



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



NRC/DOE Quarterly Quality Assurance Meeting

Las Vegas, Nevada
September 29, 2004



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



NRC/DOE Quarterly Quality Assurance Meeting

Presented to:
NRC/DOE Quarterly Quality Assurance Meeting

Presented by:
R. Dennis Brown
OFFICE OF QUALITY ASSURANCE (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**
 - DOE Human Performance Workshop
 - BSC Human Performance Team
 - Performance Indicators





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



Quality Assurance Requirements and Description, Revision 17

Presented to:
NRC/DOE Quarterly Quality Assurance Meeting

Presented by:
Michael L. Ulshafer

September 29, 2004
Las Vegas, Nevada

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 possess
 - 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**
- **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**



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
 - NUREG-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**



Reference Titles

- 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”

