



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



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# DOE/NRC Quality Assurance Technical Exchange

**June 26, 2007**  
**Las Vegas, Nevada**



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



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# Building Quality Into the Yucca Mountain License Application

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**Bob Warther**

**Federal LA Project Director**

**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**Las Vegas, NV**

**June 26, 2007**

# Topics

- **Quality Requirements for the LA**
- **Primary Challenges to a High Quality LA**
- **LA Project Organization**
- **Development of the LA**
- **Methods and Metrics to Confirm Quality**
- **DOE OQA Oversight**



# Quality Requirements for the LA

- **LA is complete**
  - Addresses all applicable regulations (Part 63, Part 73, etc.)
  - Addresses all applicable guidance (YMRP, etc.)
  - LA supports NRC's Safety Evaluation Report for construction authorization
- **LA is accurate**
  - Accurately reflects underlying engineering and science products that are prepared in accordance with the QARD





# Integration has been the Biggest Challenge

- **One License Application**
  - Six major organizations
  - Five groups among the six organizations
  - 71 sections to the LA
- **Integrated team approach with all organizations participating**
  - Engineers, scientists and LA authors (~135 team members)
  - Senior Management Team (licensing, science, engineering, NNPP, legal)
- **Weekly LA section meetings with all groups represented**
- **Monthly Integrated Project Team (IPT) meetings**
- **LA integration achieved throughout four-phase development process**

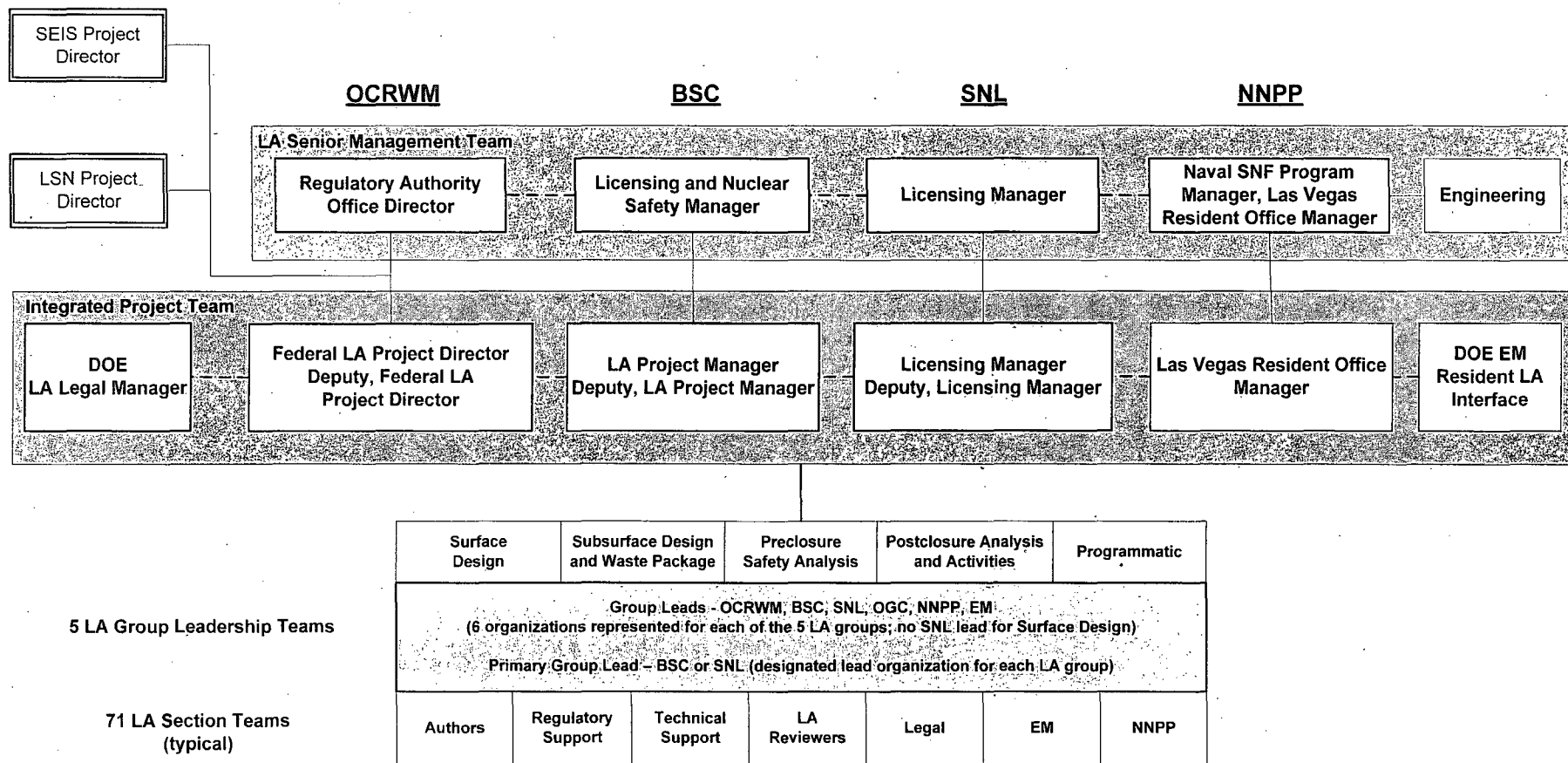


# **Parallel Development of LA and Underlying Design/Science Products**

- **Product Integration achieved throughout four-phase development process**
- **All underlying design/science products identified early in LA planning process**
- **Integrated project schedule identifies products and links to specific LA sections**
- **Proposed changes in design approved by Technical Management Review Board considering impact on LA**



# LA Project Organization



# Organizational Roles and Responsibilities

- **License Applicant: DOE**
- **Design Authority: BSC**
- **Lead LA Integrator: BSC**
- **Lead Laboratory: Sandia National Lab**
- **Support Organizations: DOE-EM and NNPP**





# LA Development Process

- **The OCRWM approach to submitting a high quality LA consists of 3 key elements**
  - **Build quality into the LA development process (3 month planning effort)**
  - **Complete review of LA sections at 4 separate phases to provide confidence that quality is being maintained as the LA matures**
  - **Conduct self assessments, surveillances and independent third party reviews of the LA to provide additional assurance that quality is achieved**



# LA Project Planning Documents

- **Management Plan for Development of the Yucca Mountain License Application**
- **Yucca Mountain Repository License Application Conceptual Design Reports**
  - Surface Design
  - Subsurface Design and Waste Package
  - Preclosure Safety Analysis
  - Postclosure Analysis and Activities
  - Programmatic
- **License Application Performance Baseline**
- **License Application Product Baseline**



# LA Management Plan

- **Establishes LA development process**
  - **Organizational responsibilities and authorities**
  - **LA project management**
  - **LA draft development, review and approval by phase**
  - **Configuration control and integration**
  - **LA assurance reviews (self-assessments)**
  - **Issue resolution and escalation (Licensing Strategy Team)**
  - **Final LA review, validation and production**



# Four-phased LA Development

- **Phases**
  - Storyboard Draft
  - Interim Draft
  - Final Draft
  - Final Validated Section
- **Review and Approval at Each Phase**
  - By all organizations
  - By Senior Management Team



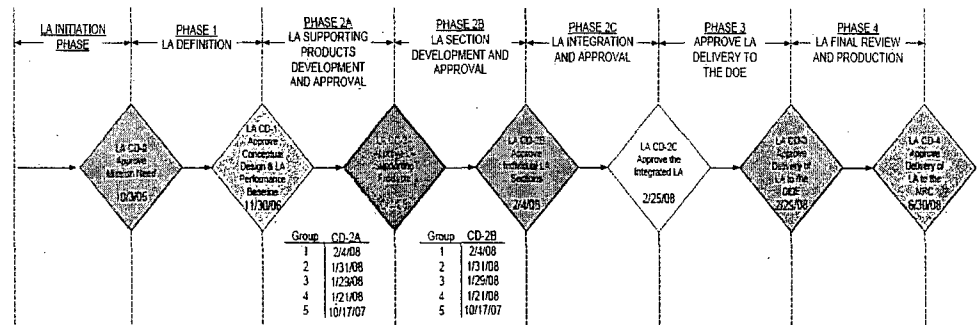


# Management Plan Ensures Compliance with NRC Regulations, Guidance Documents and Expectations

- Regulation and NUREG 1804 compliance crosswalks
- Project Organization charts
- Schedule requirements
- LA development process

16 CFR 21.1 - Content of application and compliance with NRC requirements	LA Section Addressing Requirement	YMW PROJECT TEAM Addressing Requirement	LA SECTION Addressing Requirement
16 CFR 21.1(a) - The application shall contain the following information:			
16 CFR 21.1(b) - The application shall contain the following information:			
16 CFR 21.1(c) - The application shall contain the following information:			
16 CFR 21.1(d) - The application shall contain the following information:			
16 CFR 21.1(e) - The application shall contain the following information:			
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16 CFR 21.1(n) - The application shall contain the following information:			
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16 CFR 21.1(p) - The application shall contain the following information:			
16 CFR 21.1(q) - The application shall contain the following information:			
16 CFR 21.1(r) - The application shall contain the following information:			
16 CFR 21.1(s) - The application shall contain the following information:			
16 CFR 21.1(t) - The application shall contain the following information:			
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16 CFR 21.1(y) - The application shall contain the following information:			
16 CFR 21.1(z) - The application shall contain the following information:			

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# Conceptual Design Reports (CDRs)

- **Establish the Scope and Content of the LA**
  - Group 1 - Surface Design
  - Group 2 - Subsurface Design and Waste Package
  - Group 3 - Preclosure Safety Analysis
  - Group 4 - Postclosure Analysis and Activities
  - Group 5 - Programmatic
- **Each CDR describes (for each LA section)**
  - Regulatory requirements and NRC guidance (YMRP, etc.)
  - Planned content
  - Expected level of detail
  - Supporting products
  - Interfaces within LA



# Monthly Reporting to OCRWM Director and Senior Management

- **Topics Covered**
  - Accomplishments during reporting period
  - Performance to date
  - Critical path
  - Quality summary
  - Key issues
  - Near term milestones (30 day look ahead)
  - Interfaces and data feeds over next 60 days



# Methods and Metrics to Confirm Quality

- **LA quality surveys**
- **LA assurance reviews**
- **Senior nuclear industry consultants integrated into DOE staff**
- **Section team certification for completeness and accuracy**
- **Final validation process at phase 4**
- **Certification by SNL and BSC General Manager at phase 4**





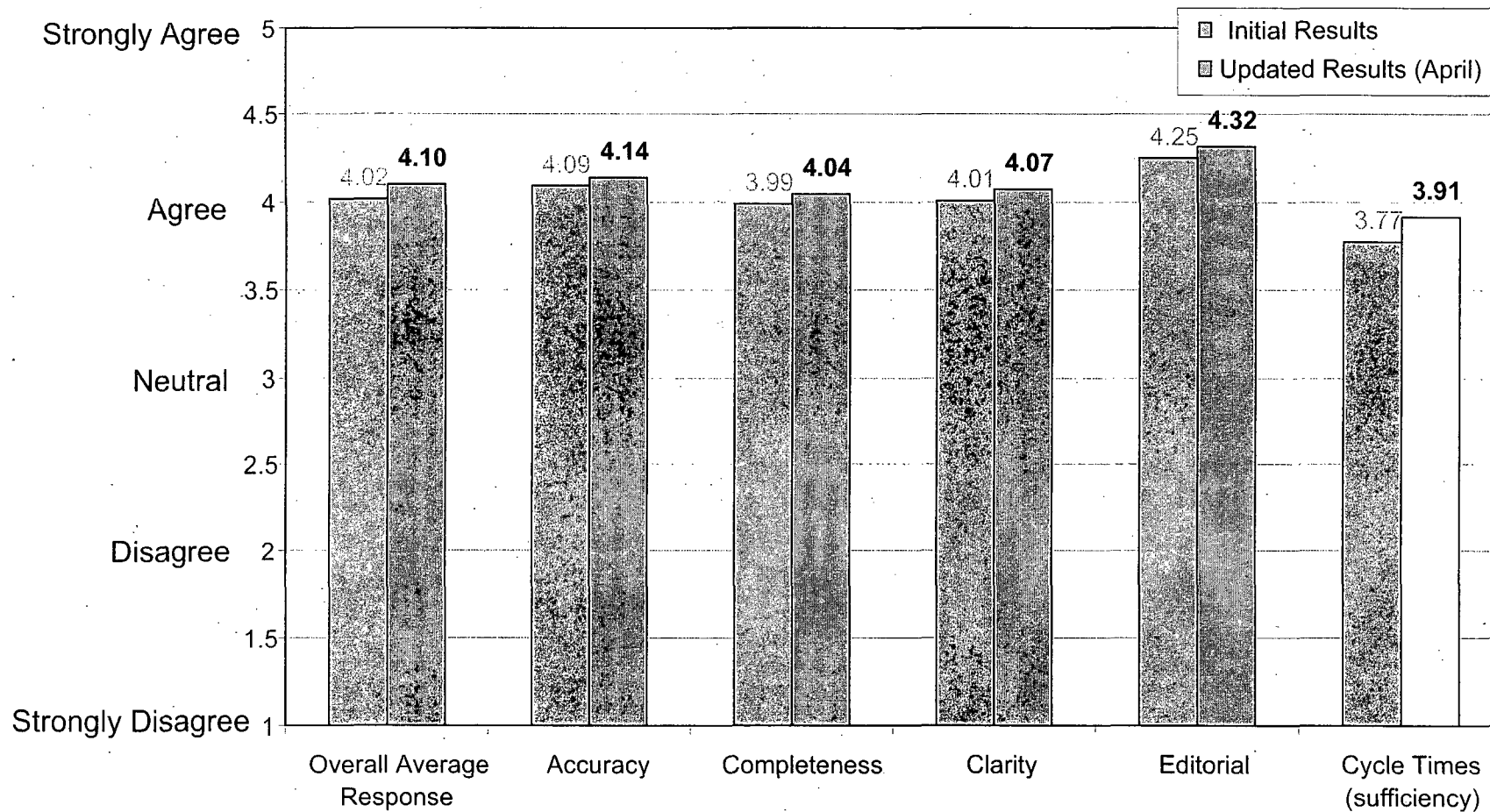
# LA Quality Surveys

- **Quality attributes measured at each phase**
  - Accuracy
  - Completeness
  - Clarity
  - Editorial
  - Cycle times (sufficiency)
- **LA Quality surveys for 34 Interim Drafts and 24 Final Drafts were sent June 5<sup>th</sup> and 6<sup>th</sup>; Surveys closed June 14, 2007**
- **The six-month rolling average of LA Quality Survey responses increased to 4.10 and is reported as "Green"**
- **Interim Draft sections showed modest improvement in quality compared with their Storyboard Draft versions**



# LA Quality Surveys

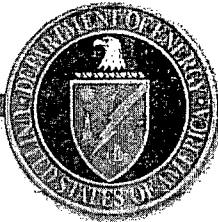
## Quality Survey Responses: Updated Results for Interim Drafts (April)



# LA Quality Assessment Initiatives

- **LA self assessments are ongoing**
- **LA independent review (third party contractor)**
- **Assessing condition reports for potential impact on the LA**
- **Joint QA planning/coordination activities**
  - **Integrated oversight plan of LA Project**
  - **Over 30 surveillances anticipated**





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# Quality Assurance Oversight for the Yucca Mountain License Application

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**Jerry McMahon**

**Project Enhancement Corporation**

**June 26, 2007**

**Las Vegas, Nevada**

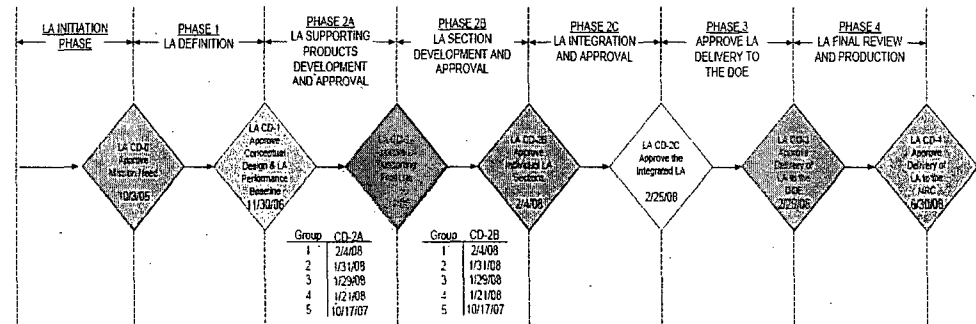


# Management Plan Ensures Compliance with NRC Regulations, Guidance Documents and Expectations

- Regulation and NUREG 1804 compliance crosswalks
- Project Organization charts
- Schedule requirements
- LA development process

10 CFR 62.21 - Content of Application	LA DESIGN	THIRD (THIRD-TEAM) CHARTER/TEAM	LA DESIGN
10 CFR 62.21(a) - General Requirements	10 CFR 62.21(a) - General Requirements	10 CFR 62.21(a) - General Requirements	10 CFR 62.21(a) - General Requirements
10 CFR 62.21(b) - Specific Requirements	10 CFR 62.21(b) - Specific Requirements	10 CFR 62.21(b) - Specific Requirements	10 CFR 62.21(b) - Specific Requirements
10 CFR 62.21(c) - Additional Requirements	10 CFR 62.21(c) - Additional Requirements	10 CFR 62.21(c) - Additional Requirements	10 CFR 62.21(c) - Additional Requirements
10 CFR 62.21(d) - Other Requirements	10 CFR 62.21(d) - Other Requirements	10 CFR 62.21(d) - Other Requirements	10 CFR 62.21(d) - Other Requirements
10 CFR 62.21(e) - Final Requirements	10 CFR 62.21(e) - Final Requirements	10 CFR 62.21(e) - Final Requirements	10 CFR 62.21(e) - Final Requirements

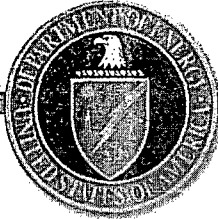
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# Recent Root Cause Analysis Summary / OCRWM Strategic Objective: Organizational Development

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**Richard L. Craun**

**Senior Policy Advisor**

**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**June 26, 2007**

**Las Vegas, NV**

# Recent Performance Indications

- **Self-assessments, audits, and surveillances performed by the OCRWM and oversight by external agencies GAO, DOE Office of Inspector General (OIG) and NRC during 2005 and 2006 indicated multiple performance effectiveness issues**
- **The Nuclear Energy Institute (NEI) was invited to visit OCRWM to assess the effectiveness of the OCRWM Quality Assurance Program**
- **The NEI Team concluded that elements of the program were not effectively implemented**

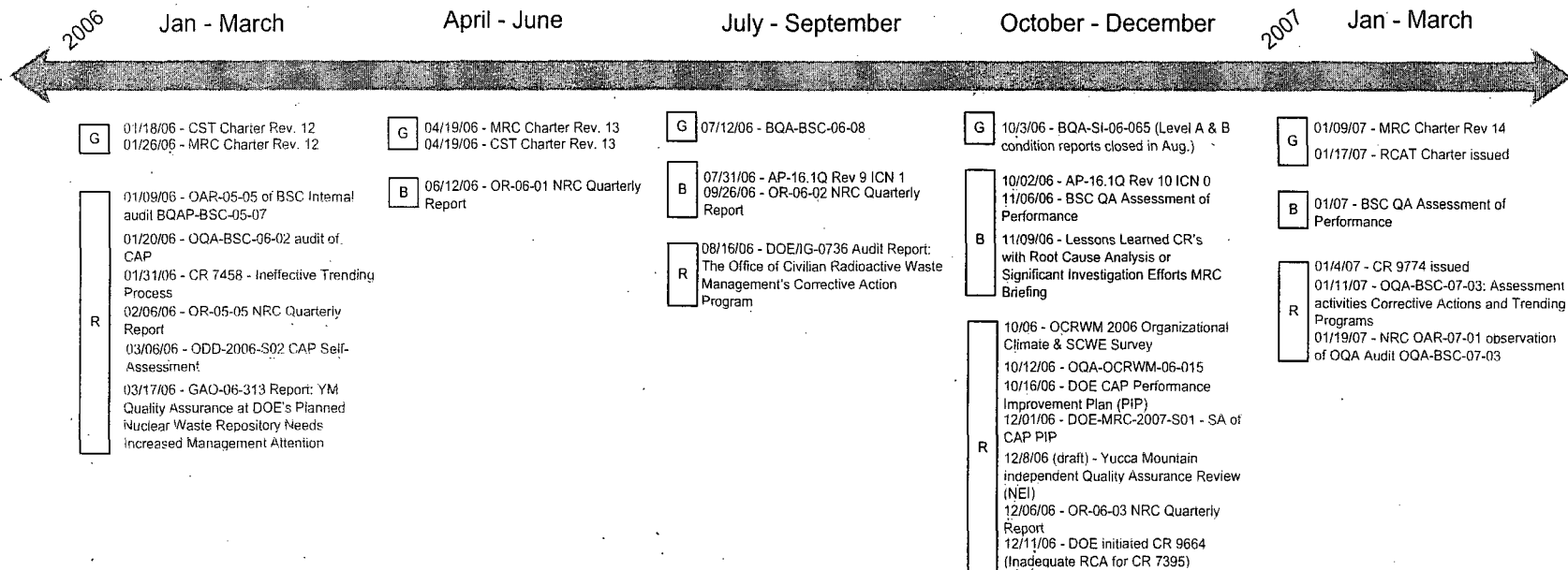


# NEI Report Summary

- **The focus of the assessment was excellence in the Quality Assurance Program**
- **Using industry standard of excellence the NEI team concluded:**
  - **The YMP QA Program meets requirements**
  - **Progress is being made to improve the overall QA performance**
  - **Improvements needed in a number of areas to achieve the goal of excellence**



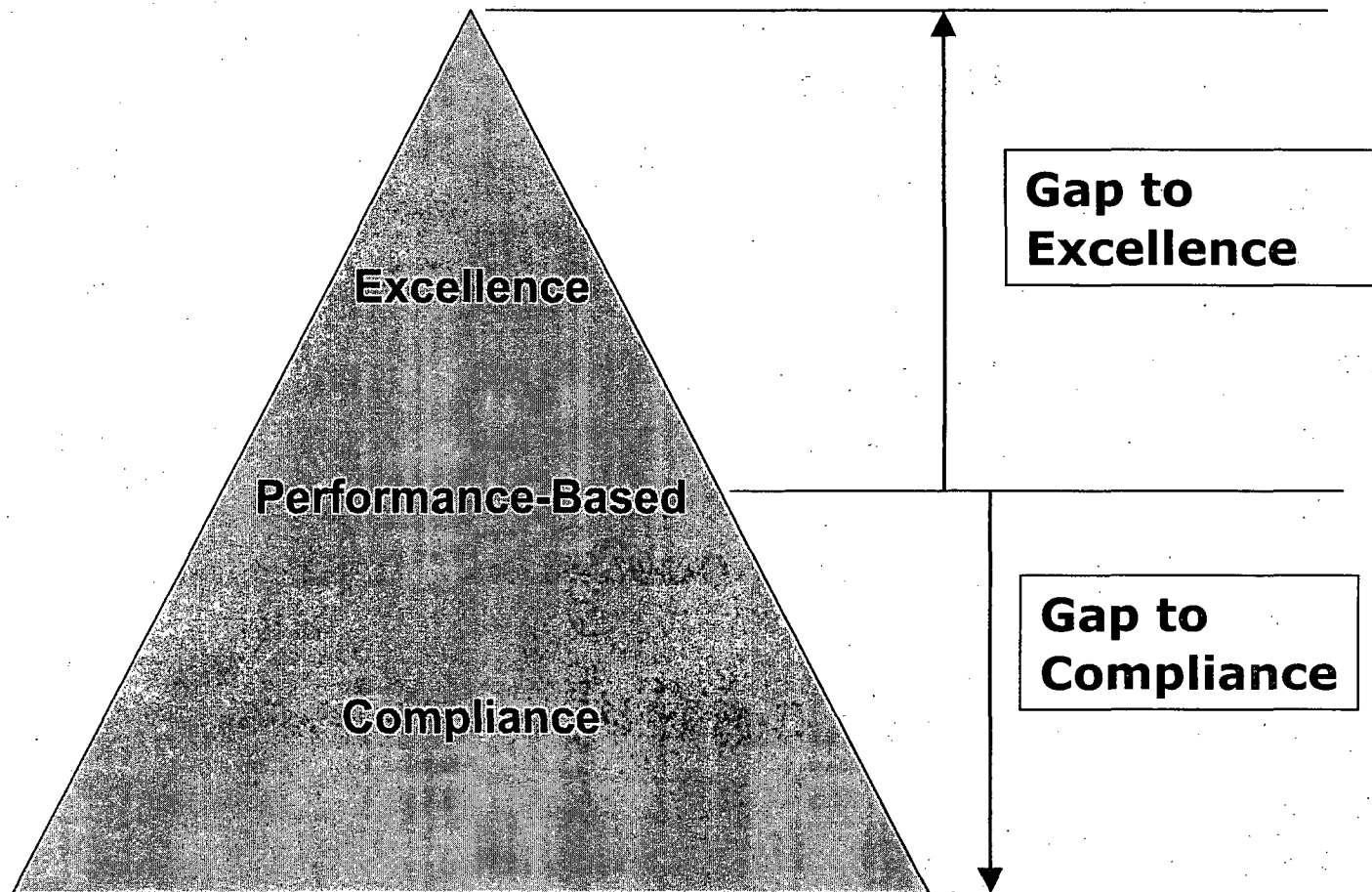
# Information Time Line Corrective Action Program



- (G) Change to the CAP Process (procedure, software, etc.) or CAP and/or Trending was assessed to be effective, satisfactory or no significant issues were identified
- (B) Change to the CAP Process (procedure, software, etc.) was reversed or Assessment of CAP and/or Trending identified multiple issues
- (R) CAP and/or Trending was assessed to be ineffective



# Continuous Improvement Strategy



# Underlying Causes for Excellence Gap

- **OCRWM senior management failed to establish and hold the OCRWM organization accountable for meeting quality expectations with regard to the infiltration products**
- **OCRWM senior management failed to consistently exercise leadership by establishing expectations and standards for CAP performance and enforcing them as a core business activity for all project personnel**
- **OCRWM senior management, as a team, has not demonstrated the skill, knowledge, aptitude, and experience necessary of leadership to establish expectations, standards, and culture for Self-Assessment Program (SAP) performance and enforce SAP as a core business continuous improvement activity for all Program personnel**





# Contributing Causes for Excellence Gap

- OCRWM did not fully implement quality assurance requirements (and culture) with line management
- Lack of effective barriers contributed to the lack of recognition by management of the ineffective performance
- Significant unresolved issues identified by internal and external assessments have been tolerated by management
- The organizations' self-assessments for continuous improvement are not self critical
- Line management does not effectively utilize CAP to drive continuous improvement and does not demonstrate ownership and follow-through necessary to resolve issues and prevent recurrence
- Authority and accountability for CAP effectiveness have not been either clearly defined or effectively enforced
- DOE has not provided a central vision to implement a self-critical culture focused on excellence rather than compliance
- Senior management team does not model appropriate behaviors that indicate that Self-Assessment is a core business process
- Lack of OQA oversight to drive performance





# Recommended Corrective Actions

- **Create Vision** (*Based on Industry*)
- **Set Expectations** (*Individual and Organizational*)
- **Communications** (*Buy in from all OCRWM Personnel*)
- **Mentoring** (*Ensure Management Behaviors*)
- **Measuring** (*Measure Effectiveness*)
- **Complete the Quality Improvement Plan**



# Initial Review Results CR-10141

- **The Root Cause Analysis (RCA) investigation did not discover evidence or information that differed significantly from that documented by the previous recent RCA reports**
- **Based on the investigation, the RCA team concluded that it was unlikely to identify further substantive evidence or to arrive at conclusions that differed from previous recent RCAs and assessments**
- **The team could provide more value by analyzing the consolidated evidence, conclusions and recommended corrective actions from the previous RCAs to assess completeness**



# Extent of Cause & Condition

- **The extent of cause is that management behaviors actively impede the effectiveness of the Quality Assurance, Corrective Action, and Self Assessment programs and thus the achievement of performance excellence**
- **The extent of condition affects other OCRWM processes and procedures**
- **The causes and conditions identified are potentially present throughout OCRWM**



# **Recommended Corrective Actions CR-10141 (Summary)**

- **The OCRWM Director commission a group of senior managers to develop a comprehensive "Nuclear Quality Culture and Quality Implementation Change Management Plan"**
- **The OCRWM Director identify and charter a senior management team to oversee and ensure accountability for implementation of the plan, as noted above**
- **The OCRWM Director initiate a mentor program for select senior managers (Engineering, Science, and Licensing) for DOE, BSC, and SNL**



# Conclusions from CR-10141

- **The Root Cause Analysis team concluded that the Condition Reports shared a common cause:**
  - **Senior management has consistently failed to exercise leadership by not establishing a nuclear quality culture to drive performance excellence**
  - **Senior management has attempted to address this chronic weakness through several previous improvement initiatives**
  - **The RCAT was unable to conclude that the senior management team had a consistent position on the need for urgent change**



# Organization Development

- **To design, staff, and train the OCRWM Organization such that it has the skills and culture needed to design, license, and manage the construction and operation of the Yucca Mountain Project with safety, quality, and cost effectiveness**



# Organization Development Plan Elements (underdevelopment)

- **Business Process Improvement**
- **Human Capital (skills/competencies)**
- **Structure (organization)**
- **Performance (individual and organizational)**
- **Leadership/Culture (current and sustaining)**



# Summary

- **Organizational Development action plan is under development**
- **The recommended actions from the discussed root cause analyses and the Quality Improvement Plan will be integrated into this plan**
- **The corrective actions are progressing**







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Office of Civilian Radioactive Waste Management



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# Quality Improvement Plan 2007

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**Michael Ulshafer**

**Office of Quality Assurance**

**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**Las Vegas, NV**

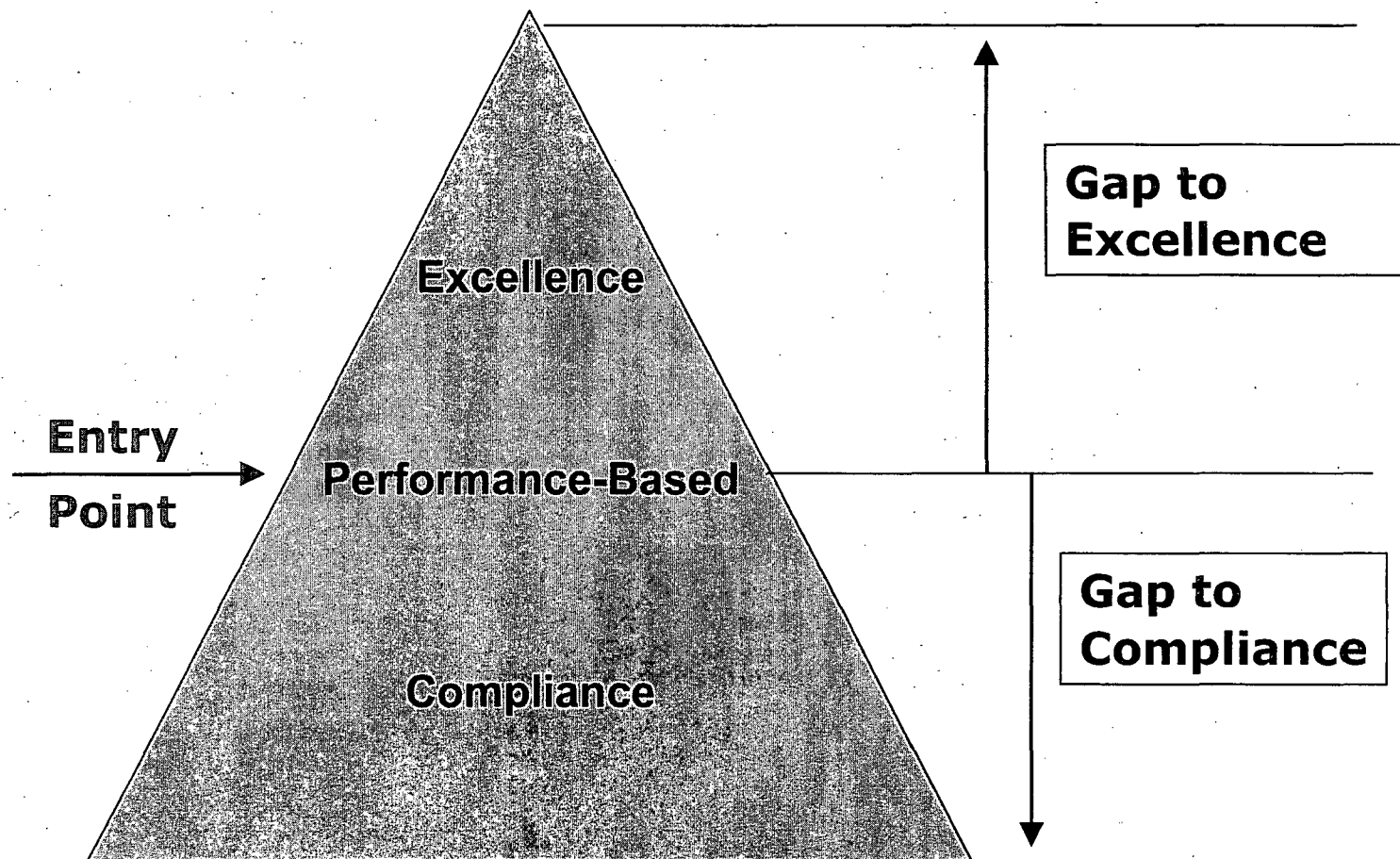
**June 26, 2007**

# Background

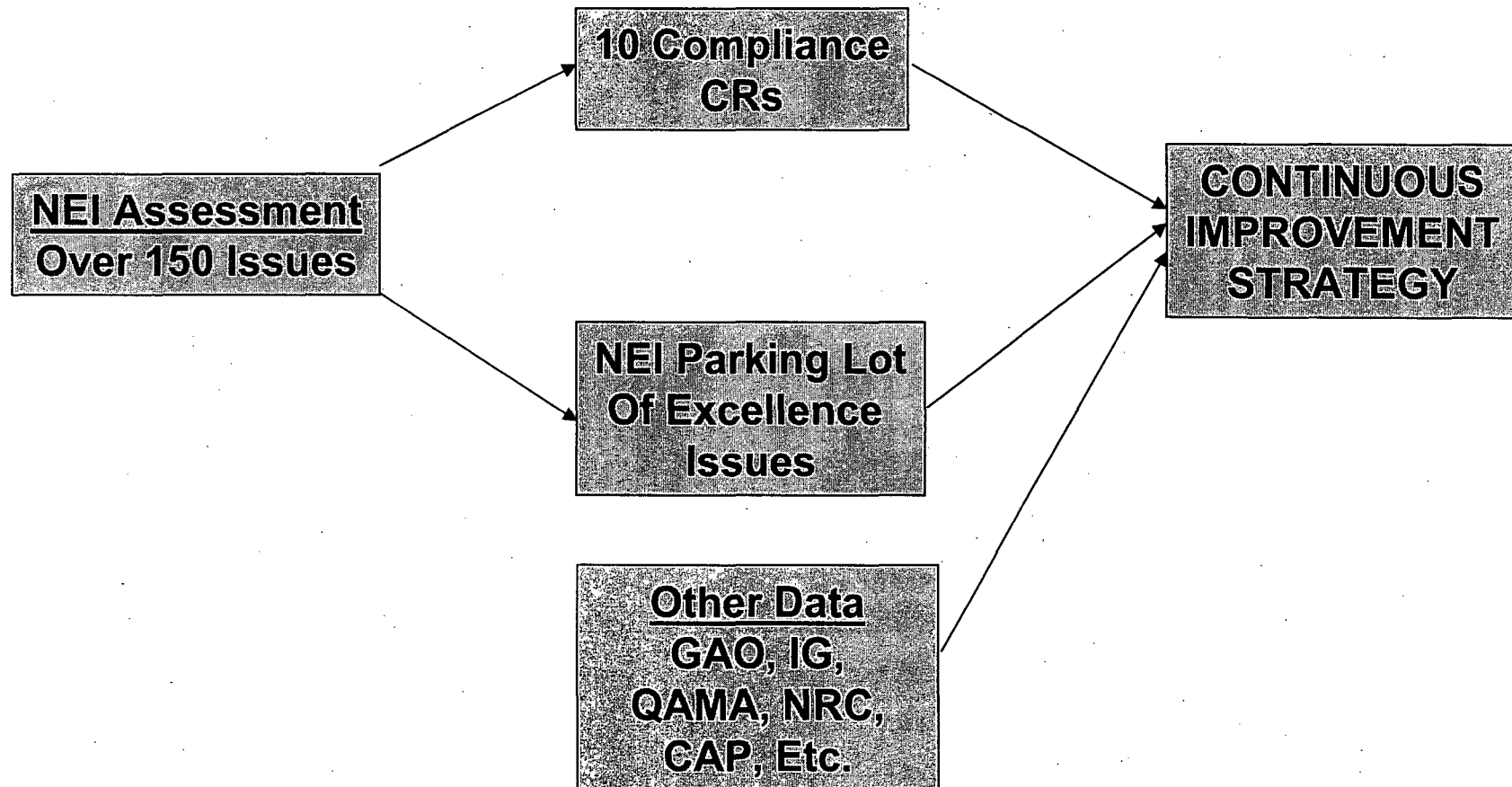
- **December 2006 five experienced nuclear utility QA managers performed an assessment of OQA against excellence criteria used by industry**
- **Issued report on March 1, 2007**



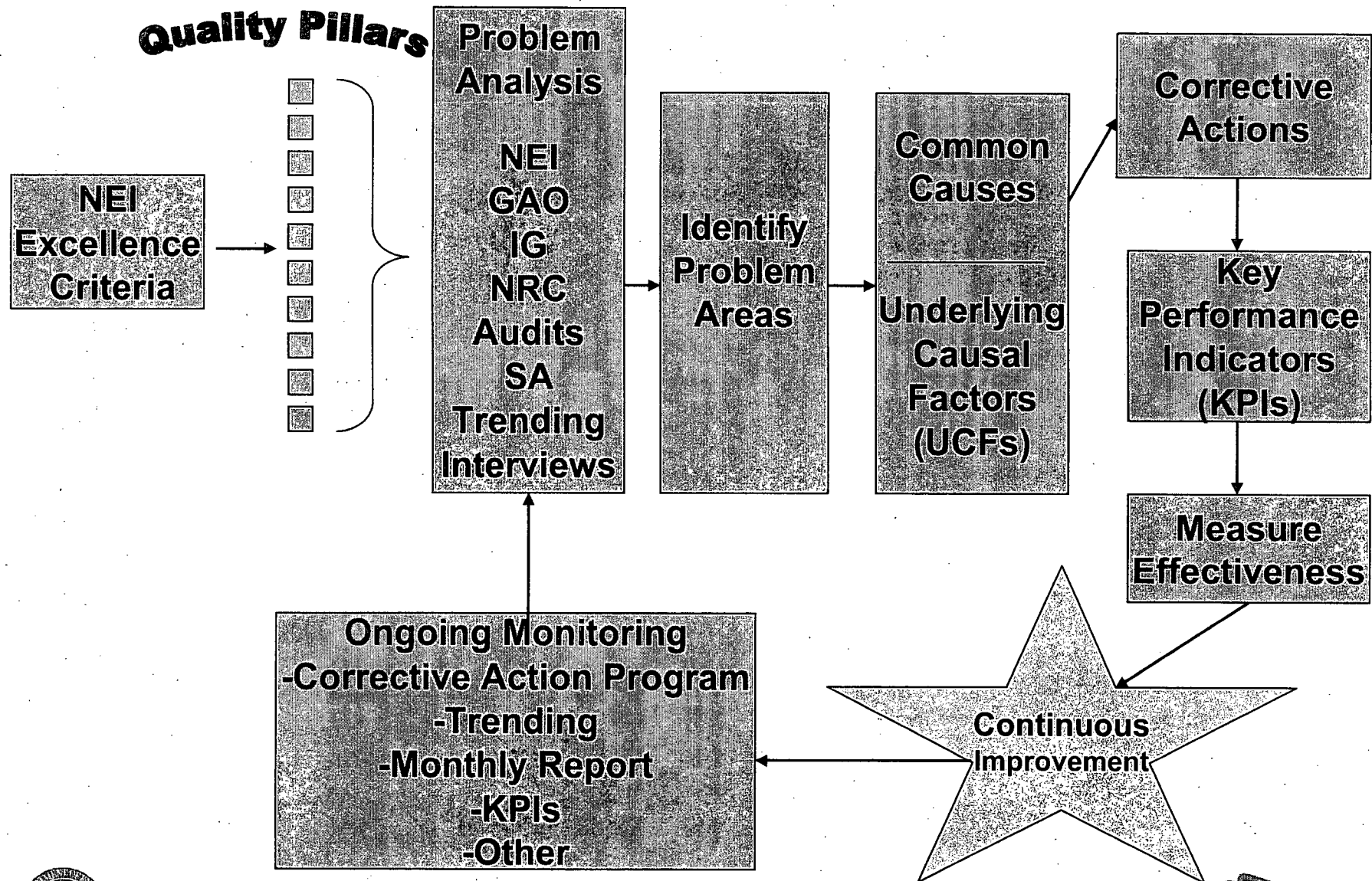
# Continuous Improvement Strategy



# Source of Input to the Quality Improvement Plan

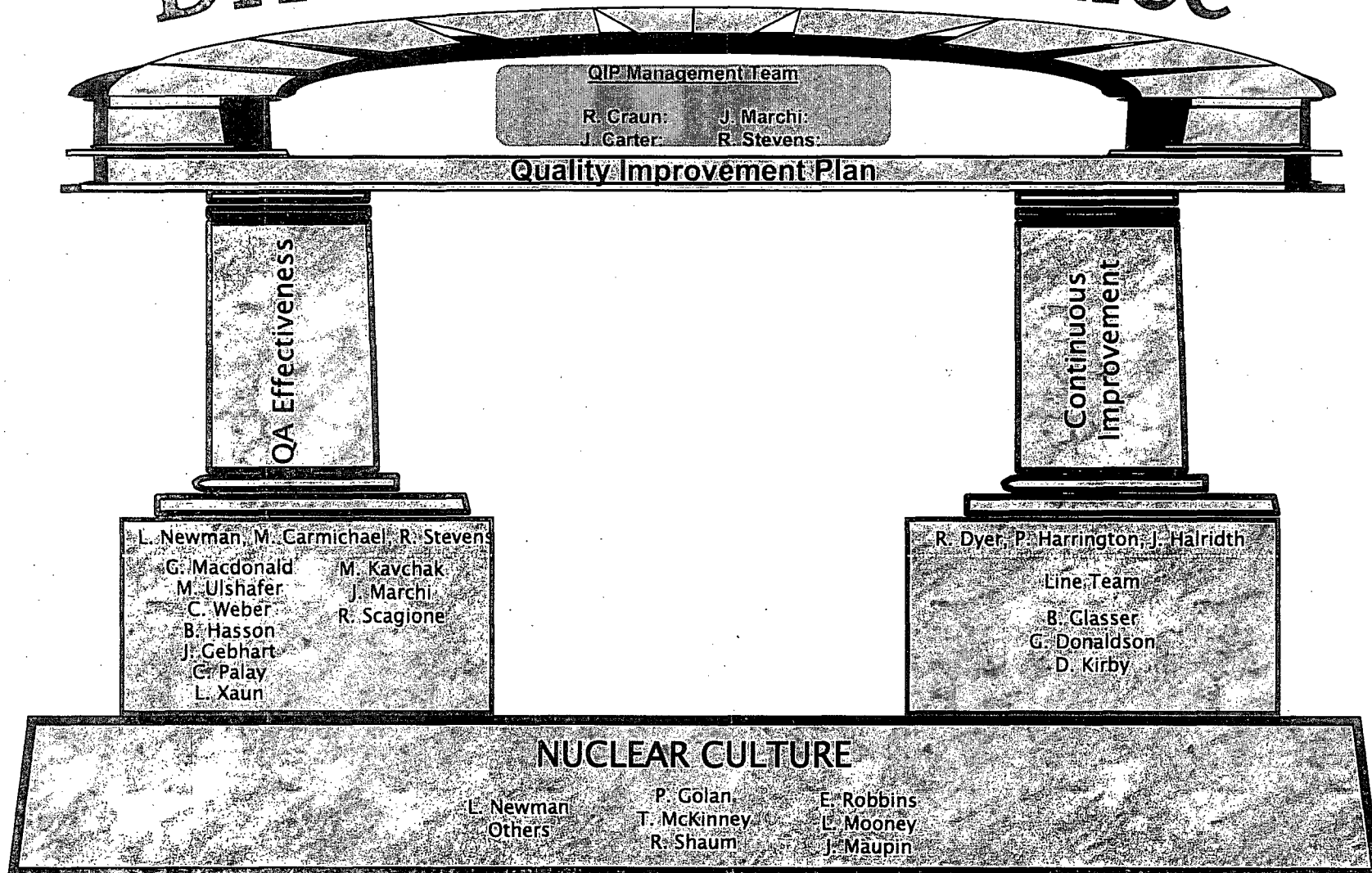


# Continuous Improvement Strategy





# Drivers of Excellence





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Office of Civilian Radioactive Waste Management

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# Line Ownership of Quality – Science for the License Application

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**J. Russell Dyer, Director**

**Office of the Chief Scientist**

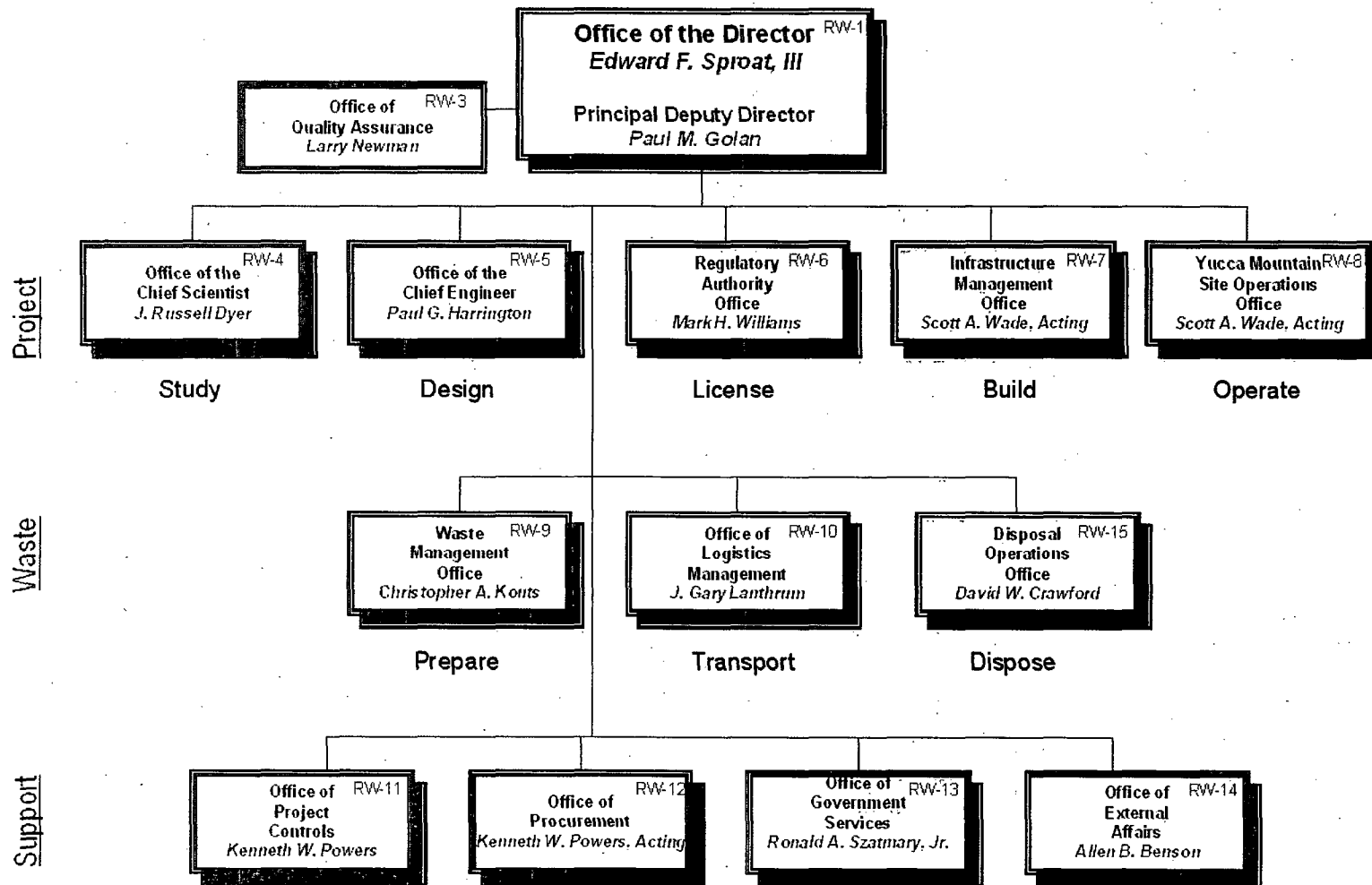
**Office of Civilian Radioactive Waste Management**

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**June 26, 2007**

**Las Vegas, NV**

# OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT



6/11/2007



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# **Office of the Chief Scientist (OCS)**

## **ROLES AND RESPONSIBILITIES**

### **(Partial)**

- **Ensure technical and regulatory adequacy of postclosure safety assessment and performance confirmation results**
- **Defend technical and regulatory adequacy of performance assessment and performance confirmation results and criteria in licensing proceedings**



# Overview of Work

- **Review and Acceptance of Work Plans**
  - All Postclosure Technical Work Plans are Deliverables
- **Review and Acceptance of Analysis and Model reports**
  - All AMRs are Deliverables
- **Corrective Action program**
  - Participate in CAP Screen Team
  - DOE owned Condition Reports
  - Oversight of Contractor CRs
- **Self Assessments**
- **Support and Participate in Audits and Surveillances**
- **External Review**
- **Review of LA Chapters**
  - Technical Quality
  - Transparency
  - Traceability



# **Review and Acceptance of Deliverables – Deliverable Acceptance Criteria (from LP-7.5Q-OCRWM)**

- **Have all Condition Reports that could adversely impact the quality of the deliverable been closed?**
- **Does the deliverable comply with the criteria documented in the Multi-Year Plan?**
- **Does the deliverable address all appropriate source document requirements?**
- **Does the deliverable contain the appropriate level of detail?**
- **Has the contractor provided objective evidence that the contractor has verified that the deliverable conforms to applicable OCRWM requirements as stated in the appropriate procurement document and Deliverable Definition Sheet?**



# **Review and Acceptance of Deliverables – Deliverable Acceptance Criteria (from LP-7.5Q-OCRWM)**

(Continued)

- **Access OQA and contractor audit and surveillance reports relating to the activities associated with the development and contents of the deliverable to determine if any problem areas were identified, and what, if any, adverse impact they may have on the acceptability of the deliverable**
- **Verify all CRs associated with the deliverable are closed, and have no impact on the acceptability of the deliverable**



# Audits and Surveillances

- **Lead Lab Readiness Review - 9/06**
- **Audits and Surveillances**
  - **OQA**
    - ♦ Internal Audits FY07 – 3 complete, 3 in progress, 1 planned
    - ♦ Surveillances FY07 – 4 complete, 3 planned
  - **BSC**
    - ♦ Internal Audits FY 07 – 1 complete
    - ♦ Surveillances FY07 – 5 complete, 1 scheduled
  - **SNL**
    - ♦ Internal Audits FY07 – 1 complete, 2 planned
    - ♦ Surveillances FY07 – 11 complete, 6 in process, 4 planned



# Review of LA Chapters

## Postclosure LA Project Team

LA Section	Section Title
<b>Group #4</b>	<b>POSTCLOSURE ANALYSIS AND ACTIVITIES</b>
GI-05.00	Site Characterization
SAR-02.00	Repository Safety After Permanent Closure
SAR-02.01	System Description and Demonstration of Multiple Barriers
SAR-02.02	Scenario Analysis and Event Probability
SAR-02.03	Model Abstraction
SAR-02.03.01	Climate and Infiltration
SAR-02.03.02	Unsaturated Zone Flow
SAR-02.03.03	Water Seeping into Drifts
SAR-02.03.04	Mechanical Degradation of the Engineered Barrier System
SAR-02.03.05	In-Drift Physical and Chemical Environment



# Review of LA Chapters

## Postclosure LA Project Team (Continued)

<b>Group #4</b>	<b>POSTCLOSURE ANALYSIS AND ACTIVITIES</b>
<b>SAR-02.03.06</b>	<b>Waste Package and Drip Shield Corrosion</b>
<b>SAR-02.03.07</b>	<b>Waste Form Degradation and Mobilization and Engineered Barrier System Flow and Transport</b>
<b>SAR-02.03.08</b>	<b>Radionuclide Transport in Unsaturated Zone</b>
<b>SAR-02.03.09</b>	<b>Saturated Zone Flow and Transport</b>
<b>SAR-02.03.10</b>	<b>Biosphere Transport and Exposure</b>
<b>SAR-02.03.11</b>	<b>Igneous Activity</b>
<b>SAR-02.04</b>	<b>Demonstration of Compliance with the Postclosure Public Health and Environmental Standards</b>
<b>SAR-04.00</b>	<b>Performance Confirmation Program</b>



# **Corrective Action Program Open OCS Owned Level A CRs**

- **Level A**
  - **Potential Noncompliance with Qualification Requirements (USGS issues)**
  - **27 Actions spread across four organizations**
    - ♦ **DOE, BSC, SNL/LL, U.S. Geological Survey**





# Instilling Personal Accountability

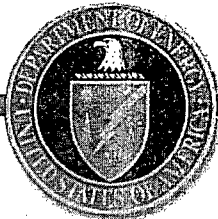
- **Federal staff performance standards emphasize quality**
  - Performance standards include separate elements on
    - ♦ Promote Licensing Culture
    - ♦ Implementation of QA Program
  - Quality, accountability, and continuous improvement metrics incorporated into performance appraisal elements
- **Federal staff review all deliverables and advise Director on appropriate action (accept, accept with conditions, reject)**
- **Federal staff sign off on LA section content**



# Summary

- **Accomplishments**
  - **Emphasis on Corrective Action Program**
  - **Emphasis on line ownership of technical quality, traceability, and transparency of products**
  - **Established quality as a standard for performance**
- **Ongoing activities to ensure quality**
  - **Incorporating results of audits, surveillances and external reviews into final work products**
  - **Ongoing review/acceptance of LA supporting products**
  - **Ongoing review of LA as it is developed to ensure quality**





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# Line Ownership of Quality – Engineering and Preclosure Safety Analysis for the License Application

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**Kirk Lachman**

**Engineering Design Group Supervisor**

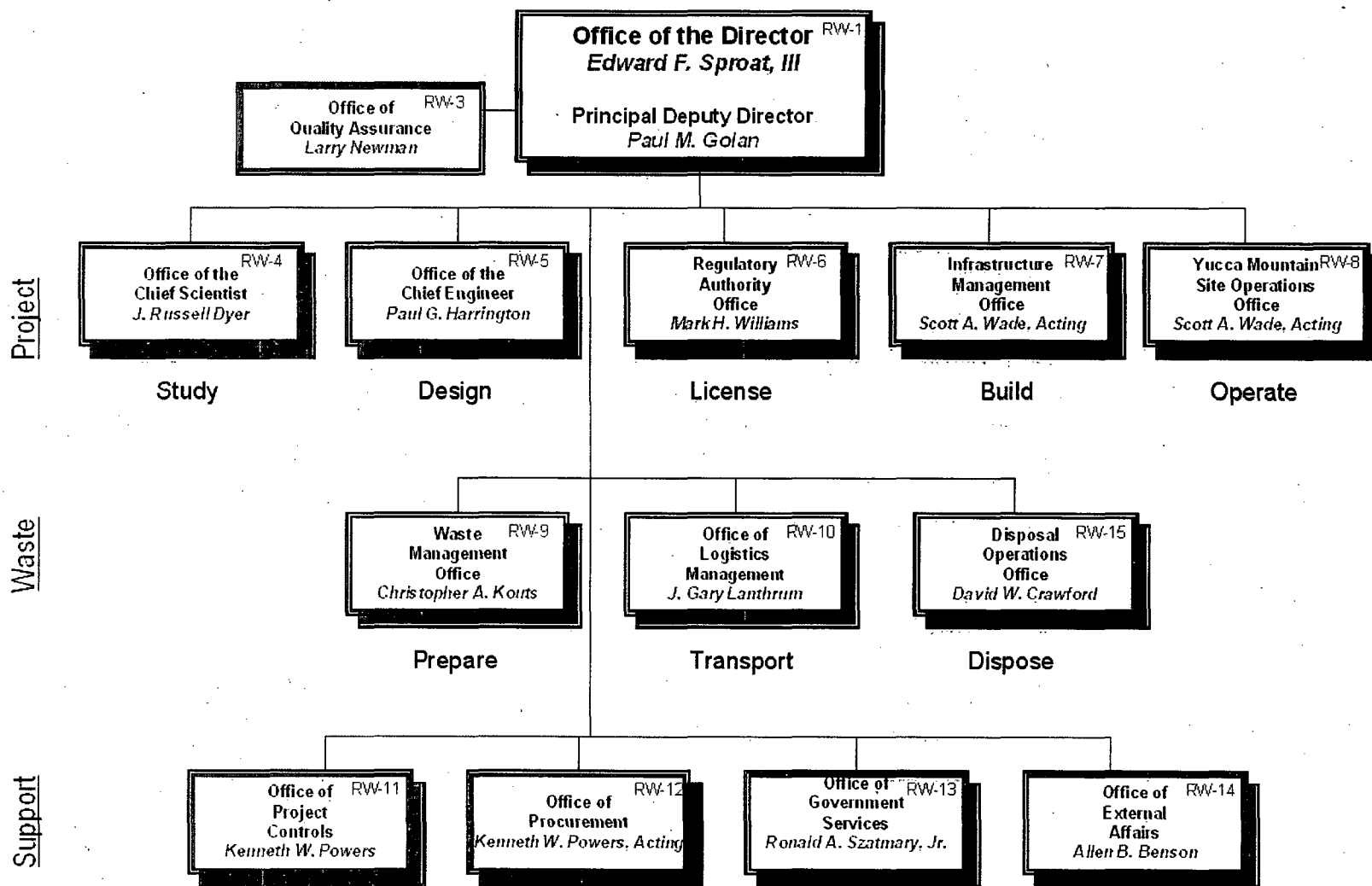
**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**June 26, 2007**

**Las Vegas, NV**

# OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT



6/11/2007



# **Office of Chief Engineer (OCE) Roles and Responsibilities (partial)**

- **Ensure technical and regulatory adequacy of design and preclosure safety analysis**
- **Defend technical and regulatory adequacy of design and preclosure safety analysis in licensing proceedings**



# Overview of Work

- **Review and Acceptance of Design and Preclosure Safety Analysis Products**
  - Line ownership of technical quality, traceability, and transparency of products
- **Responsible for development and maintenance of project-level requirements**
- **Corrective Action Program**
  - Participate in CAP screen team
  - DOE owned Condition Reports
  - Oversight of Contractor CRs
- **Self Assessments and Independent Assessments**
- **Support and Participate in Audits and Surveillances**
- **External Reviews**
- **Review of LA Chapters**
  - Technical Quality
  - Transparency
  - Traceability



# **Review and Acceptance of Engineering Design and PCSA Products, LP-7.21Q-OCRWM**

- **Acceptance Criteria Include:**
  - Have the requirements in 10 CFR Part 63 been met?
  - Have the requirements in the CRWMS Requirements Document been met?
  - Have the requirements in the MGR Requirements Document been met?
  - Has the guidance in NUREG-1804 been incorporated?
  - Have industrial codes and standards been identified appropriately, selected, and followed?
  - Is the documentation provided fully traceable and transparent?
- **Additional criteria can be added by Lead Reviewer, as appropriate**



# Audits and Surveillances

- **Audits and Surveillances**
  - **OQA**
    - ♦ Internal Audits FY07 – 1 complete, 1 ongoing, 2 scheduled
  - **BSC**
    - ♦ Internal Audits FY07 – 1 complete, 3 scheduled
- **Engineering Readiness Review – 6/06**





# Review of Surface Design Chapters

LA Section	Section Title
<b>Group #1</b>	<b>SURFACE DESIGN</b>
SAR-01.00	Repository Safety Before Permanent Closure
SAR-01.01	Site Description as it Pertains to Preclosure Safety Analysis
SAR-01.02	Surface Facility Structures, Systems, and Components and Operational Process Activities
SAR-01.02.01	Surface Operations Overview
SAR-01.02.02	General Surface Design Considerations
SAR-01.02.03	Initial Handling Facility
SAR-01.02.04	Canister Receipt and Closure Facility
SAR-01.02.05	Wet Handling Facility
SAR-01.02.06	Receipt Facility
SAR-01.02.07	Aging Facility
SAR-01.02.08	Balance of Plant Facilities
SAR-01.04	Infrastructure Structures, Systems, Components, Equipment, and Operational Process Activities
SAR-01.04.01	Electric Power
SAR-01.04.02	Controls and Monitoring
SAR-01.04.03	Fire Protection
SAR-01.04.04	Plant Services
SAR-01.04.05	Waste Management



# Review of Subsurface Design Chapters

LA Section	Section Title
<b>Group #2</b>	<b>SUBSURFACE DESIGN AND WASTE PACKAGE</b>
SAR-01.03	Subsurface Structures, Systems, and Components and Operational Activities
SAR-01.03.01	Subsurface Operations Overview
SAR-01.03.02	General Subsurface Design Considerations
SAR-01.03.03	Non Emplacement Areas of the Subsurface Facility
SAR-01.03.04	Emplacement Areas of the Subsurface Facility
SAR-01.03.05	Subsurface Facility Ventilation
SAR-01.03.06	Subsurface Facility Closure
SAR-01.05	Waste Form and Waste Package
SAR-01.05.01	Characteristics of Spent Nuclear Fuel and High Level Radioactive Waste
SAR-01.05.02	Waste Packages and Their Components



# Review of PCSA and Criticality Chapters

LA Section	Section Title
<b>Group #3</b>	<b>PRECLOSURE SAFETY ANALYSIS AND CRITICALITY</b>
SAR-01.06	Identification of Hazards and Initiating Events
SAR-01.07	Event Sequences
SAR-01.08	Consequence Analyses
SAR-01.09	Structures, Systems, and Components Important to Safety; Safety Controls; and Measures to Ensure Availability of the Safety Systems
SAR-01.14	Nuclear Criticality Safety



# **Corrective Action Program Open OCE Owned Level A CRs**

## **The Office of the Chief Engineer Owns 1 Level A CR**

- **CR 6278, Yucca Mountain Site Characterization Project Requirements Document (YMP-RD), is not current.**
  - **All DOE requirements documents have been revised and are current and correct**
  - **There were 18 actions**
    - ♦ **11 Actions are closed**
    - ♦ **7 Actions remain open**
      - » **Projected completion date – End of FY 2007**



# **Corrective Action Program**

## **Open Contractor Owned Level A CRs**

**The Office of the Chief Engineer has Oversight for 1 BSC-owned Level A CR**

- **CR 10381, Inadequate corrective actions to prevent recurrence for conditions related to requirements management**
  - **Initiated April 6, 2007**
  - **Root Cause Analysis is well underway**
    - ♦ **Investigation is complete**
    - ♦ **Results are being formulated**



# Instilling Personal Accountability

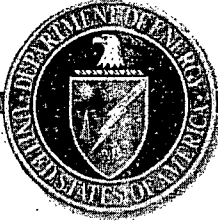
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# Summary

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  - **Emphasis on Corrective Action Program**
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- **Ongoing Activities**
  - **Incorporating results of audits, surveillances, CRs, and external reviews into final work packages**
  - **Ongoing review/acceptance of LA supporting products**
  - **Ongoing review of LA as it is developed to ensure quality**





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# Corrective Action Program Performance Improvement

Presented to:

**DOE/NRC Quality Assurance Technical Exchange**

Presented by:

**Scott Wade, Acting Director**

**Yucca Mountain Site Operations Office**

**Office of Civilian Radioactive Waste Management**

**U.S. Department of Energy**

**June 26, 2007**

**Las Vegas, NV**



# **CAP Performance Improvement: Introduction**

- **Performance improvements previously discussed:**
  - Integrated OCRWM Improvement Plan
  - Recent Route Cause Analyses (RCAs)
  - Quality Improvement Plan
  - Integrated Audit Program
  - Line Ownership of Quality
- **Next: CAP Performance Improvement**
  - Root Cause Assessment 9774
  - Accomplishments to Date
  - Future Plans

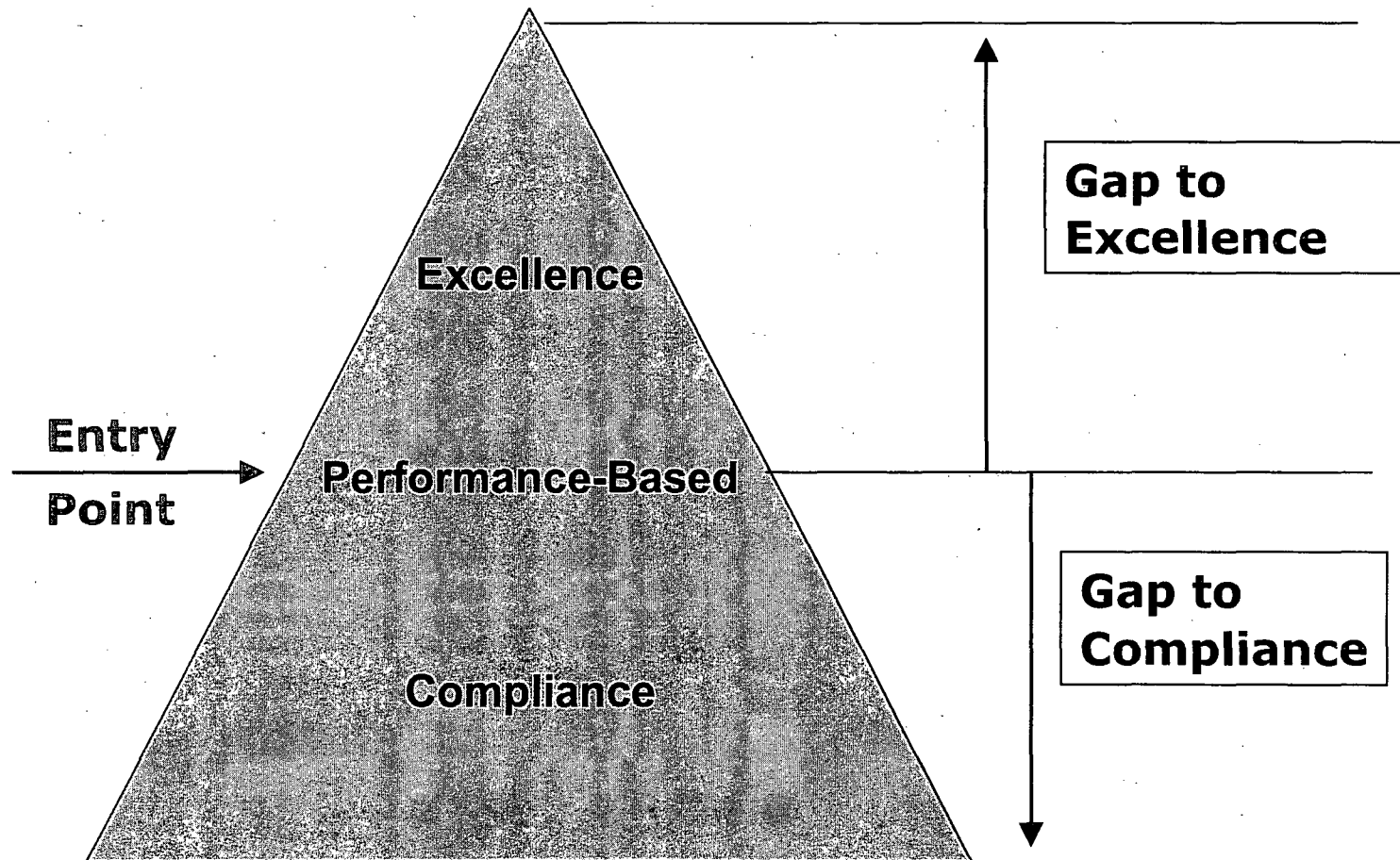


# RCA 9774: Background

- **Internal & External Assessments in 2005, 2006 found:**
  - CAP was *not fully effective*
  - CAP was *not being effectively implemented*
- **OQA (December 2006) concluded:**
  - CAP was *not being effectively implemented*
- **Level “A” CR 9774 (1/4/2007) initiated a Root Cause Analysis**
- **OCRWM Director personally reviewed and approved RCA 9774 and corrective actions**



# Continuous Improvement Strategy



# Root Cause 9774 Problem Statement

**Management failed to recognize the significance of repeated external and internal reviews that identified the CAP as ineffective and did not take aggressive actions to correct the identified problems and ensure effectiveness of the CAP**



# Root Cause of CAP Ineffectiveness

**OCRWM senior management failed to consistently exercise leadership by establishing expectations and standards for CAP performance and enforcing them as a core business activity for all Project personnel**



# Contributing Causes

- **Lack of effective barriers (e.g., management expectations, MRC oversight, QA oversight)**
- **Management tolerated significant unresolved CAP issues**
- **Ineffective self-assessments**
- **Lack of Line ownership and use of CAP**
- **Authority and accountability for CAP effectiveness not clearly defined, not effectively enforced**



# RCA 9774: 5 Categories of Corrective Actions

- **Create Vision** (*Based on Industry*)
- **Set Expectations** (*Individual and Organizational*)
- **Communications** (*Buy in from all OCRWM Personnel*)
- **Mentoring** (*Ensure Management Behaviors*)
- **Measuring** (*Measure Effectiveness*)



# INPO Guidelines for CAP 'Excellence'

- **Ownership**
  - Organization "owns" CAP
  - CAP is "core business", used as management tool
- **Focus**
  - One system for identification, tracking and trending of problems
  - OCRWM currently has multiple systems
- **Management Sponsorship**
  - Management has "questioning attitude"; accepts issues and determines cause and solution
- **Timeliness**
  - CRs are initiated quickly
  - Significant CR actions are identified and implemented promptly
- **Learning**
  - Actively seek opportunities to improve behaviors and processes
  - Discourage defensive behavior





# Management Behavioral Factors

- Problem Identification (e.g., the writing of CRs)
- Problem Categorization (e.g., assigning “levels” to CRs)
- Causal Investigation (e.g., finding the causes, Extent of Condition, and Extent of Cause of the problems identified in CRs)
- Corrective Action (e.g., designating and implementing actions to address effects, causes, and extent)
- Closeout (e.g., determining the completeness, timeliness, and effectiveness of corrective actions)
- Trending (e.g., determining the numerical performance of CAP in the above areas)
- Self-assessment (e.g., CAP participants finding issues in the above areas and using CAP to correct them)

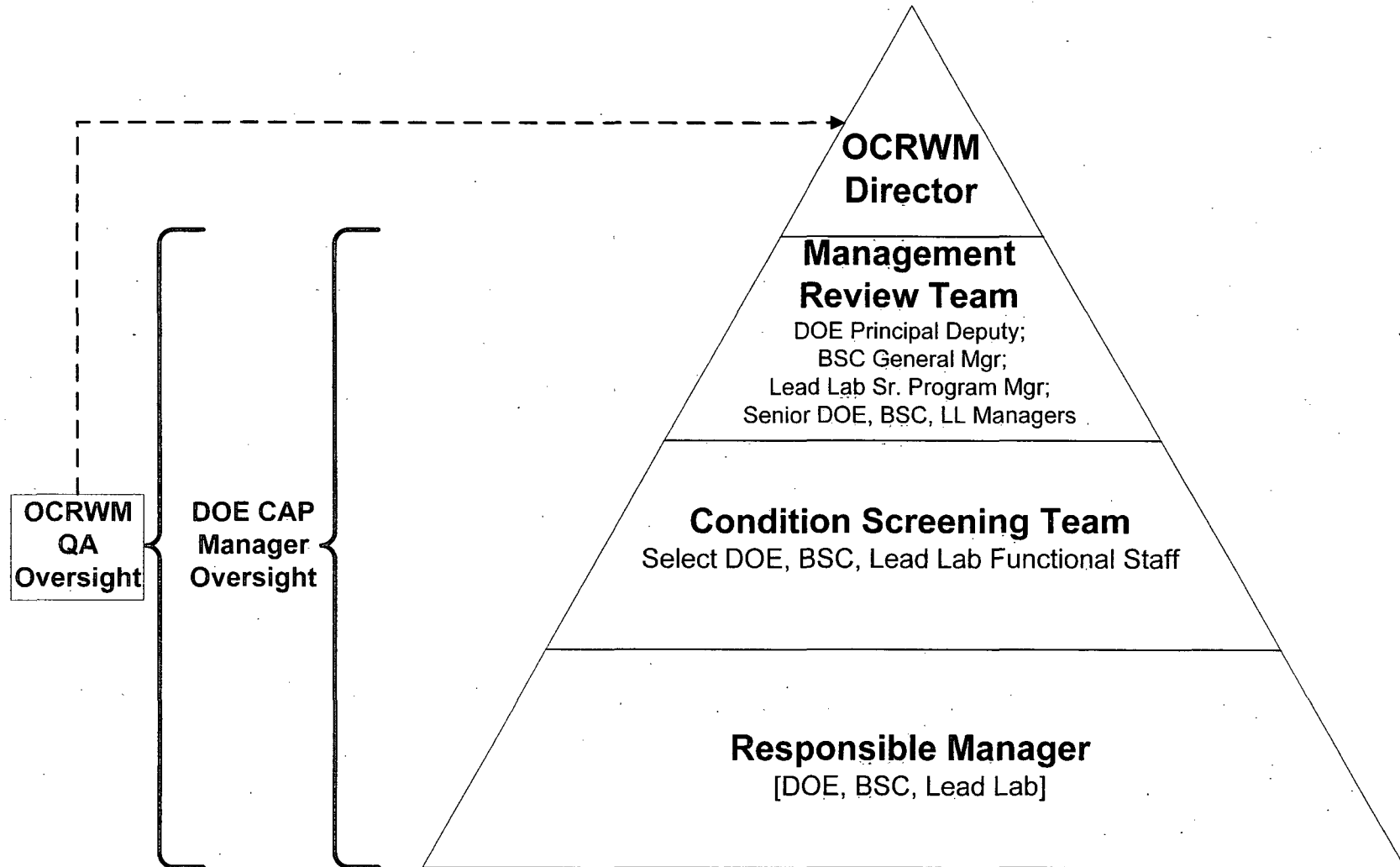


# **Actions in Response to CAP Issues**

- **Restructured Management Review Committee (7/2006)**
- **Issued CAP Performance Improvement Plan (10/2006)**
- **Hand-picked RCA Team formed (1/2007)**
- **QA temporarily placed in the CR closure process**
- **QA began revising Root and Apparent Cause Analysis programs**
- **RCA Report Issued (3/2007)**
- **Condition Screen Team reconstituted; responsibility reassigned to DOE manager (3/2007)**



# Progressive Levels of CAP Oversight and Management






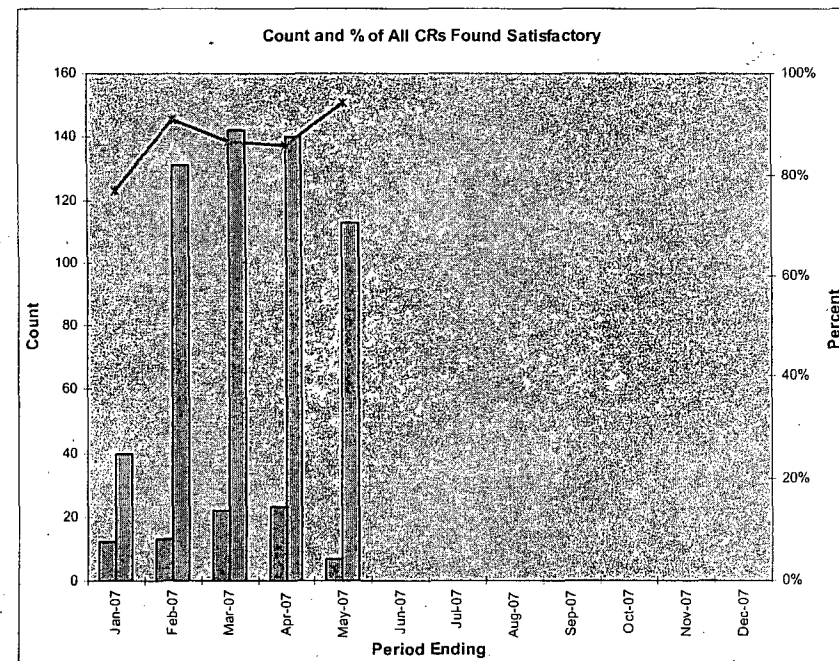
# Focus on Quality of CRs

- CST actions for screening and closure prioritize responses and traceability
- Condition Reports have been returned for inadequate extent of condition, causal analysis, and documentation
  - Rate of return is decreasing

SCORE		
Feb-07	Mar-07	Apr-07
May-07		

LEGEND	
	# All w/ issues
	# All w/o issues
	% All w/o issues



# Focus on Quality of CRs

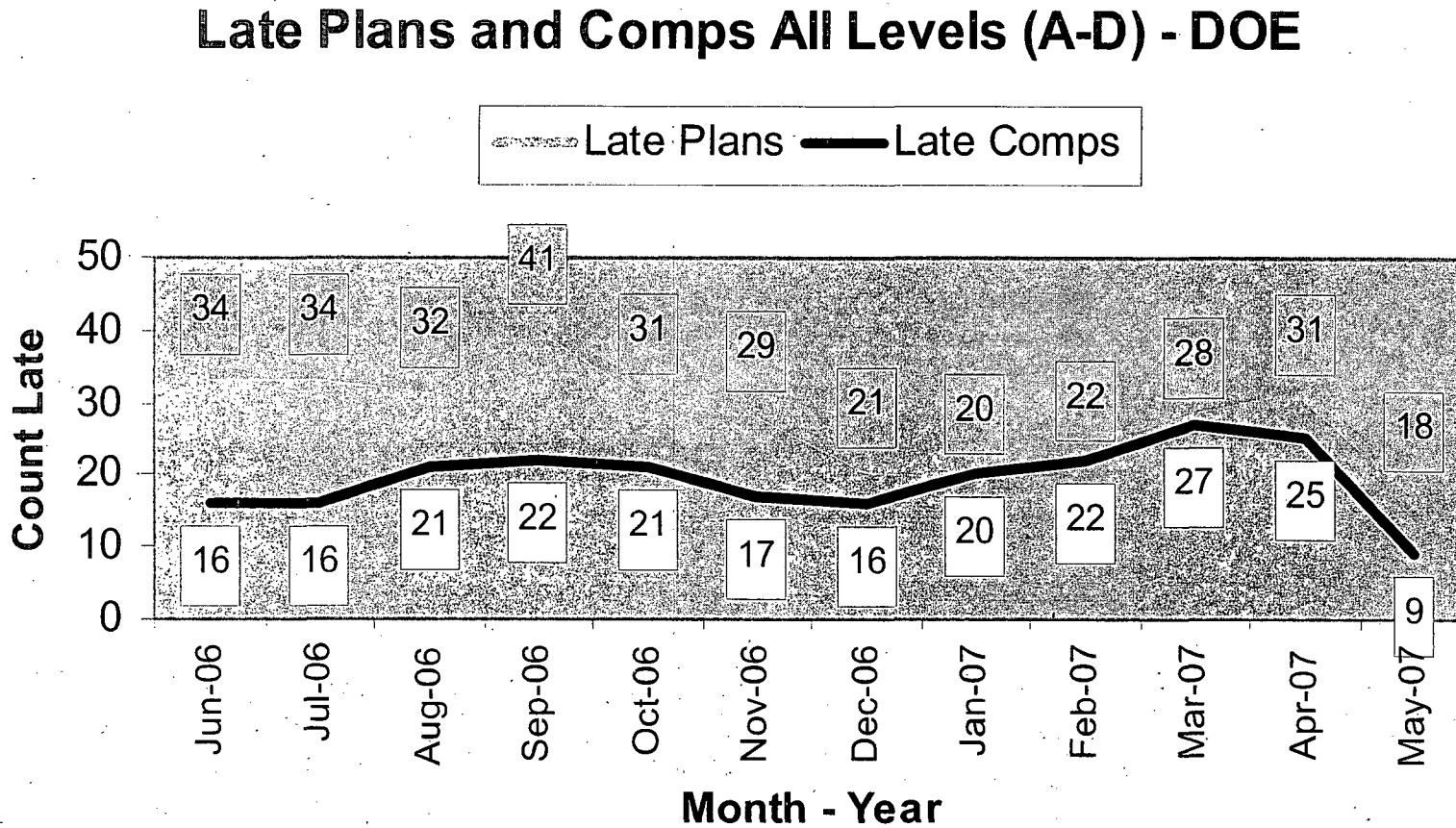
(Continued)

- **MRC monitors overall performance of CAP:**
  - **CAP Performance Metrics**
    - ♦ **Focus on responsible manager accountability for managing CRs**
  - **Review and approve Level A, select Level B CRs**
  - **Review Root and Apparent Cause Analyses**
  - **Review of trends**
  - **Monitor Effectiveness Reviews of Corrective Actions**



# Late Plans and Completions - All Levels

This graphic provides data on the number of late plans and late action completions for Level A through Level D Condition Reports by month for DOE as an organization.



The goal is to have 0 late plans and 0 late action completions.



# Trending Program Improvements

- **Trend Working Group established to revise trend program; Patterned after successful nuclear utility trend programs**
- **New OCRWM trend procedure issued April 2007**
- **New trend codes instituted and retrofitted to CRs**
- **OCRWM Trend Report issued June 14, 2007**



# Continuing Actions

- **Further restructuring of MRC and CST to foster accountability**
- **Management supports and celebrates CR identification**
  - **Managers tasked to thank originators**
  - **Recognition given for well-written CRs**
- **Senior management meeting (May 2007) focused on value of CAP and appropriate CAP 'Management Behaviors'**
- **Improvements in CAP procedures to promote quality, timeliness, accountability for action**





# CAP: Summary

- **CAP was not being used as performance improvement tool**
- **CAP improvement is sponsored by OCRWM Director & Principal Deputy Director**
- **Actions from RCA 9774 will drive overall CAP corrective actions**
- **An effective CAP is critical to Project success**

