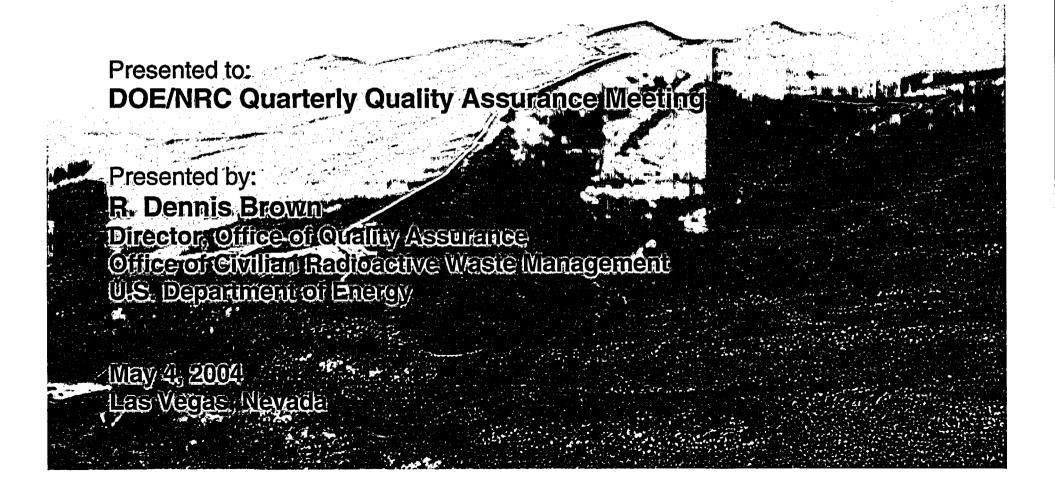
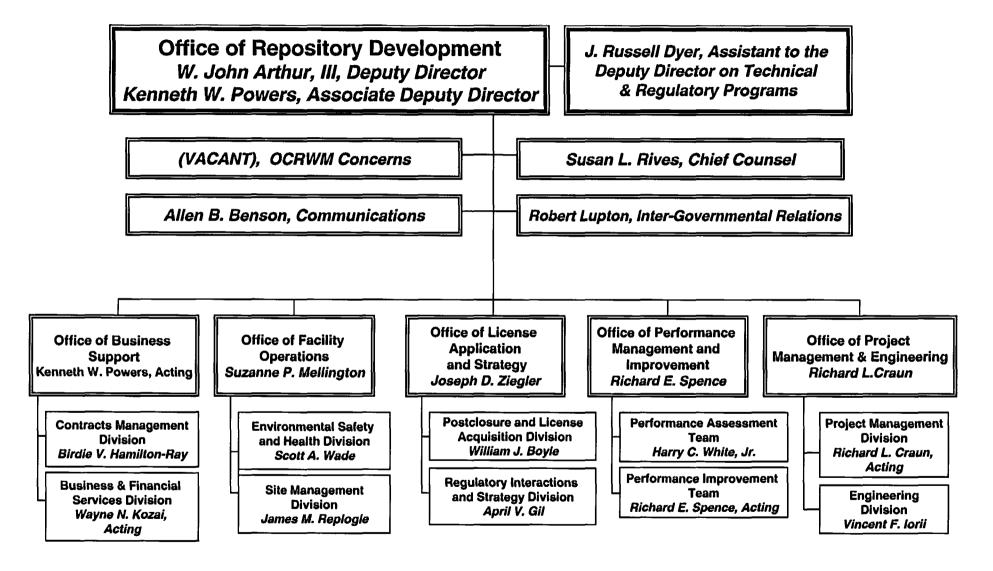




Quality Assurance Overview



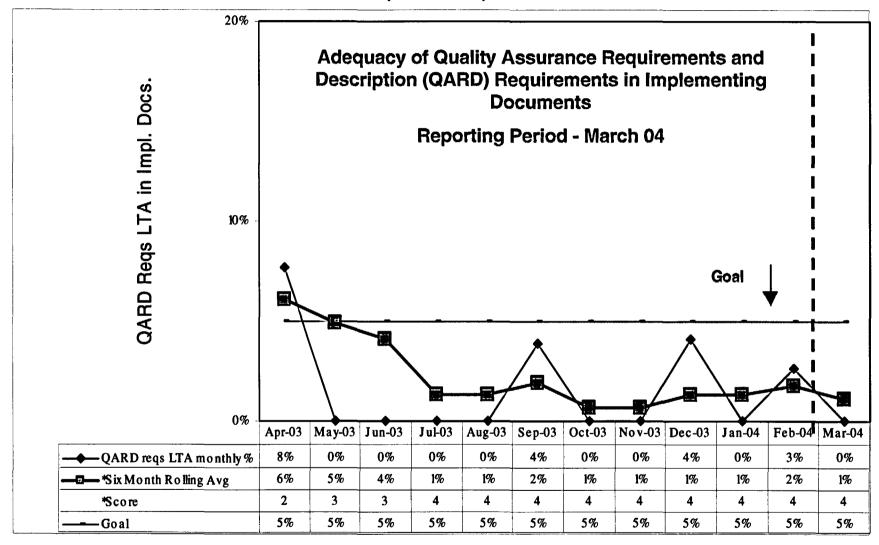
Office of Repository Development







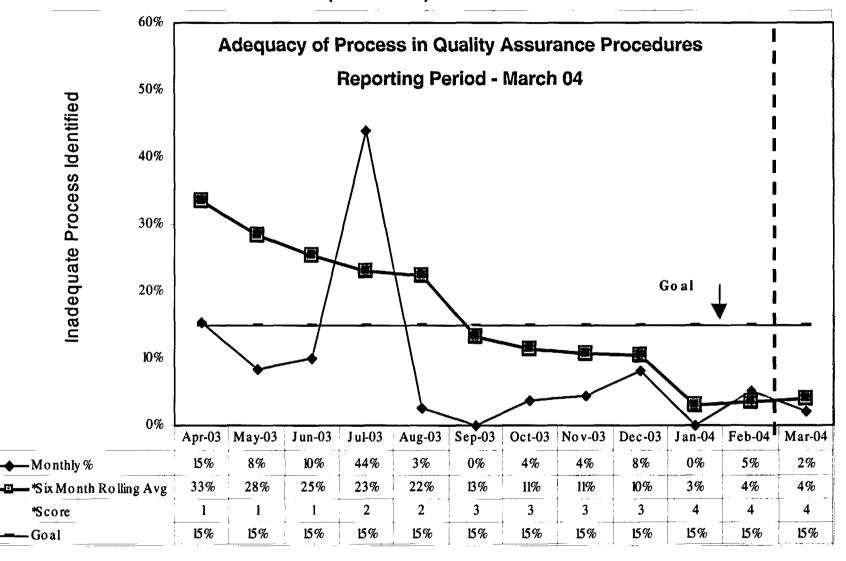
Quality Assurance Overview







Quality Assurance Overview



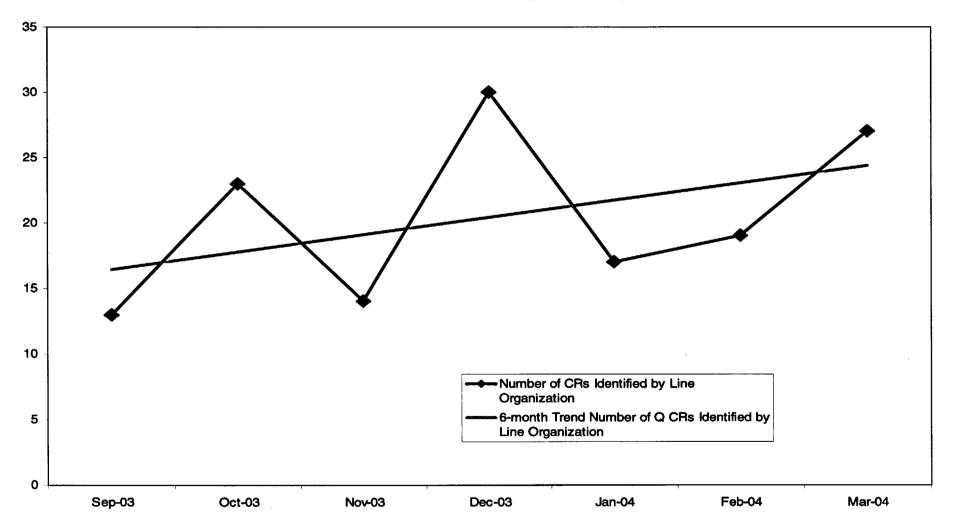




Quality Assurance Overview

(Continued)

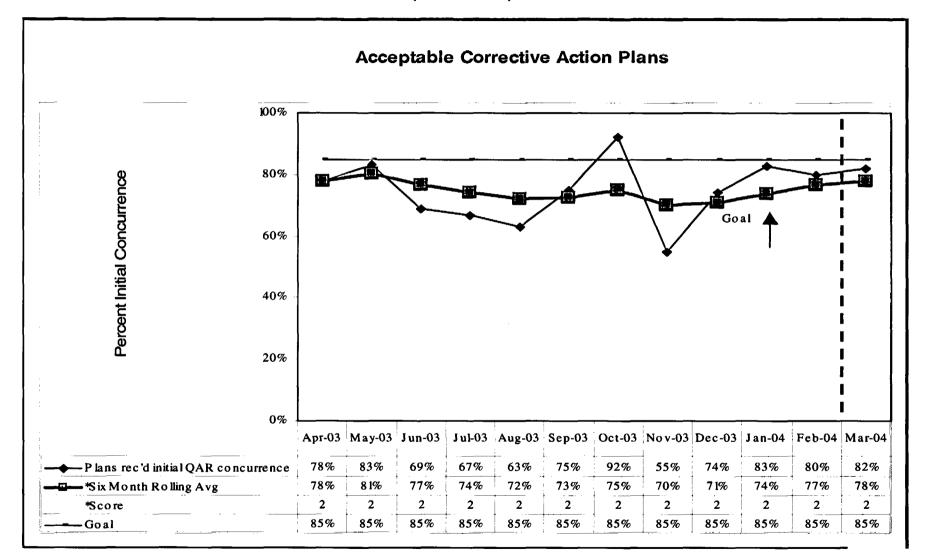
Number of Q CRs Identified by Line Organziation







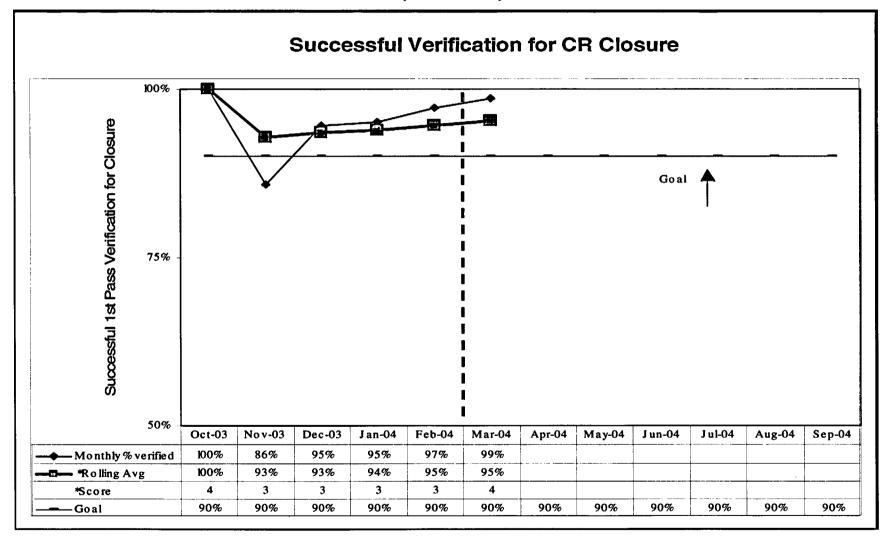
Quality Assurance Overview





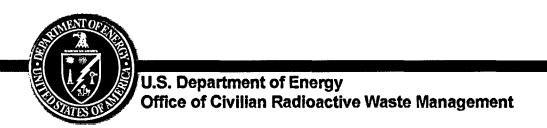


Quality Assurance Overview











Corrective Action Program



Enhancements to the Corrective Action Program

- **Objectives of Enhancements**
 - Improve the software system usability
 - Enhance ability of the line organization to manage their corrective action scope
 - Expand ability to trend Corrective Action data
 - Simplify process for low significance issues
 - Refine metrics for measuring Corrective Action Program (CAP) performance





Recently Completed Enhancements

- Expanded reporting capabilities to meet user requirements
- Trained line personnel in trend software and trending techniques
- Brought more formality to Condition Screen Team activities
- Refined CAP system metrics





Near Term Enhancements (May)

- Training to Managers/Supervisors on CAP and subsequent rollout to workforce
- Continue to enhance screening process clear expectations and knowledge requirements
- Implement non-process software changes to enhance usability
- Issue a CAP users guide to assist personnel with computer manipulations
- Implement trending software establish expectations for line use





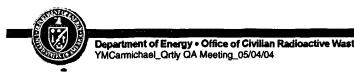
Longer Term Enhancements (June – September)

- CAP process changes
 - Revise significance levels
 - Allow for simple process for "find and fix" and "corrected on the spot" Condition Reports (CRs)
 - Simplify process flow and software usability



Significance Levels

- A-Significant Adverse Conditions
 - Root cause analysis required
- B-Conditions of Moderate Risk or Impact
 - Apparent cause analysis required
- C-Conditions of Low/No Risk or Impact
 - Find and fix
 - Trend to identify adverse patterns
- D-Recommendations for Improvement and Enhancements





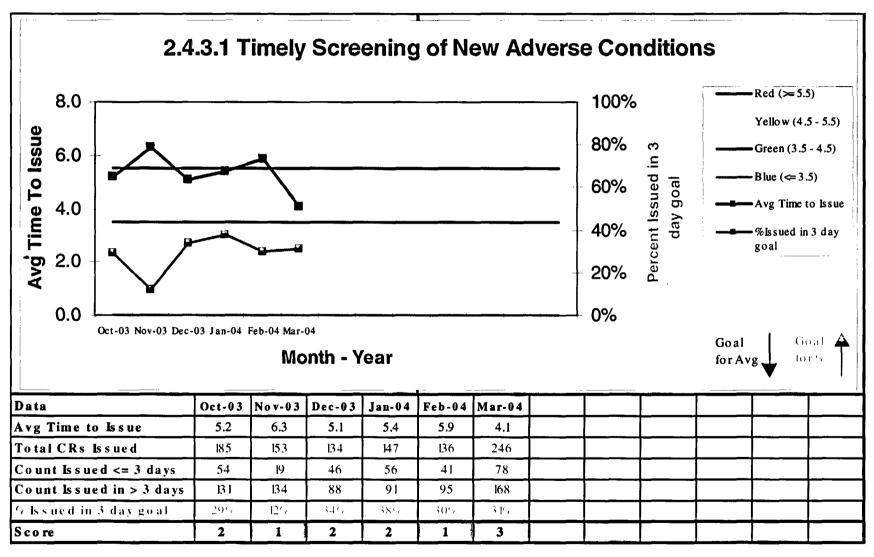
Measure of Effectiveness

- How will we know if what we are doing is effective?
 - Volume of CRs initiated by line organization continues to increase
 - Line identification of potential adverse trends
 - Significant issues are fixed no repeat events





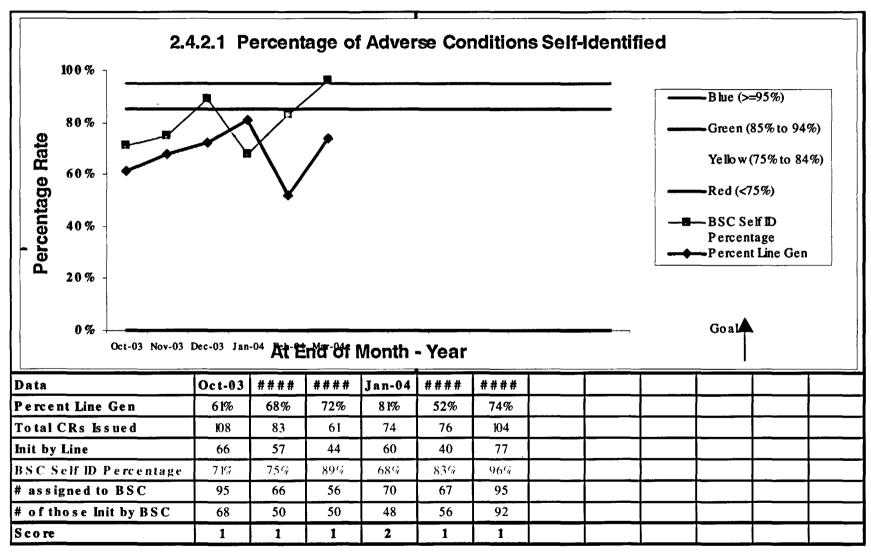
Performance Indicators







Performance Indicators

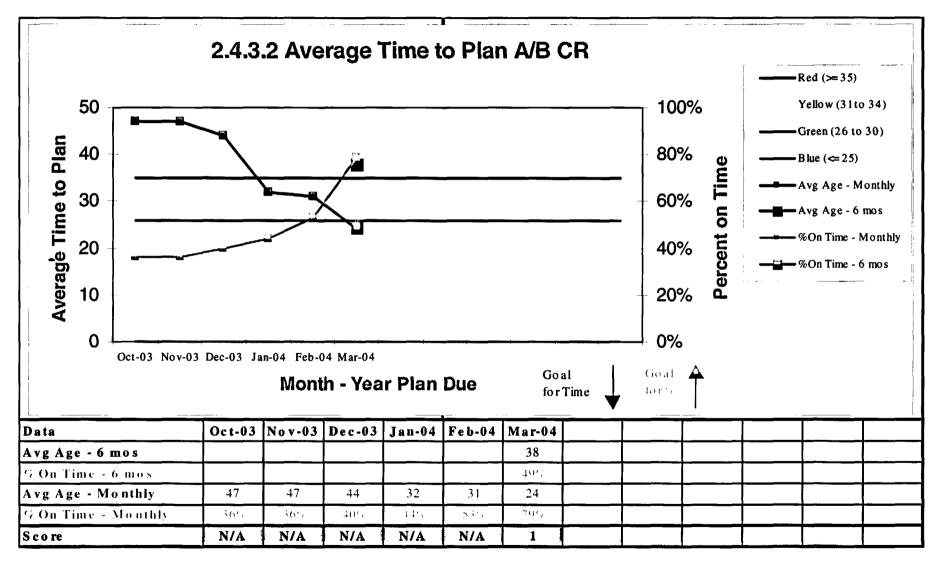






Performance Indicators

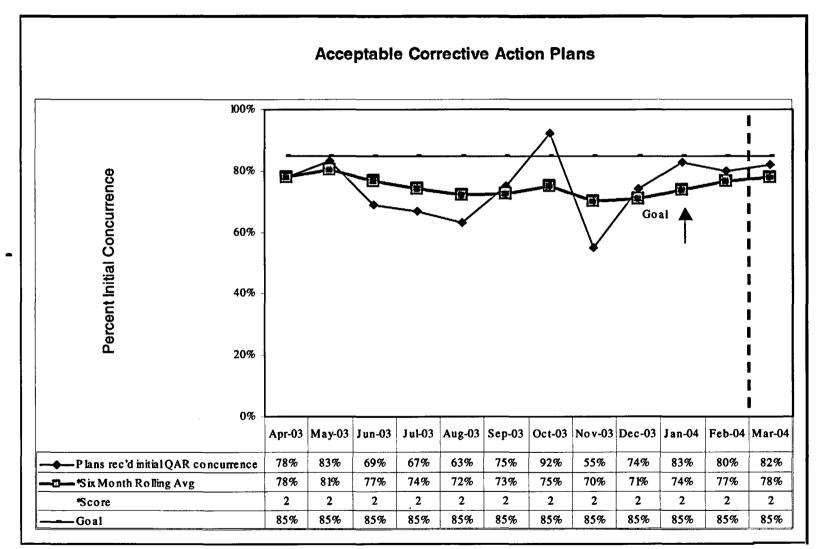
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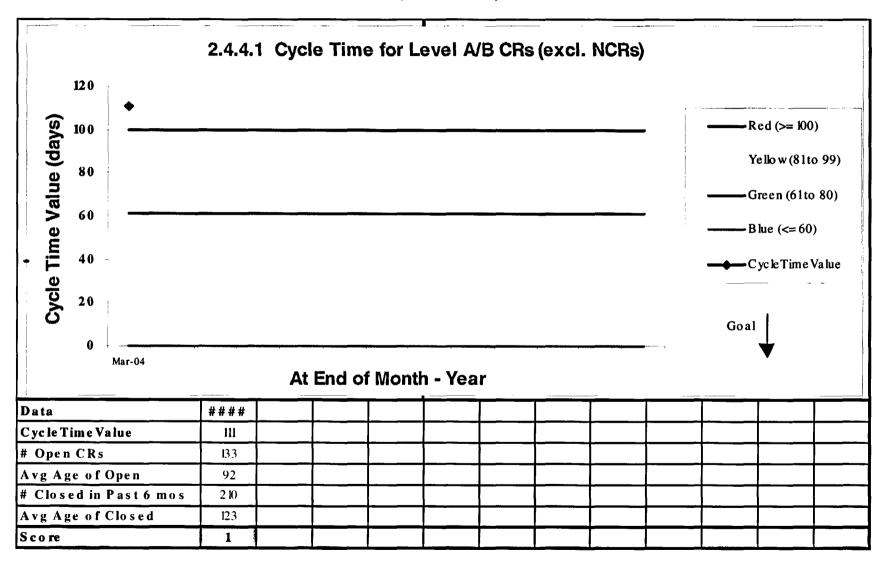
Performance Indicators







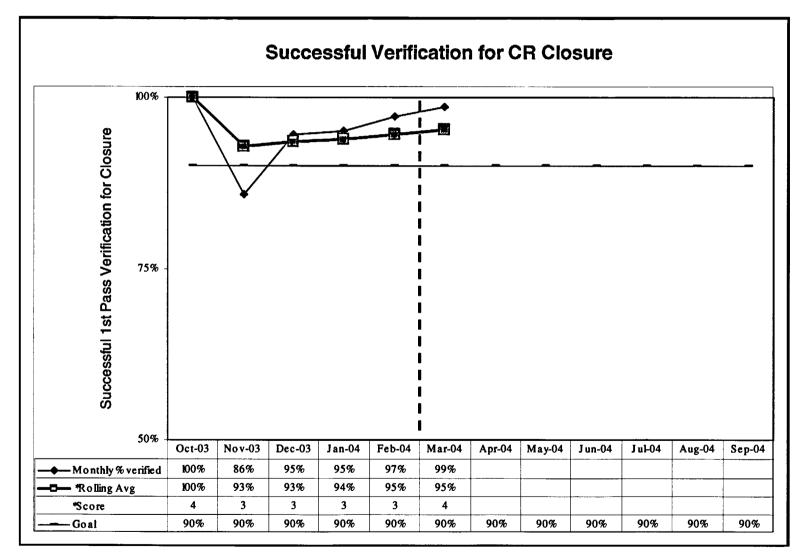
Performance Indicators





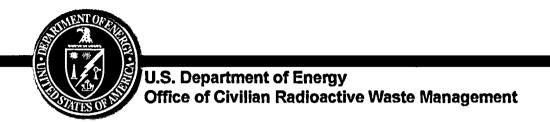


Performance Indicators



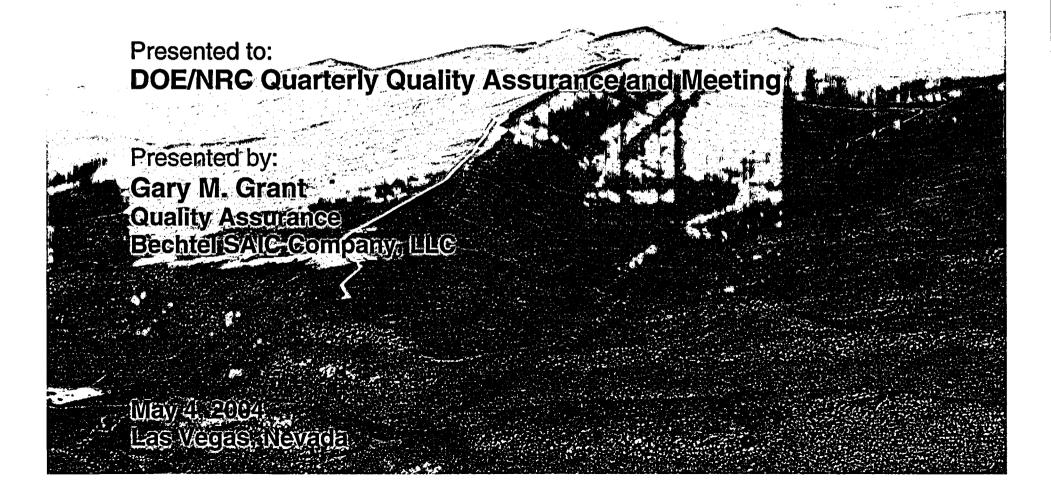








Trend Evaluation and Reporting



Trend Evaluation and Reporting Activities

- 1st Quarter FY-2004 Report issued (February 2004)
 - Over half of the condition reports were associated with 6 procedures
 - The most common cause was human performance related to procedure implementation
 - Content (requirements) issues associated with procedures were not identified
 - Condition reports were primarily related to documentation errors
 - Excessive pace (schedule over quality) was identified in only of the 1.3 percent causal factors





Trend Evaluation and Reporting Activities

- Conducted a self-assessment (SA-ATSS-2004-009)
 on the completeness of condition report
 information and the application and use of trend
 codes
 - Identified a number of opportunities to improve the process to strengthen trending results
- Surveillance (BQA-SI-04-0012) cause evaluation process
 - Adequate cause analysis is performed and in alignment with the stated problem
 - The stated corrective actions are appropriate for the stated causes



Trending Process Improvements

- Developed Trend Analysis and Reporting Handbook
 - Contains guidance on how to conduct trending based on best industry practices
- Conducted trending principles and skills development training
 - Approximately 30 Trending Coordinators identified and trained across the project (line personnel)
 - "Trend Manager" software use and applicability
 - Trends and patterns analysis techniques





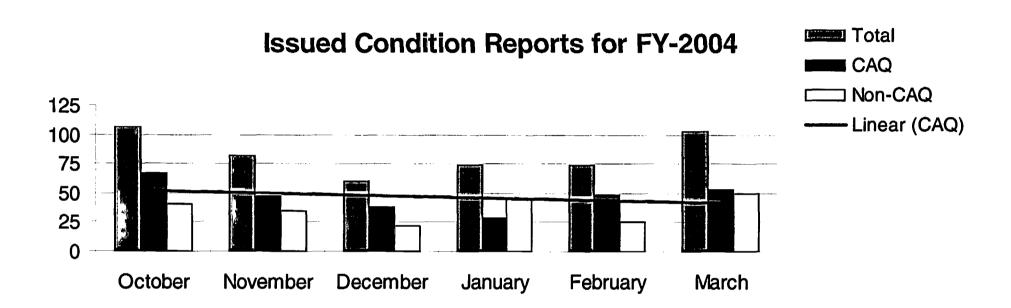
Trend Evaluation Results/Findings

- Recent results for second quarter FY-2004
 - Consistent performance in condition reporting
 - Over 50 percent of the condition reports are associated with four procedures
 - AP-SIII.10Q, Models
 - * AP-5.1Q, Procedure Preparation, Review, and Approval
 - AP-17.1Q, Records Management
 - AP-SIII.9Q, Scientific Analysis
 - Improvements noted in some procedures as a result of recently implemented corrective actions (Condition Report (CR)-1497)





Condition Report Trend Results



Analysis Results

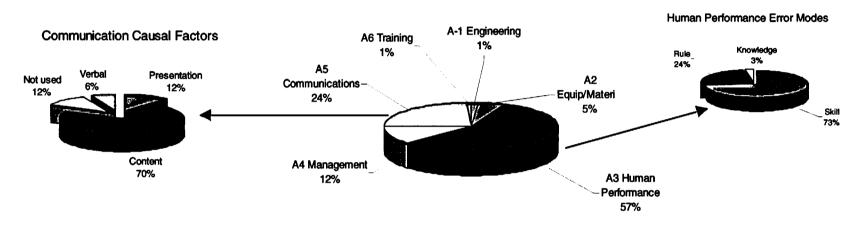
Plotted linear trend is not statistically significant. Indicates consistent reporting performance since deployment of the new Corrective Action Program (CAP) system.





Overall Causal Factor Distribution

Condition Report Causal Factors



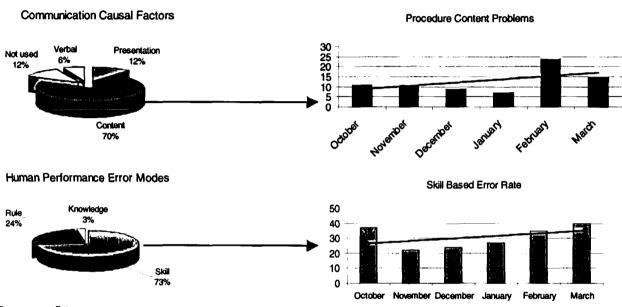
Analysis Results

Relative distribution of causal factors remains unchanged as compared to 1st Quarter FY-2004 Report. Within the human performance- and communications-related causal factors, some change has been observed associated with the human error types and procedure content.





Causal Factor Trend Results



Analysis Results

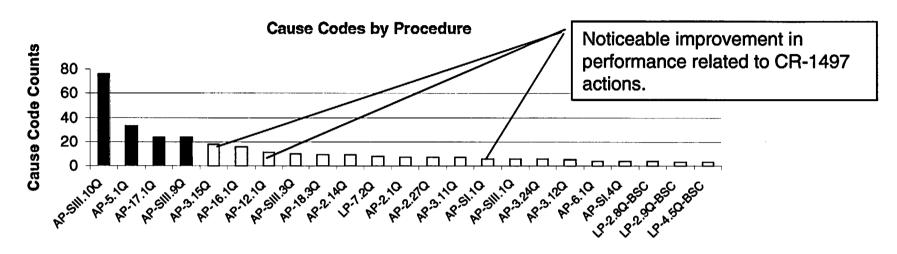
- Plotted linear trends are not statistically significant
- Procedure content problems changed because of an audit conducted in February

• Increase in skill based error rate as a result of finding latent documentation errors





Trends and Patterns Analysis



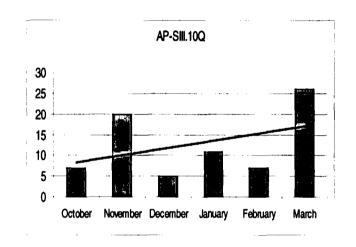
Distribution of principal causal factors for each of the selected procedures.

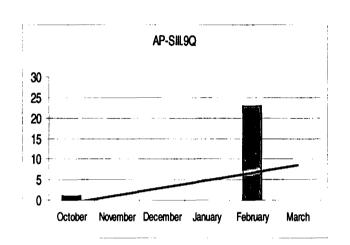
Procedure	Principal Cause Category					
	A1 Design Engineerin g	A2 Equipment/ Material	A3 Human Performanc e	A4 Management	A5 Communications	A6 Training
AP-SIII.10Q Models	0	0	48	18	10	0
AP-5.1Q Procedure Preparation, Review, and Approval	0	0	27	2	4	0
AP-17.1Q Records Management	0	0	17	1	6	0
AP-SIII.9Q Scientific Analysis	0	0	17	2	5	0

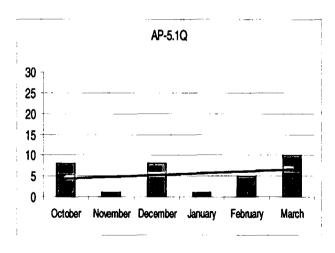


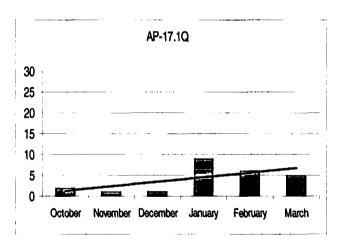


Procedure Related Trends













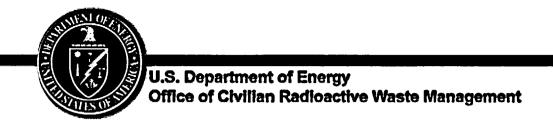
Analysis Results

- AP-SIII.10Q, Models and AP-SIII.9Q Scientific Investigation. Errors relating to proper documentation and/or lack of transparency of technical reports
 - Inadequate documentation due to less than adequate check of work.
 The issues are primarily administrative in nature
 - Increase in reported conditions is related to audit and surveillance activity
- AP-5.1Q, Procedure Preparation, Review, and Approval.
 The problems with AP-5.1Q were administrative errors relating to documentation
- AP-17.1Q, Records Management. The problems with AP-17.1Q were administrative errors relating to record submittals to the Records Processing Center; improvement noted since January

Conclusion

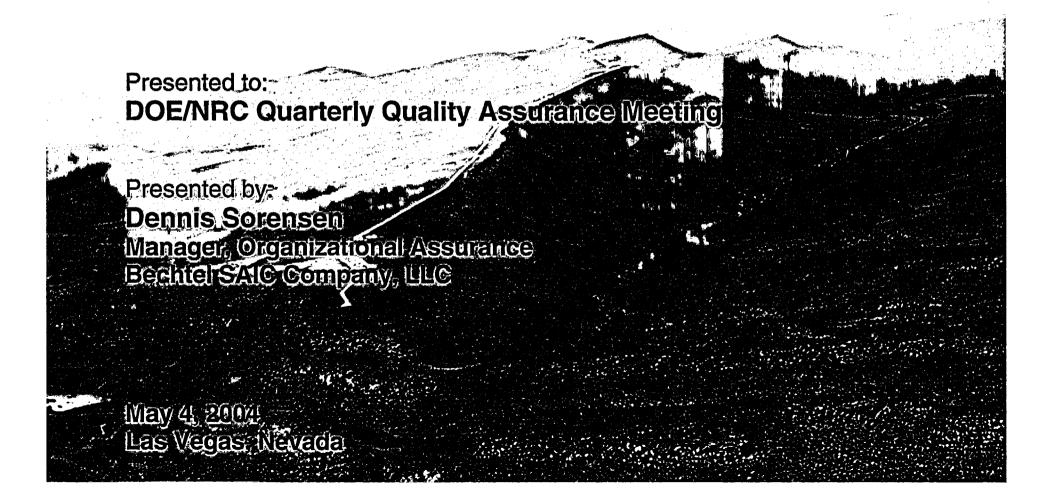
- The trend evaluation and reporting process is working
- Improvement activities should continue to strengthen the process







Human Performance



Human Performance

- Condition Report (CR) #1497, "Human Performance Problems"
 - **Initiated December 17, 2003**
 - No adverse trends
 - Pattern of errors
 - Skill-based human errors
 - **Error-likely processes**
 - Barriers to prevent or reduce human error are less than adequate (LTA)
 - Closed April 6, 2004
 - Pre-job briefings clarified expectations and awareness
 - Procedures enhanced for identification of critical steps
 - Affected training modules incorporated discussion of errors and error-likely situations

Lessons Learned submitted





Human Performance

- CR #1772, "Coordinated Approach to Human Performance"
 - CR initiated January 30, 2004
 - Develop coordinated approach to human performance improvement
 - » Near-term: Implement performance expectations for Regulatory Integration Team derived from CR 1497 solutions
 - Initiate human performance expectations with management directive
 - Approval of change management plan by Leadership Council
 - Implement performance indicators
 - Target closure date: June 30, 2004





Human Performance

(Continued)

Path Forward

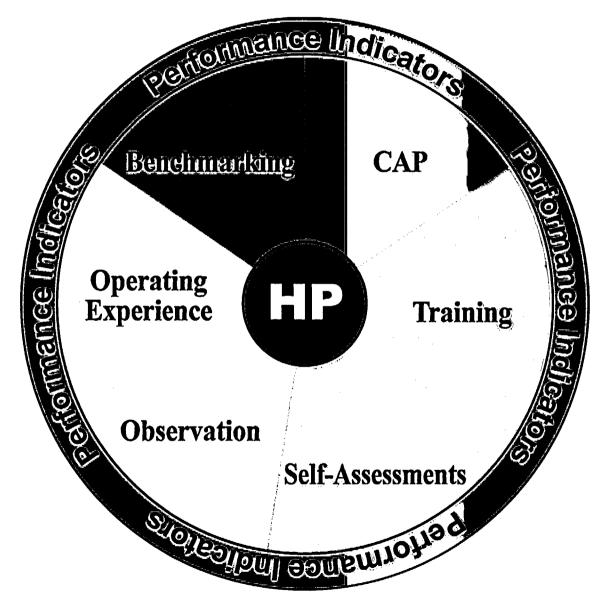
- Implement human performance technology
 - Interdependent system of Individuals, Leaders and **Organizational Processes and Values**
- Adopt program elements from industry leaders
- Continue developing knowledge and understanding

- Improve system components
- Reinforcement of desired behaviors
- **Monitor Performance Indicators (initiated April 21, 2004)**
 - Error prevention behaviors
 - **Human performance awareness**
 - **Backlog management**
 - Learning culture





Human Performance Wheel





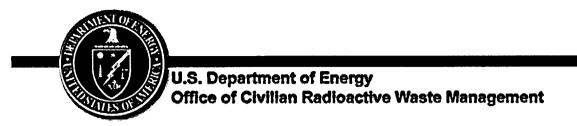


Human Performance











Revisions to the Quality Assurance Requirements and Description

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

Michael L. Ulshafer

Fleam-Lead, Office of Quality Assistance

Office or Civillan Racioactive Waste Management

US Department of Energy

May 4, 2004

Las Vecas Nevada

Outline

- **Quality Assurance Requirements and Description** (QARD) Revision 14
- **QARD Revision 15**
- **QARD (10 CFR 63)**





Revision 14

- **QARD Revision 14 approved**
 - Effective April 1, 2004
 - **Supported Office of Repository Development (ORD)** reorganization
 - + Office of Project Management and Engineering
 - + Office of Performance Management and Improvement
 - + Office of Business Support
 - Office of Project Control and Monitoring
 - Office of Project Support
 - Clarified "Performance Assessment" definition in glossary





Revision 15

- Significant Changes
 - Items <u>not</u> important to safety or waste isolation moved out of QARD - such as Radiation Protection, Fire Protection, Physical Security, etc
 - Removes direct involvement of Quality Assurance (QA) organization in:
 - Concurrence on corrective action plans
 - Verification of corrective action implementation
 - Performance of trending
 - QA is indirectly involved in these three areas through the audits and surveillances





Revision 15

- Significant Changes (Continued)
 - QARD Rev 15 Requires
 - Verification of corrective action implementation
 - Trending
 - » Does not specify organization





Revision 15

- Current Status of QARD Revision 15
 - Formal review/comment cycle complete
 - Comment resolution complete
 - QARD sent to NRC for review and acceptance
 - Effective TBD





Revision 15

- QA still required to do audits/surveillances of Corrective Action Program (CAP)
- For Level A and B Condition Reports QA to:
 - Concur on corrective action plans
 - Verify corrective action implementation
 - Continue until performance assured
 - Changes require Deputy Director, ORD and Director Office of Quality Assurance (OQA) approval

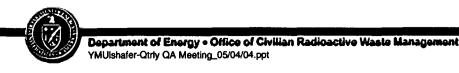


Revision 15

(Continued)

Basis for change

- Strengthens line ownership for product quality
- Reinforces line management accountability and responsibility to achieve and maintain quality
- Improves independence and objectivity of the QA Organizations
- Aligns project with nuclear industry





Revision 15

- To monitor performance BSC plans to:
 - Emphasize Quality Engineer involvement in CR processing
 - Evaluate adequacy of 100 percent of Level C Condition Reports (CRs) processed each month by BSC
 - Continue until performance acceptable
 - Review adequacy of line self-assessments
 - Report results to BSC Management





Revision 15

(Continued)

- To monitor performance OQA plans to:
 - Observe BSC QA oversight activities
 - Evaluate adequacy of 100 percent of Level C CRs processed each month by DOE
 - Continue until performance acceptable
 - Report results to DOE Management
 - Audit CAP performance pre- and post-transition



QARD (10 CFR 63)

- QARD (Preliminarily identified as Rev 0) sent out for internal formal review
 - 10 CFR 63, Subpart G, Quality Assurance
 - NUREG 1804, Yucca Mountain Review Plan
 - Takes us through the Construction Phase
- To facilitate the NRC review, provide:
 - Full text requirement matrices to QARD
 - A complete Revision History
 - A list of differences between Revision 15 and Revision 0



QARD (10 CFR 63) (Continued)

Significant Changes:

- Incorporate commercial grade procurement
- **Remove QA Grading**
- Revise records retention requirements
- Revise software to be consistent with NQA-1, 2.7, 2000
- Separate out 10 CFR 71 activities

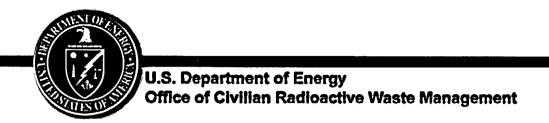




QARD (10 CFR 63)

- Path Forward for QARD Revision 0
 - Formal review/comment cycle
 - Resolve comments
 - Interactions with the NRC to discuss proposed changes
 - Approval by DOE
 - Review by NRC
 - Effective 1st Quarter FY05







Models



Condition Report 99 Model Development and Validation: Background

- Condition Report (CR) 99/BSC-01-C-001 issued **May 2001**
 - Corrective Actions (CAs) included new procedures, extensive training to those procedures, and upgrades to deficient technical products
- BSC completed CAs and requested DOE/Office of **Quality Assurance (OQA) verification August 2003**





Condition Report 99 Model Development and Validation: Background

- Comprehensive model audit was conducted by DOE/OQA October 2003
 - Audit timing corresponded with availability of Model Reports for review
 - Audit findings
 - Procedures adequate upper tier requirements flowed down
 - Processes effective in producing acceptable products
 - Procedure implementation unsatisfactory





Condition Report 99 Model Development and Validation: Background

(Continued)

- August-November 2003, DOE/OQA verified 11 of the 12 CR 99 CAs were complete
 - DOE/OQA Verification Team selected 20 model reports for independent technical review
 - 5 of 20 model reports sampled were unsatisfactory with respect to model validation
- On November 18, 2003, DOE/OQA concluded CR 99 could not be closed
 - Implementation of AP-SIII.10Q, *Models* unsatisfactory





Condition Report 99 Supplemental Corrective Actions

- BSC submitted 3 supplemental corrective actions December 5, 2003
 - Self-Assessment to investigate procedural implementation problems
 - 100 percent surveillance of remaining model reports
 - Resolve issues with 5 "unsatisfactory" model reports
- DOE Line and OQA approved these supplemental actions December 10, 2003





Condition Report 99 Supplemental Corrective Actions

(Continued)

- **BSC Supplemental Action #1: conduct** Self-Assessment
 - Completed January 15, 2004
 - Two level D CRs to improve models and technical work plan procedures
- **BSC Supplemental Action #2: surveillance of 36** additional model reports
 - Surveillance report issued March 19, 2004
 - Conclusion: "Unsatisfactory implementation of procedure requirements"





Condition Report 99 Supplemental Corrective Actions

- BSC Supplemental Action 2# (Continued)
 - Surveillance resulted in 4 level B condition reports related to model validation
 - Incomplete model validation
 - Inadequate model validation criteria
 - Same data used to develop and validate model
 - Model not valid over range of application
 - 16 of 36 model reports had unsatisfactory findings with regard to model validation





Condition Report 99 Supplemental Corrective Actions

(Continued)

- BSC Supplemental Action #3: revise 5 model reports judged as "unsatisfactory" by DOE/OQA Verification Review Team
 - Completed: model reports were revised to address model validation issues (December 2003 - March 2004)



Next Steps

- Actions to prevent recurrence include:
 - Clarification of process steps causing repetitive problems
 - Training materials for models procedure updated to address problem areas
 - "Time out for quality" sessions to be held at critical process steps during revision cycle for model reports
 - Model report outline revision underway to clarify documentation requirements





Next Steps

- Revised model reports addressing model validation issues will be prepared and issued
- Detailed schedule for production of revised model reports is in preparation









Software Qualification

Presented to: DOE/NRC Quarterly Quality Assurance Weeting Presented by: Richard A. Aukieson Wanage, Wissian Applications
Bedia 15/416 company, ULC WEN 44, 2004 प्रकारकार अध्यक्ति वहा

Software Qualification Topics

- Software Qualification Overview
- **Qualified Software Categories**
- Status: Legacy Software Retesting
- Status: Transition Software Remediation
- Status: Quality Assurance Requirements and **Description** (QARD) Revision 13 Software Qualification
- **Metrics** (chart)
- Summary





Software Qualification Overview

- There are 2 types of software qualification used in technical products supporting the License **Application (LA):**
 - **Baselined software**
 - Software qualified in other technical products (SQOTP)
 - Note: The ("Q") software procedures no longer allow software to be qualified in other technical products
- Baselined software falls into one of two categories:
 - **Qualified software**
 - **Retired software**





Qualified Software Categories

- The "Letter of Agreement on Documentation Requirements for Software Used in Support of LA," dated October 24, 2003, divided qualified software into 3 bins:
 - Legacy Software: Software which was qualified prior to January 13, 2003. This software did not go through an independent verification and validation (IV&V) process.
 BSC is in the process of retesting legacy software
 - Transition Software: Software which was qualified after
 January 13, 2003 but before March 23, 2004, the effective date
 of the current revision to the "Q" software procedures. BSC
 is in the process of updating transition software packages to
 address the requirements of the current "Q" procedures
 - QARD Revision 13 Software (hereafter referred to as QARD Software) is defined as software qualified after March 23, 2004 (the effective date of the current revision to the "Q" software procedures)





Status: Legacy Software Retesting

- Total number of legacy software items going forward to LA: 316
- Number ready for LA: 75
- Number of remaining items: 244
- Status of remaining items:
 - In process: 105
 - In escalation per LP-SI.14Q: 85
 - In escalation to IV&V manager: 14
 - Software license issue resolution: 40
 - Goal is 30+ weekly
 - BSC Quality Assurance (QA) will choose and review packages weekly





Status: Transition Software Remediation

- Total number of transition items going forward to LA: 92
- Number ready for LA: 26
- Number of remaining items: 66
- Status of remaining items:
 - Items are being worked with a goal of 10 packages remediated and to Software Configuration Management week
 - BSC QA will choose and review packages weekly





Status: Quality Assurance Requirements and Description Revision 13 Software Independent Verification and Validation

- Total number of QARD 13 software items going forward to LA: 18
- Number ready for LA: 1
- Number of remaining items: 17
- Status of remaining items:
 - Awaiting final packages to IV&V

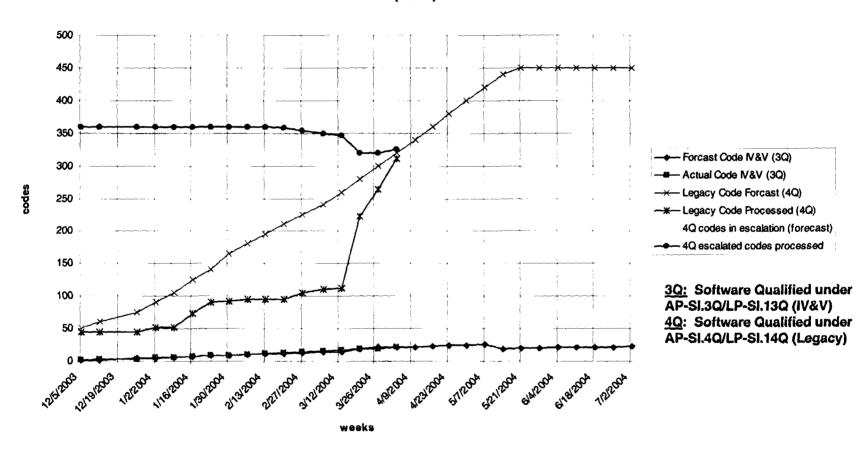




Quality "Q" Software Metrics

(as of April 15, 2004)





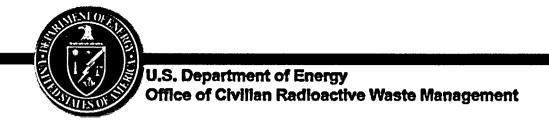
These numbers are based on the list of analysis model reports going forward to LA as of April 15, 2004.





Software Qualification Summary

- The DOE/BSC team has successfully addressed the issues associated with "Q" software management and has closed CR-102 (CAR 002)
 - DOE/Office of Quality Assurance verified the actions by selecting and auditing a sample of 25 documentation packages (each) from legacy software testing and transition software remediation
 - The "Q" software procedures were rewritten to include greater granularity/defensibility in the software documentation by using checklist, templates, and improved guidance information
- The lessons learned from these efforts are being carried forward in the testing, remediation, and IV&V efforts to ensure that the software used in support of LA meets DOE and BSC standards of high quality
- This project is on task to meet its June 30th delivery date





Audits

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

Lany Vaughan/Kany IVE Grooms
Office of Environmental Menecement
Office of Switch Recipe with Wester Menecement
US. Department of Energy

Wey 4, 2004 Les Weiges, Mexicoli

Environmental Management/Office of Civilian Radioactive Waste Management Audits

- Audits are of:
 - DOE High-Level Waste (HLW) and Spent Nuclear Fuel (SNF) **Quality Assurance (QA) Programs**
 - Several sites, e.g., West Valley Project, Savannah River Site
- Audits are joint Environmental Management (EM) and Office of Civilian Radioactive Waste Management (OCRWM) audit teams
 - Audit team lead from EM
 - Audit team combination of EM and OCRWM personnel
- Scope focuses on inputs to License Application (LA)





Environmental Management/Office of Civilian Radioactive Waste Management Audits

- Completed Audits
 - National Spent Nuclear Fuel program
 - 2 conditions adverse to quality (CAQs) identified
 - 2 noteworthy practices
 - Savannah River Defense Waste Processing Facility
 - Audit completed April 30, 2004





Environmental Management/Office of Civilian Radioactive Waste Management Audits

(Continued)

Audit Schedule - EM/OCRWM Audits of DOE HLW and SNF Quality Assurance programs

Audit Date	Organization to be Evaluated	Location	
March 2004	National Spent Nuclear Fuel Program (SNF)	Idaho Falls, ID	
April 2004	Savannah River Site (SRS) Defense Waste Processing Facility (HLW)	Aiken, SC	
May 2004	West Valley Demonstration Project (HLW)	West Valley, NY	
June 2004	Idaho National Engineering and Environmental Laboratory (SNF)	Idaho Falls, ID	
July 2004	Office of River Protection-Hanford (HLW)	Richland, W A	
August 2004	Hanford (SNF)	Richland, W A	
September 2004	SRS (SNF)	Aiken, SC	





Quality Assurance Audits

- Internal Audits completed
 - BSC Records Management Integrated Compliance Audit (BSC Lead), 5 CAQs identified
 - BSC Procurement Integrated Compliance Audit (BSC Lead), 6 CAQs
 - Lawrence Livermore National Laboratory Integrated Compliance Audit (Office of Quality Assurance Lead), 5 CAQs



Quality Assurance Audits

(Continued)

- 35 Surveillances completed
- Examples of completed Surveillances
 - BQA-SI-04-002, Analysis Reports per AP-SIII.9Q, 9 CAQs
 - BQA-SI-04-012, Causal Analysis Process, No CAQs
 - BQA-SI-04-014, Legacy Software Verification and Validation,
 2 CAQs
 - BQA-SI-04-048, Independent Technical Evaluation of Model Development and Validation, 9 CAQs
 - OQA-SI-04-003, BSC Inter-Contractual Purchase to Idaho
 National Engineering and Environmental Laboratory,
 1 Significant CAQ, 2 CAQs
 - OQA-SI-04-006, BSC Direct Support Contractors, 1 CAQ
 - OQA-SI-04-010, Corrective Action Program Processing, No CAQs
 - OQA-SI-04-014, Staff Augmentation Job Function Matrix, No CAQs



Quality Assurance Audits

- Scheduled performance-based surveillances
 - Analysis Reports May
 - Software (limited scope) June
 - Features, Events, and Processes August



Quality Assurance Audits

(Continued)

Internal Audit Schedule

Audit Dates	Audit Number	Audit Description	Lead Organization
Apr-04	OCRWMC-LLNL-04-07	Compliance Audit of LLNL	OQA
May-04	OCRWMC-USGS-04-09	Compliance Audit of USGS	BSC
May-04	OCRWMP-BSC-04-16	Performance-Based Audit of Science Analysis	BSC
Jun-04	OCRWMC-LANL-04-08	Compliance Audit of LANL	BSC
Jun-04	OCRWMC-SNL-04-11	Compliance Audit of SNL	BSC
Jul-04	OCRWMC-LBNL-04-10	Compliance Audit of LBNL	BSC
Jul-04	OCRWMC-BSC-04-03	Compliance Audit of OCRWM Corrective Action Program	OQA
Jul-04	OCRWMP-BSC-04-05	Performance-Based Audit of BSC Performance Assessment (Part 1)	OQA
Aug-04	OCRWMP-BSC-04-17	Performance-Based Audit of BSC Performance Assessment (Part 2)	OQA
Aug-04	OCRWMC-OQA-04-12	Compliance Audit of OQA	OQA
Aug-04	OCRWMC-ORD-04-13	Compliance Audit of ORD and OCRWM	OQA
Sep-04	OCRWMP-BSC-04-14	Performance-Based Audit of Repository Design Project	BSC
Sep-04	OCRWMC-BSC-04-15	Compliance Audit of BSC, East and West/DC	OQA



