# Path Forward

- **Monitor effectiveness**
- **Evaluate process enhancements**





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# Performance Indicators

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Michael L. Ulshafer**

Team Lead, Office of Quality Assurance

Office of Civilian Radioactive Waste Management

U.S. Department of Energy

November 14, 2003

Las Vegas, Nevada

# Performance Indicators

- Indicators are quantitative versus subjective
- Indicators under configuration control
- Data available project wide
  - Data feeds are updated monthly



# Performance Indicators

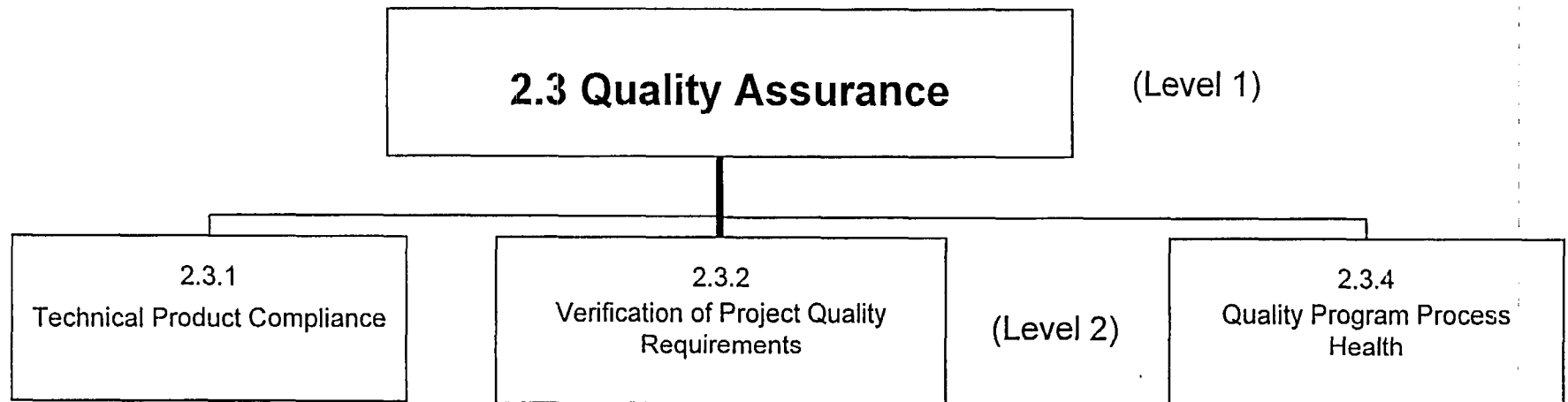
(Continued)

- **Level 1 Performance Indicators**
  - Quality Assurance Program
  - Problem Identification and Resolution
  - Level 1 indicators fed by Level 2 and Level 3 indicators
- **Level 2 and 3 Performance Indicators**
  - Weighted to feed next level up indicator
  - Some are weighted “0” until data can be obtained



# Performance Indicators

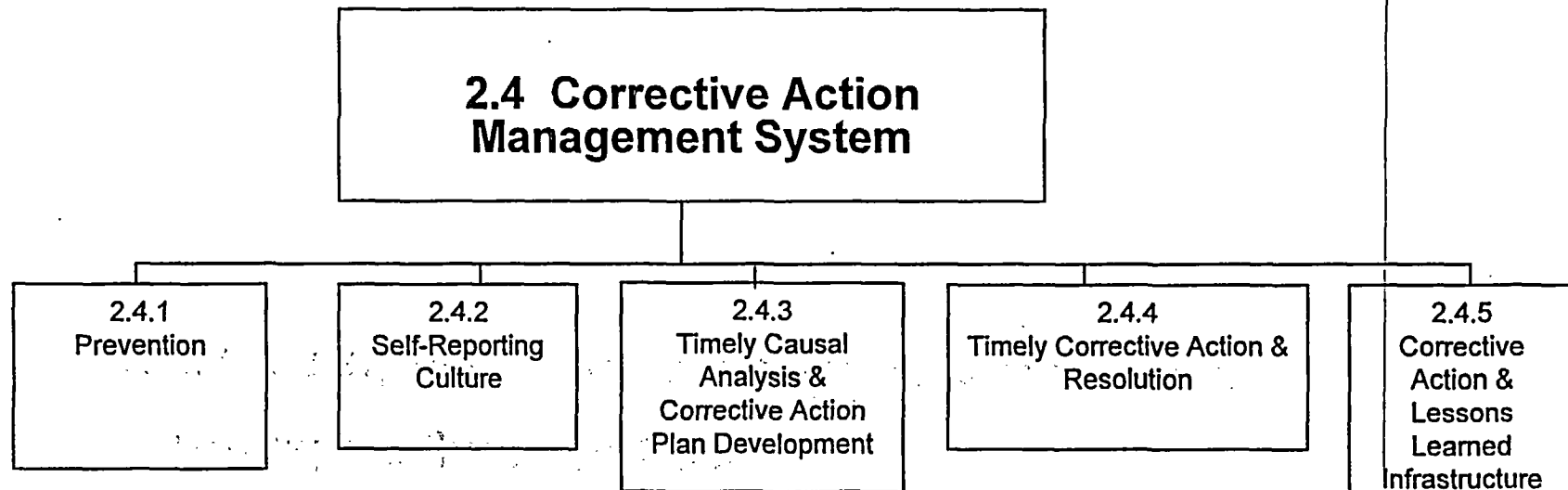
(Continued)





# Performance Indicators

(Continued)



# Performance Indicators

(Continued)

- **Path Forward**
  - **Continue to evolve**
    - ◆ **Add/modify indicators and feeds based on performance**
    - ◆ **Adjust weights and goals**
  - **Identify and respond to levels of performance**





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



# Trending Program Improvements

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Michael J. Mason**  
Manager of Quality Assurance  
Bechtel SAIC Company, LLC

November 2, 2006  
Las Vegas, Nevada

# Trending Program Improvements

- Requirements
- Industry Best Practices
- Trend Process Improvements



# Trending Program Improvements

(Continued)

- **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**

- **Industry Best Practices**

- **Institute of Nuclear Power Operations (INPO) - Information in performance reporting/corrective action systems is periodically assessed for trends needing additional evaluation or corrective action**



# Trending Program Improvements

(Continued)

- **AP-16.3Q Trend Evaluation and Reporting revised, effective September 30, 2003**
  - Process changed to focus on trend evaluation and analysis through resolution of identified adverse trends
  - Uniform cause codes implemented
  - Reporting frequency increased to quarterly
  - New criteria and process for identifying repetitive problems and trends
  - Adverse and emerging trends documented in corrective action system to track associated actions



# Trending Program Improvements

(Continued)

- Improved the causal analysis process based on current commercial nuclear industry best practices
  - AP-16.4Q, *Causal Analysis and Corrective Action Plan Development* completely revised, effective September 30, 2003
  - Developed Causal Analysis Handbook to support the new causal analysis process
  - Improved training on causal analysis to improve cause identification and subsequent coding
  - Improved training on root cause analysis process



# **Trending Program Improvements**

(Continued)

- **Electronic tracking system has improved capability for supporting the trend evaluation process**
- **Trending and analysis performed on a larger population of data (Q and Non-Q) to improve the identification of emerging trends**
- **New software purchased and being deployed to aid real-time identification of emerging trends**
- **Senior Management will be briefed on trend results and recommended actions to address adverse trends**







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# Quality Assurance Requirements and Description

Presented to:  
**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:  
**Michael L. Ulshafer**  
Team Lead, Office of Quality Assurance  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy

November 2003  
Las Vegas, Nevada

# Quality Assurance Requirements and Description

- **Quality Assurance Requirements and Description (QARD) Rev. 13 currently under revision**
  - **Revision 14**
    - ♦ 10 CFR 63, Subpart G, Quality Assurance
    - ♦ NUREG 1804, Yucca Mountain Review Plan
- **Requirements matrices nearly complete**
  - 95 percent complete



# **Quality Assurance Requirements and Description**

(Continued)

- **Path Forward**

- **Formal review/comment cycle - 1st Quarter FY04**
- **Resolve comments - 2nd Quarter FY04**
- **Discussion meetings with NRC - 1st and 2nd Quarters FY04**
- **Approval by DOE - 2nd Quarter FY04**
- **Review/approval by NRC - 2nd Quarter FY04**





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# Results of Compliance Audit of BSC (OQAP-BSC-03-13)

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Carl Weber**

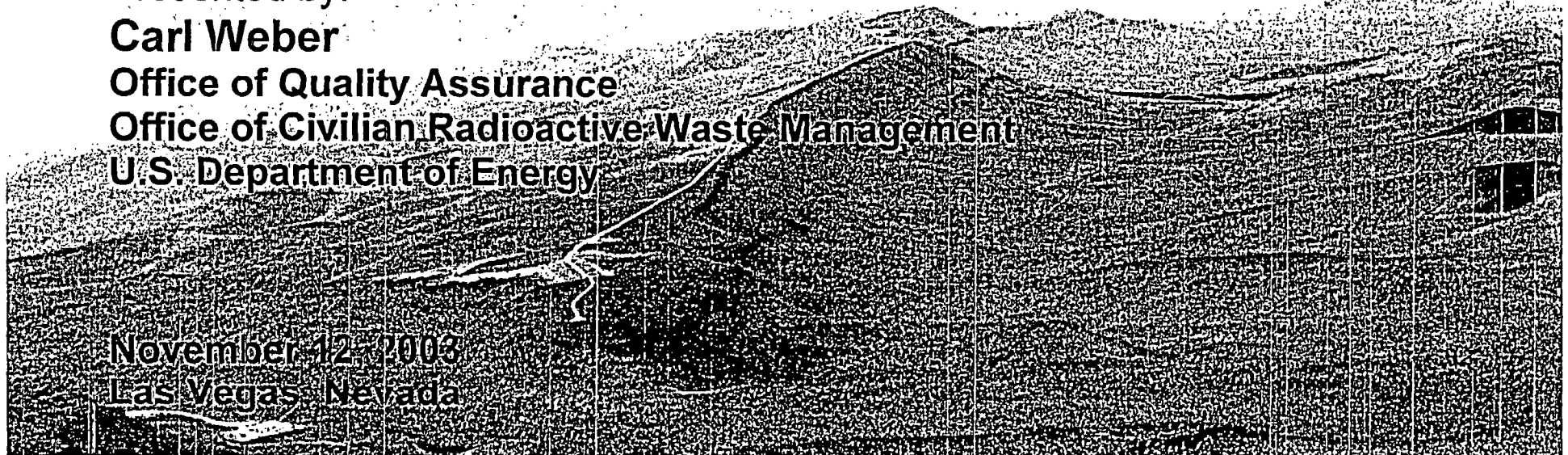
**Office of Quality Assurance**

**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**November 12, 2003**

**Las Vegas, Nevada**



# **Results of Compliance Audit of BSC (OQAP-BSC-03-13)**

(Continued)

- **September 22-26, 2003**
- **Office of Civilian Radioactive Waste Management (OCRWM) Led Audit (Integrated team)**
- **Limited Scope**
  - **BSC Compliance with implementing procedures**
  - **Effectiveness of corrective actions related to closed Deficiency Documents**



# **Results of Compliance Audit of BSC (OQAP-BSC-03-13)**

(Continued)

- **Thirteen Conditions Adverse to Quality (CAQ) identified - Three closed during audit**
- **Two recommendations for process improvement**
- **One best practice associated with a procurement document package**



# **Results of Compliance Audit of BSC (OQAP-BSC-03-13)**

(Continued)

- **Audit team concluded BSC was effective in its implementation of the Quality Assurance (QA) Program**
- **All 13 of the CAQs were considered isolated and/or minor in nature**
- **None of the CAQs appeared to impact technical work**

