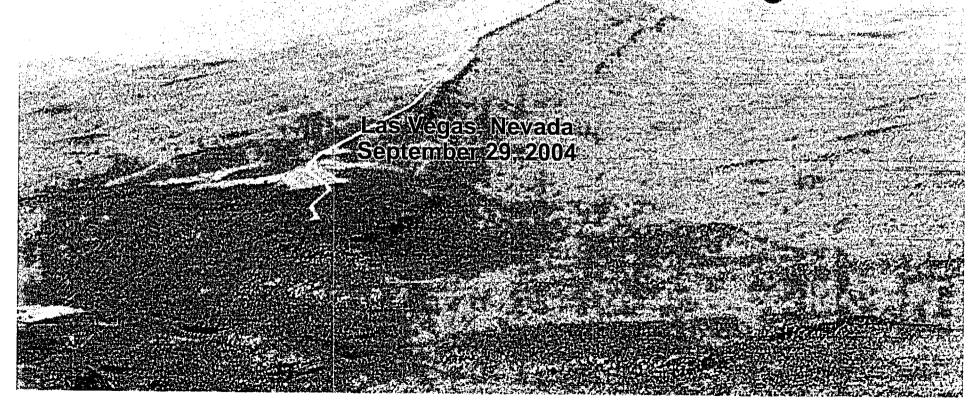
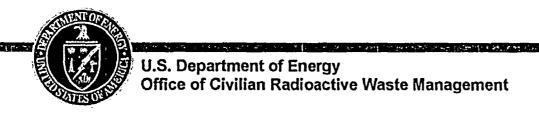


NRC/DOE Quarterly Quality Assurance Meeting







NRC/DOE Quarterly Quality Assurance Meeting

Presented to:

NRC/DOE:Quarterly:Quality:Assurance:Meeting

Presented b

R:Dennis Brown

OFFICE OF QUALITY ASSURVANCE (OQA)

September 29: 2004

Las-Vegas NV

Quality Assurance Overview

- © Corrective Action Program Oversight
- Level A Condition Reports
- Office of Quality Assurance Audits/Surveillances
- Environmental Management Activities
- Quality Assurance Management Policy
- Trend Evaluation and Reporting
- Human Performance





Quality Assurance Requirements and Description Status

- QARD Rev 14 (April 1, 2004) ORD Organizational Realignment
- QARD Rev 15 (August 13, 2004) Allowed for line ownership of the Corrective Action Program and addressed the applicability of items important to safety and important to waste isolation
- QARD Rev 16 (August 23, 2004) Realigned OQA to report to ORD
- QARD Rev 17 (Signed September 14, 2004) Incorporates the requirements of 10 CFR 63.142 and addresses the acceptance criteria of NUREG 1804





Corrective Action Program Oversight

- Bechtel/SAIC (BSC) Quality Assurance (QA) reviewing 100% of Level C Condition Reports (CRs) processed by BSC
- BSC QA performing surveillances of Corrective Action Program (CAP) implementation
- Office of Quality Assurance (OQA) reviewing 100% of Level C CRs processed by Department of Energy (DOE)
- OQA observing BSC QA surveillances
- Results show effective implementation of CAP by BSC
- Office of Quality Assurance (OQA) CAP surveillance in FY05
- OQA CAP audit in FY05





Level A Condition Reports

- Condition Report (CR) 0082 Radiation Program Procedures Do Not Meet Quality Assurance and Description Document (QARD) Requirements
- CR-0099 (BSC-01-C-001) Validation of Analyses and Models is Not Being Documented
 - OQA Surveillance OQA-SI-04-023
- CR-1720 Unqualified Supplier Performing Quality Affecting Work
- CR-3235 Improper CR Closure, Ineffective Corrective Actions





Office of Quality Assurance Audits/Surveillances

- Regulatory Integration Team Part 2
 (surveillance) No Conditions Adverse to Quality (CAQs)
- Compliance Audit of Design 7 CAQs
- Compliance Audit of Office of Repository Development (ORD) – 8 CAQs
- Compliance Audit of OQA
- Compliance Audit of OCRWM (East)
- Compliance Audit of BSC (East)
- Compliance Audit of BSC (West)
- BSC QA Audit Activity Update





Environmental Management Audits

Completed

- Desktop Audit of Office of River Protection High Level Waste (HLW)
- Hanford Spent Nuclear Fuel (SNF) 8 CAQs

In Progress

Limited Scope Audit of Savannah River HLW

Planned

- Office of River Protection HLW November 2004
- Savannah River SNF December 2004





Quality Assurance Management Policy

- Overall OCRWM QA Policy Quality Assurance Management Policy (QAMP)
 - Quality Assurance Requirements & Description Document (QARD)
 - Augmented Quality Assurance Program (AQAP)
 - Cask Quality Assurance Program (CQAP)





Trend Evaluation and Reporting

Recent 3rd Quarter FY2004 Results

- Consistent performance in reporting CRs (42/month for the 12 months)
- Increase in the number of CRs identified through self-assessment activities
- Adverse trend related to the Project Requirements Document (actions addressed in CR-2343)
- Improvements made to AP-SIII.9Q&10Q and AP-3.15Q as part of Regulatory Integration Team process (revising procedures to reflect actual practices)
- Human error, 51% of CR causal factors (Human Performance Improvement Team formed, Management Directive written (GM-BC-14) and improvement plan drafted and approved to address this causal factor)



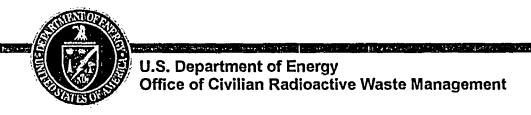


Human Performance

- CR 1772 established a two-year YMP Management Plan for Human **Performance**
 - **Short-term Objectives:**
 - Improve learning systems
 - **Develop Observation and Coaching Program**
 - Educate workforce on principals and practices
 - Reinforce the practice of desired behaviors
 - **Near-term Objectives:**
 - **Create an Event Prevention Mindset**
 - **Long-term Objective:**
 - YMP culture reflective of INPO-1 rated nuclear quality and safety cultures
- **Human Performance Competency** 0
 - **DOE Human Performance Workshop**
 - **BSC Human Performance Team**
 - Performance Indicators









Quality Assurance Requirements and Description, Revision 17

Presented to:

NRC/DOE Quarterly Quality Assurance Meeting

:Presented by

Michael L. Ushafer

September 29: 2004

Easavegas ANevada.

Quality Assurance Requirements and Description, Revision 17

The QARD Rev 17 is:

- The Yucca Mountain Project's QA Program that meets the regulatory requirements of 10 CFR 63.142
- The Yucca Mountain Project's QA Program that addresses the acceptance criteria of NUREG 1804, Section 2.5.1, Quality Assurance Program, and the commitments listed in 2.5.1.5, with some justified exceptions, alternatives and clarifications
- The Yucca Mountain Project's QA Program up to time of receipt of license to receive and posses
- Similar to previous NRC accepted QARD revisions in the level of detail and the description of programs and processes





Quality Assurance Requirements and Description, Revision 17

- To facilitate an accurate and thorough review, the following actions were taken:
 - Fifteen (15) requirements matrices were developed
 - Technical product impact analysis was performed
 - Added OQA/NQS staff expertise
 - Internal and external reviews were conducted and comments resolved





Quality Assurance Requirements and Description (QARD) in FY04

- QARD Rev 14 (April 1, 2004) ORD Organizational Realignment
- QARD Rev 15 (August 13, 2004) Allowed for line ownership of the Corrective Action Program and addressed the applicability of items important to safety and important to waste isolation
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Regulatory Basis Changes in QARD Rev 17

- From 10 CFR 50 App B to 10 CFR 63.142 (No significant Change)
- From Review Plan 1989 to NUREG-1804 (Similar Requirements)
- Consensus standard
 - Adoption of Regulatory Guide 1.28 and ANSI/ASME NQA-1-1983
 - Adoption of Regulatory Guide 1.8 and ANSI/ANS 3.1-1993
- Additional specific required commitment documents:
 - NQA-1-2000, Subpart 2.7 NUREG-1563

ASNT-TC-1A-1980

NUREG-1636

NURFG-1297

NUREG-1298

- NRC Information Notice 86-21
- The QARD continues to provide the QA controls for scientific investigation - including data, models, and software in specific supplements





Notable Program/Process Changes in QARD Rev 17

Software

 From NUREG-0856 and NUREG/CR 4640 to NQA-1-2000, Subpart 2.7

Commercial Grade Definitions

- Critical Characteristics
- Dedication
- Adoption of EPRI NP-5652

Electronic Records

Adoption of RIS 2000-18

Allowance for Principal Contractors to implement their own specific QA program

- Removed the term "Affected Organization"
- Must meet the provisions of the QARD
- Must be approved by DOE/YMP
- Added Waste Generator clarification statement





ReferemceTitles

- 10 CFR 50 App B "Quality Assurance Criteria"
- 10 CFR 63.142 "Quality Assurance Criteria"
- Review Plan, 1989 "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions"
- NUREG-1804, Rev 2 "Yucca Mountain Review Plan"
- Regulatory Guide 1.28 "Quality Assurance Requirements (Design and Construction)"
- ANSI/ASME NQA-1-1983 "Quality Assurance Program Requirements for Nuclear Power Plants"
- Regulatory Guide 1.8 "Qualification and Training of Personnel for Nuclear Power Plants"
- Standard ANSI/ANS 3.1-1993 "Selection and Training of Nuclear Power Plant Personnel"
- NQA-1-2000, SP 2.7 "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications"
- NUREG-1563 "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program"
- ASNT-TC-1A-1980 "Recommended Practice for Nondestructive Testing Personnel Qualification and Certification"
- NUREG-1636 "Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs"
- NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories"
- NUREG-1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories"
- NRC Information Notice 86-21 "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders"
- Electric Power Research Institute (EPRI) NP-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications"
- Regulatory Issue Summary (RIS) 2000-18 "Guidance on Managing Quality Assurance Records in Electronic Media"



