



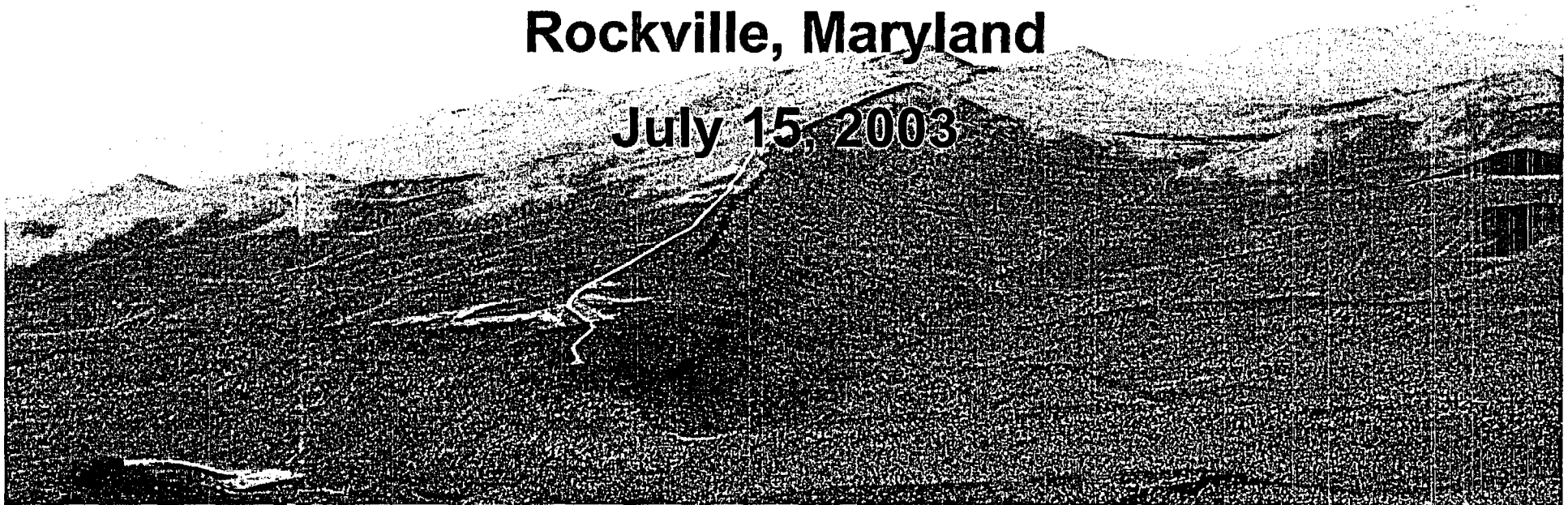
U.S. Department of Energy
Office of Civilian Radioactive Waste Management



DOE/NRC Quarterly Quality Assurance Meeting

Rockville, Maryland

July 15, 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

July 15, 2003
Rockville, Maryland



Quality Assurance Overview

(Continued)

- **Policy and Procedures**
 - **Quality Assurance Requirements and Description (QARD) status**
 - **AP-5.1Q review process**
 - **Organization/interface requirements**
 - ♦ **Procedures (DOE and BSC)**



Quality Assurance Overview

(Continued)

- **Assessments - 3rd Quarter**
 - **Audit BSCP 03-07 of software**
 - ♦ 8 Deficiency Reports (DRs) issued
 - ♦ Marginally effective
 - **BSC specific oversight activities**
 - ♦ 21 internal surveillances - 8 DRs issued
 - ♦ 8 external supplier audits - 14 DRs issued
 - **Integrated internal audits**
 - ♦ U.S. Geological Survey (USGS) - BSC Lead Compliance Audit - 1 Quality Observation (QO) issued
 - ♦ Los Alamos National Laboratory (LANL) - BSC Lead Compliance Audit - 1 QO issued

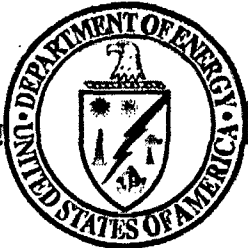


Quality Assurance Overview

(Continued)

- **DOE Line Management Accountability**
 - Quality focus stand down activities continue
 - Monthly operating review
 - Management interface meetings
 - Quality Engineering integrated with line management
 - ♦ Corrective action resolution
 - ♦ Weekly Condition/Issue Identification and Reporting/Resolution System (CIRS)/DR/Corrective Action Report (CARs) meetings





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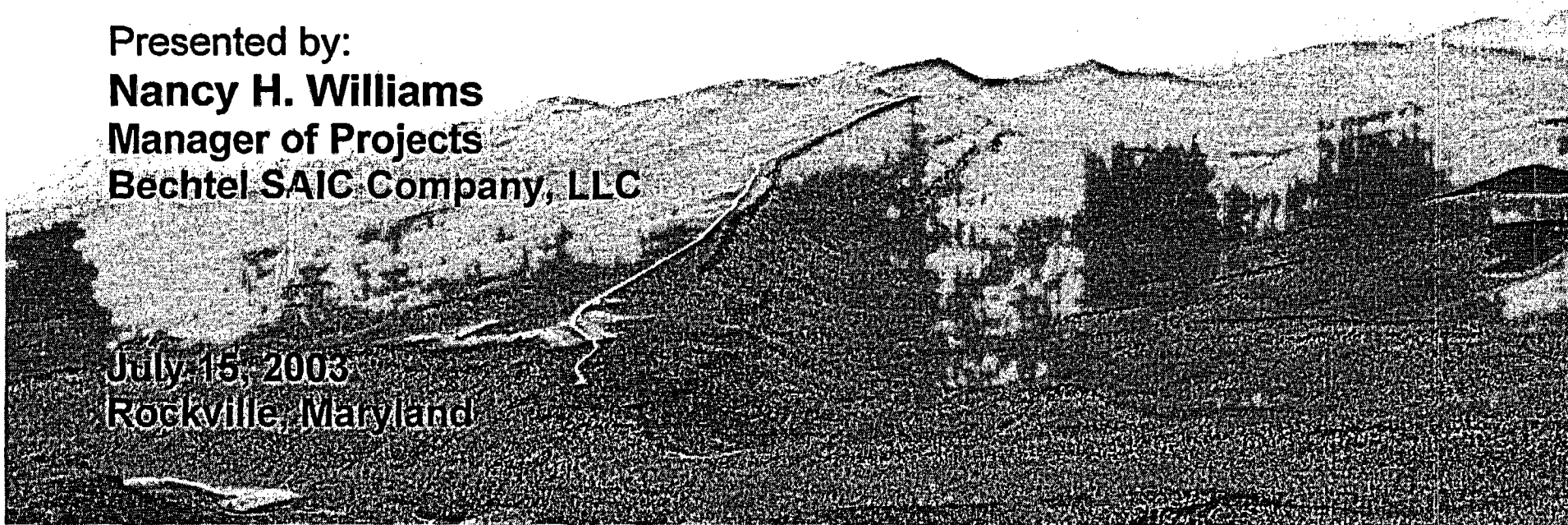


Model Validation (CAR BSC-01-C-001)

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Nancy H. Williams
Manager of Projects
Bechtel SAIC Company, LLC

July 15, 2003
Rockville, Maryland



Model Validation Corrective Action Report Actions

- **11 of 11 actions identified in September 24, 2002 response (as modified by amended response) are complete**
- **One action completed since date of the last Quarterly Quality Assurance (QA) meeting**
 - **Use of performance indicators to assess the effectiveness of the self-identification process**
 - **Performance indicators show process of self-identification is effective**

Model Validation Corrective Action Report Actions

(Continued)

Status of In-Process Reviews (as of June 30, 2003)

- **65 model reports are being developed under the revised procedure to support the LA**
 - Includes models supporting features, events and processes screening and implementation of the criticality methodology
 - Technical Work Plans for each model, including model validation criteria, approved by the Chief Science Officer (CSO)
 - 51 model reports started in-process model validation review
 - 42 model reports approved by CSO during in-process model validation review
 - 22 model reports completed CSO technical review





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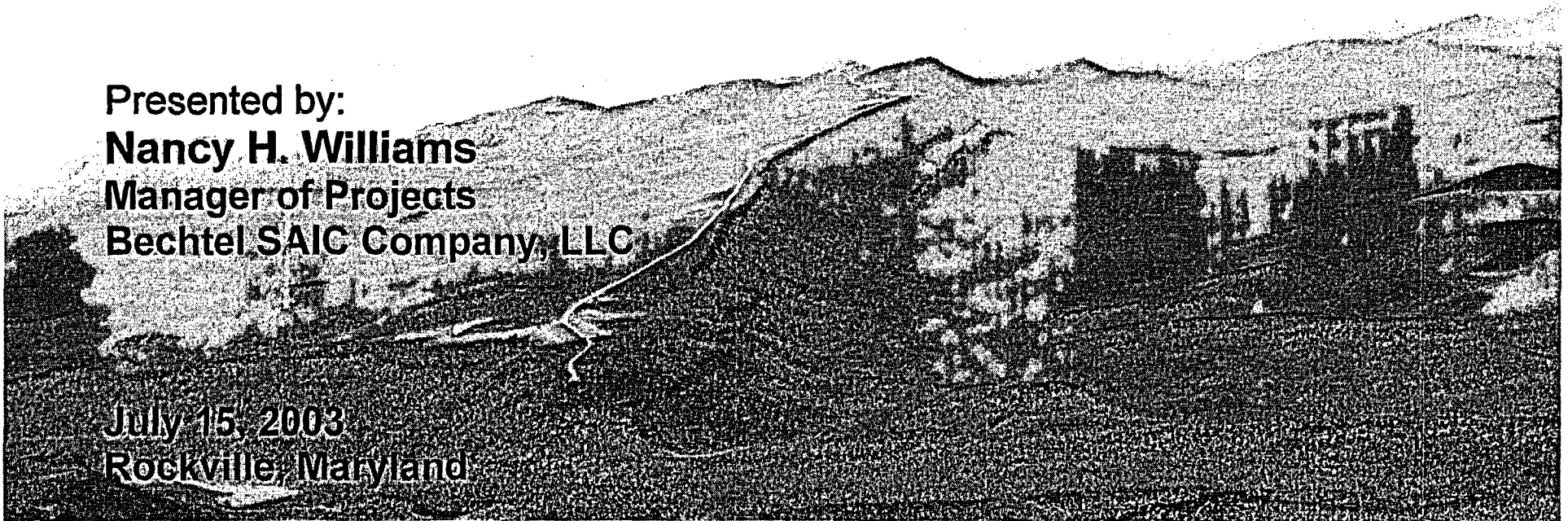


Software Development (CAR BSC-01-C-002)

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
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Bechtel SAIC Company, LLC

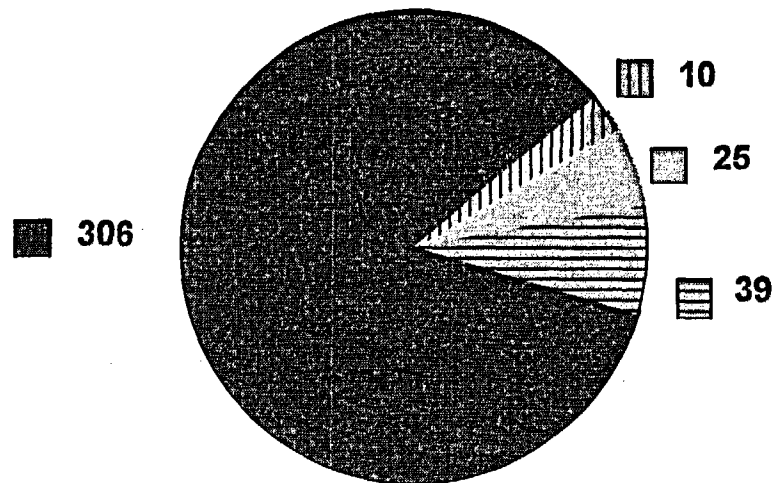
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Software Code Status

(Counts as of June 26, 2003)

Codes (Estimate)

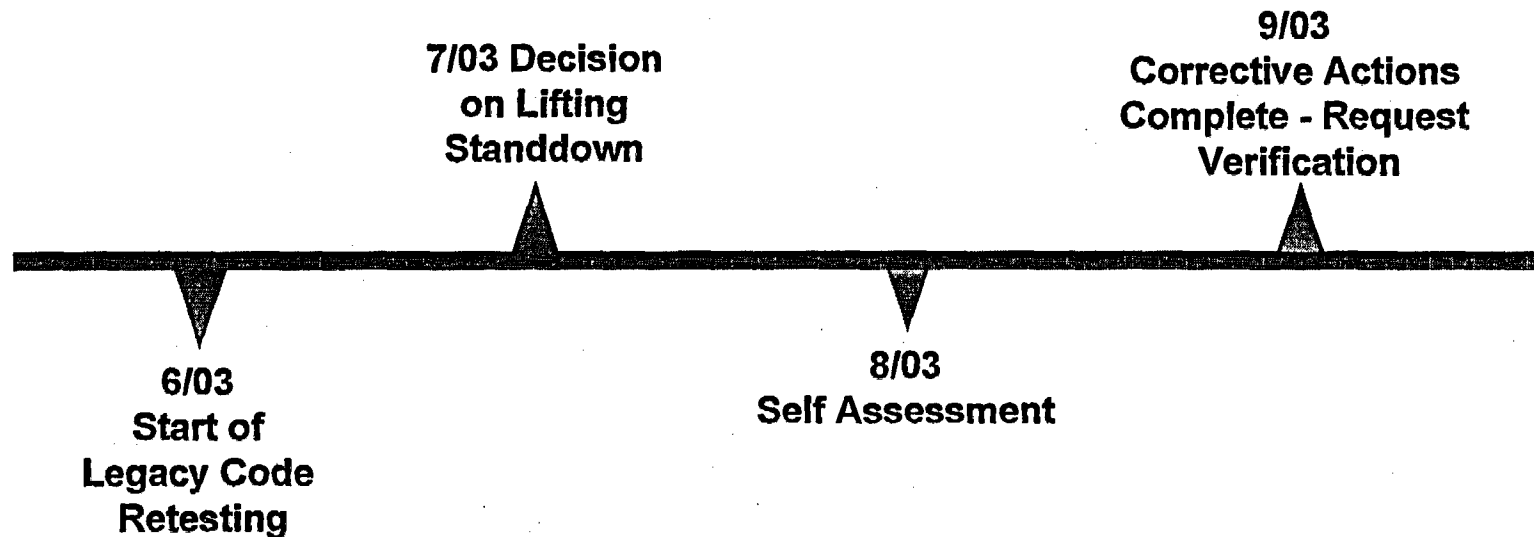


Total Codes: 380

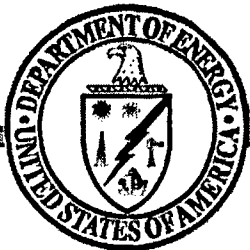
-  **Qualified and completed IV&V: 39 (10%)**
-  **Submitted for IV&V: 10 (3%)**
-  **Qualified, Need Re-testing (Legacy Software): 306 (80%) estimated**
-  **Under Development = 25 (7%)**



Timeline for Completion



YUCCA MOUNTAIN PROJECT



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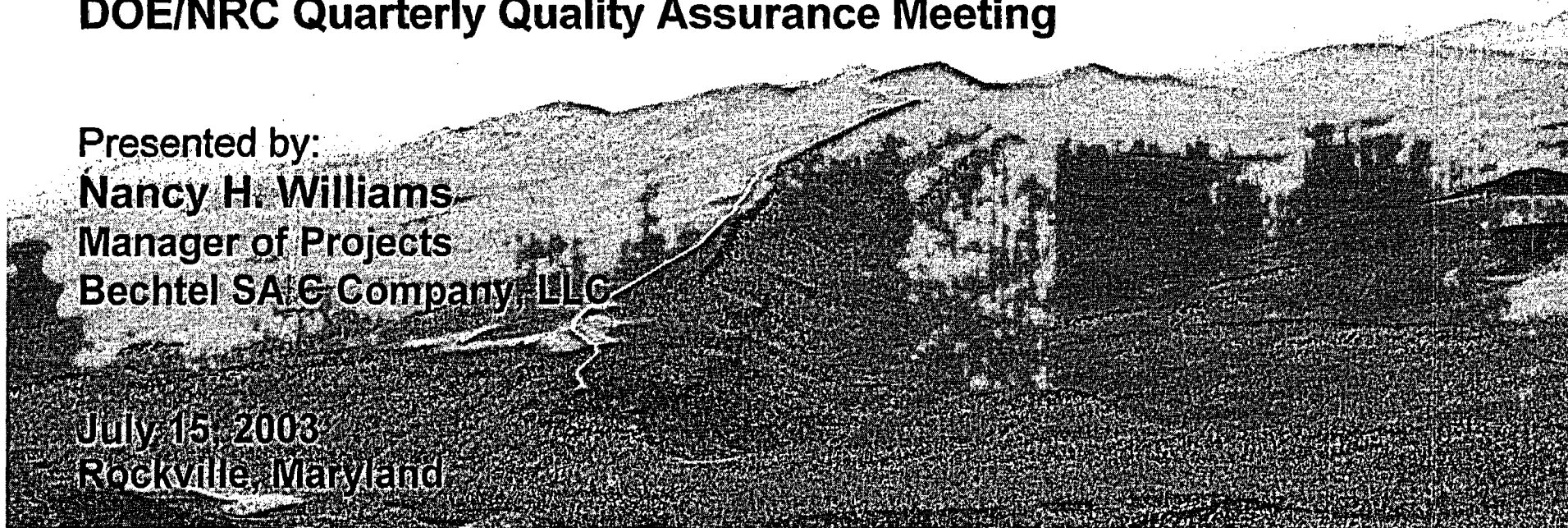


Management of Data (CAR BSC(B)-03-C-107) and Data Qualification

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Nancy H. Williams
Manager of Projects
Bechtel SAIC Company, LLC

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Data Confirmation Project

- **Incorporated into checking and review functions**
- **Separate data checklist developed**
 - **Phase I addresses compliance issues**
 - **Phase II will address technical adequacy**
- **Checklist review will document lessons learned for process improvements**

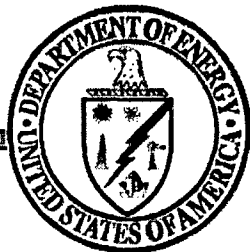


Metrics

- **Data Confirmation Project**
 - **Approximately 120 technical products* support LA**
 - ♦ **35 products have completed Phase I**
 - ♦ **4 products completed Phase II**

***Analysis/model reports (AMRs) and technical reports**





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

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

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

- **OQA Evaluation**

- **OQA provided a write-up of concerns to the CAR response and Root Cause Report - June 19, 2003**
- **11 Corrective Action (CA) issues required a response and 21 issues required clarification to the Root Cause Report**
- **BSC provided responses to OQA's comments on July 7, 2003**





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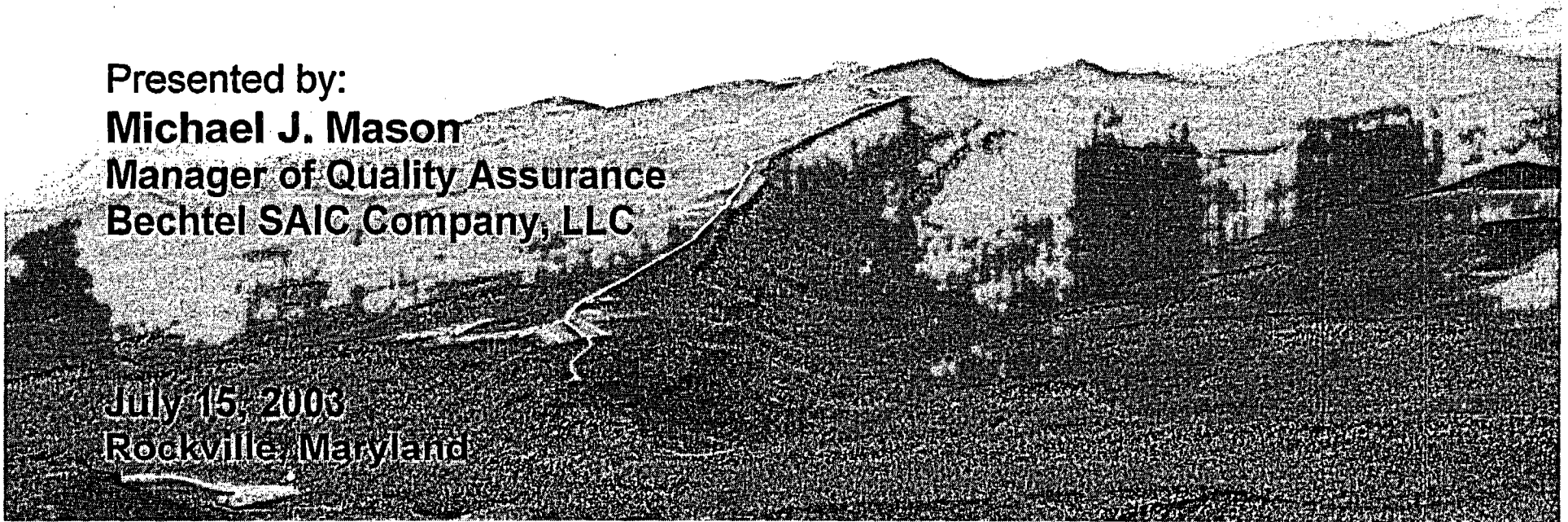
Training and Qualification

CAR BSC-02-C-001

Presented to:
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Manager of Quality Assurance
Bechtel SAIC Company, LLC

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Corrective Action Report

BSC-02-C-001

(Continued)

- **Corrective Action Report (CAR) closure dependent on closer of Deficiency Reports (DRs)**
 - **DR BSC-01-D-129: Training to procedures not performed within time requirements**
 - ♦ This DR was closed February 12, 2003
 - **DR BSC(B)-02-D-159: VoEE of personnel not located**
 - ♦ Where required, the VoEE has been documented for all BSC and subcontractor personnel
 - ♦ This DR was closed May 14, 2003
 - **DR BSC(O)-02-D-176: VoEEs do not meet Position Descriptions, no evidence of Position Descriptions for employees, VoEEs not approved by Functional Manager, and work performed prior to VoEE approval**
 - ♦ DR is still open with closure scheduled for September 30, 2003





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Office of Civilian Radioactive Waste Management



Design Oversight

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

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

July 15, 2003
Rockville, Maryland



Design Oversight

Quality Engineering's Reviews Controlled by Checklists

QE Checklists	
Engineering Products	
<ul style="list-style-type: none"> • AP-3.11Q, Technical Reports • AP-3.12Q, Design Calculations and Analyses • AP-3.15Q, Managing Technical Product Inputs • AP-3.19Q, Specifications • AP-3.24Q, Drawings 	<ul style="list-style-type: none"> • AP-3.25Q, Design Criteria • LP-3.26Q, System Description Documents • LP-4.5Q, Purchase Requisitions and Procurement Documents • AP-15.3Q, Control of Technical Product Errors
Science Products	
<ul style="list-style-type: none"> • AP-2.27Q, Planning for Science Activities • AP-3.11Q, Technical Reports • AP-15.3Q, Control of Technical Product Errors • AP-SIII.2Q, Qualification of Unqualified Data 	<ul style="list-style-type: none"> • AP-SIII.7Q, Scientific Investigation Laboratory and Field Testing • AP-SIII.9Q, Scientific Analyses • AP-SIII.10Q, Models
General Checklist Content Areas	
<ul style="list-style-type: none"> • General Subjects • Revision/Change Process • Document Contents • Software Use & Control • Document Input Reference System • Approval Process 	



Design Oversight Quality Engineering Capability Matrix

Engineering

C=Civil

E&IC=Electrical/
Instrumentation & Control

G=General Engineering

M=Mechanical

N=Nuclear

Infrastructure

DC=Document Control

L=Licensing

RM=Records Mgmt.

P=Procurement

S=Software

T=Training

Current Assignment	Capability Matrix											
Name	Engineering					Science	Infrastructure					
Science	C	E&IC	G	M	N		DC	L	RM	P	S	T
Quality Engineer			X									
Quality Engineer						X						
Quality Engineer			X									
Quality Engineer						X						
Quality Engineer						X						
Quality Engineer	X		X									
Quality Engineer												
Quality Engineer				X	X							
Quality Engineer						X						
Engineering												
Quality Engineer				X								
Quality Engineer		X										
Quality Engineer			X									
Quality Engineer				X								
Quality Engineer				X	X							
New Hire		X										
New Hire			X									
New Hire			X									
Infrastructure												
Quality Engineer							X	X	X			X
Quality Engineer				X	X						X	
Quality Engineer							X		X			X
Quality Engineer							X		X			X
Quality Engineer										X		
Quality Engineer							X	X	X			X
Quality Engineer							X	X	X			X
Quality Engineer										X		
Transfer							X		X			



Design Oversight

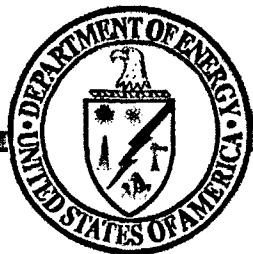
- **Audits and Surveillances**
 - **Audits**
 - ♦ Design audit scheduled for August, 2003
 - **Surveillances**
 - ♦ 10 conducted on design activities through 3rd quarter FY2003
 - ♦ 10 scheduled for design activities during 4th quarter FY2003



Design Oversight Summary

- **Design is a key program activity that is increasing in importance**
 - **BSC QA has the skill mix and numbers of Quality Engineers to ensure adequate design oversight based on design schedules**
- **Science oversight will continue**





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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

July 15, 2003

Rockville, Maryland

Corrective Action Program

(Continued)

- **Quality Assurance involvement in the Corrective Action Program (CAP)**
 - **Quality Assurance still issues Condition Reports, no loss of independence**
 - **Quality Assurance Representative:**
 - ♦ **Reviews each Condition Report before issuance**
 - » **Determines significance**
 - » **Determines if Stop Work Order needed**
 - ♦ **Approves corrective action plan**
 - ♦ **Verifies corrective actions complete**



Corrective Action Program

(Continued)

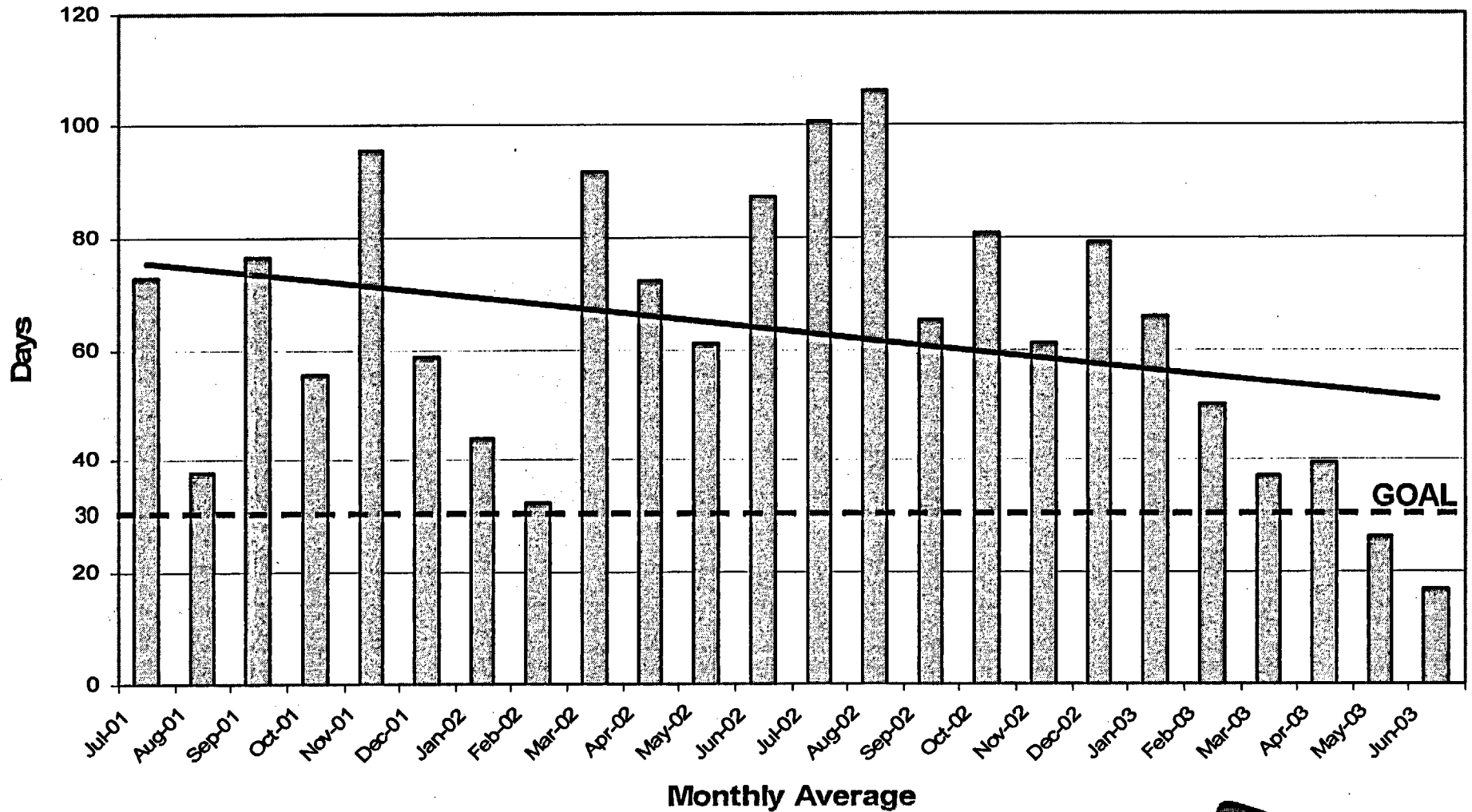
- **Improvements (September 30, 2003)**
 - **Benchmarked program against:**
 - ♦ **Institute of Nuclear Power Operations (INPO's), *Principles for Effective Self-assessment and Corrective Action Programs***
 - ♦ **Nuclear Energy Institute (NEI), *Corrective Action Program Benchmarking Report* (NEI, LP-0002)**
 - **Communications plan**
 - **Training plan**



Corrective Action Program

(Continued)

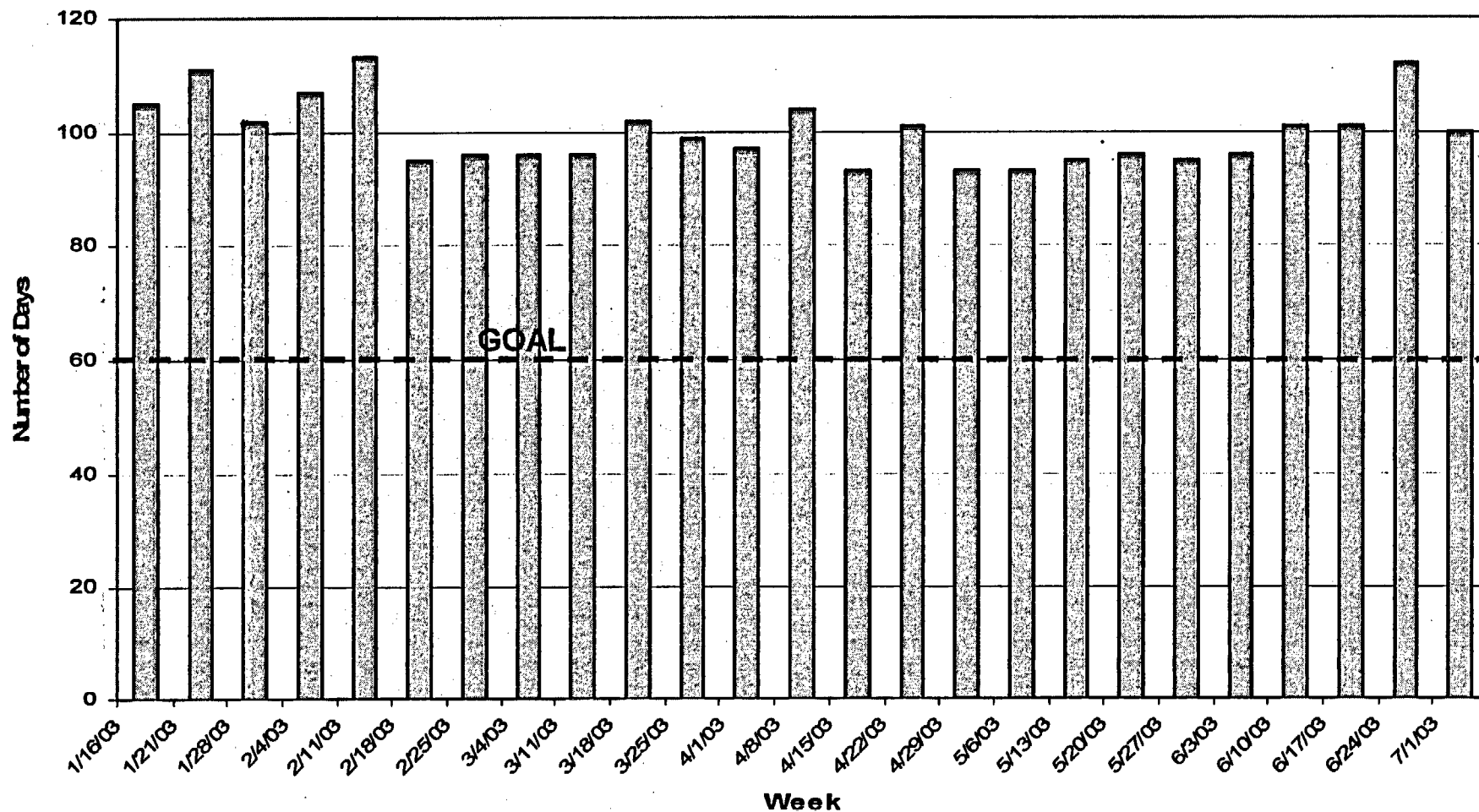
Days to Obtain Acceptable DR Response (as of July 3, 2003)

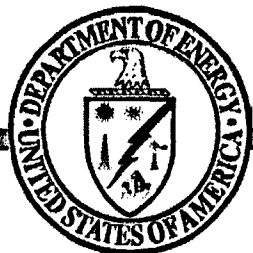


Corrective Action Program

(Continued)

Average Days Open - DRs (as of July 3, 2003)





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Office of Civilian Radioactive Waste Management



Trending Program Improvements

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Kerry Grooms
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

July 15, 2003
Rockville, Maryland

Trending Program Improvements

(Continued)

- **Actions Taken**

- Cause codes changed
 - ♦ DOE Occurrence Reporting and Processing System (ORPS) cause codes being used
- Condition Reports from May 2002 to May 2003 recoded
- New Condition Reports are being coded
- Open Condition/Issue Identification and Reporting/Resolution System (CIRS) items recoded
- All CIRS items being recoded
- New CIRS items are being coded

- **Common coding increases population for trending**



Trending Program Improvements

(Continued)

<u>Major Contributor</u>	<u>Major Contributing Factor</u>	<u>Root Cause</u>
Management problem (35%)	Management methods LTA* (62%)	Management policy, guidance, expectations not well defined, understood or enforced (73%)
Human performance LTA*(34%)	Skill based error (51%)	Check of work LTA* (48%)
Communications LTA* (21%)	Written communications content LTA* (83%)	Ambiguous instructions or requirements (39%)

*LTA = less than adequate



Trending Program Improvements

(Continued)

- Changing reporting frequency to quarterly**
- Transferred trend reporting to BSC**
 - ♦ BSC collects and analyzes data**
 - ♦ BSC identifies corrective actions**
 - ♦ DOE still responsible for issuing quarterly report**
- Continue to improve**





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Quality Assurance Requirements and Description Document Status

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Quality Assurance Requirements and Description Document Status

(Continued)

- **QARD Revision 14 approach**
 - **24 integrated teams of DOE Office of Quality Assurance (OQA), DOE Line, and contractor personnel**
 - ♦ **Teams to develop positions on aspects of 10 CFR 63 and the YMRP to assure compliance**
 - **OQA developed crosswalk checklists of YMRP and Part 63 requirements to assure coverage in the QARD**

Quality Assurance Requirements and Description Document Status

(Continued)

- **Examples of compliance checklists**
 - 10 CFR 63 Subpart G, Quality Assurance
 - NUREG-1804, *Yucca Mountain Review Plan*, final draft, Section 2.5.1, Quality Assurance Program



10 CFR 63-Subpart-G^a - QARD^b Compliance Matrix

a- Revised as of January 1, 2003

b- Quality Assurance Requirements and Description, Draft Revision 14

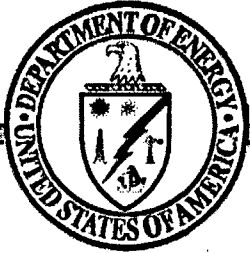
Example

Subpart G - Quality Assurance

[SOURCE DOCUMENT]

10 CFR 63 SECTION	10 CFR 63 REQUIREMENTS	QARD SECTION
.141	Scope	
	As used in this part, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, and components will perform satisfactorily in service.	
	Quality assurance includes quality control, which comprises quality assurance actions related to the physical characteristics of a material, structure, component, or system to predetermined requirements.	
.142	Quality Assurance Criteria	
(a)	<i>Introduction and Applicability</i>	
	DOE is required by 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities.	
	These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies, facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities.	
	The description must indicate how the applicable quality assurance requirements will be satisfied.	
	DOE shall include information pertaining to the managerial and administrative controls to be used to ensure safe operation in its safety analysis report.	





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Integration and Coordination of Audits

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Integration and Coordination of Audits

(Continued)

13 Audits

- **After Integration**
 - **13 audits scheduled for the remainder of FY-2003**
 - ♦ **10 are joint audits**
 - ♦ **3 are OQA only audits**
 - » **Office of Repository Development (scope)**
 - » **Software (scheduling)**
 - » **Annual audit of OQA (scope)**

Integration and Coordination of Audits

(Continued)

- **Data, Software and Modeling audits coordinated by**
 - **Sample selection overlap**
 - **Maintaining team dynamics with consistent team membership**
 - **Conducting audits in sequence**



YUCCA MOUNTAIN PROJECT

6 of 6