ENCLOSURE 1

U. S. Nuclear Regulatory Commission/U. S. Department of Energy
Quarterly Quality Assurance
and
Key Technical Issues Status Meeting
Minutes

Las Vegas, Nevada
April 17, 2001

On April 17, 2001, the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) conducted meetings on Quality Assurance (QA) and on Key Technical Issues (KTI) Status.

Quality Assurance

Model validation was discussed in some detail. Several Deficiency Reports regarding model validation have been issued recently and a Suspect Trend Identification Report is being prepared. It appears likely that a Corrective Action Request will be issued on this topic. The DOE believes the issue is primarily related to documentation of models. The NRC expressed concern that there may be a deeper underlying issue. The NRC asked if a revision to the Quality Assurance Requirements Document would be needed to help resolve the requirements, and DOE responded that such a revision might be needed.

The NRC expressed a strong interest in DOE plans to provide an evaluation of the impact of unqualified data and software as a part of the appropriate site recommendation (SR) supporting document submittal. Initially, this evaluation was planned to be included with the SR consideration report, which is no longer a part of the planned documents. DOE reiterated its commitment to provide an impact evaluation of any unqualified data and software supporting SR by the end of August 2001.

Software qualification was also discussed in some detail (including clarification on statistics). The raw reported numbers can be interpreted to indicate that completion has slipped backwards. DOE explained that changes in ongoing work changed the population of software. In some cases, this may make the percentage complete decrease despite the fact that work is being completed. DOE indicated that current plans are to close Deficiency Report LVMO-00-D-039 by September 18, 2001.

The NRC noted that it appeared that surveillance for the national laboratories and U.S. Geological Survey (USGS) were not being done. DOE indicated that due to limited resources, surveillance had decreased. However, it is planned in the future that surveillance of the national laboratories and USGS will increase.

Status of NRC Inspection Program

The NRC discussed the development of the Yucca Mountain Inspection Program and stated that NRC Region IV will be involved in the development and reviewing process.

The NRC also stated that the Yucca Mountain Inspection Manual Chapter and a few of the Inspection Procedures will be ready for issue within the fiscal year.

Key Technical Issues Status

Following the Quarterly QA Meeting, a breakout session was held on the status of the KTIs.

With regard to upcoming meetings, DOE indicated their goal for the Igneous Activities meeting was to bring as many issues as possible to closed or closed-pending. DOE also indicated that it was not clear why the NRC wanted a meeting on preclosure safety at this time.

The NRC indicated that they would provide a letter, on the record, outlining the preclosure safety areas it would expect DOE to discuss in any future license application. The NRC also indicated that the letter would identify several specific topics within these areas it would like DOE to discuss at the meeting. With regard to the Igneous Activity meeting, the NRC stated that they are primarily concerned with the Igneous Activity open items.

The NRC discussed the Microsoft Access database it uses to track agreements and the NRC's Open Item Tracking System (OITS), and indicated that all remaining issues in OITS have been closed or will be captured in KTI agreements. A report on the OITS will be issued shortly.

The NRC discussed a table showing the number of KTI agreements reached and their status. DOE requested a clarification to the table to indicate that open items are being resolved according to schedules agreed to with the NRC. The NRC discussed their review process of documents provided in support of the KTI agreements and indicated that it would formally document its review in letters to DOE. The NRC then discussed some KTI agreement issues that have been delayed and their current status.

Regarding an integrated Issue Resolution Status Report (IRSR), the NRC will use the 14 integrated subissue (ISI) model abstractions discussed in the Total System Performance Assessment Integration (TSPAI) IRSR. Future issue resolution technical exchange and management meetings should use the ISI framework to ensure all the KTI subissues are integrated properly. The transition to ISI framework from the present KTI structure will be discussed in a future meeting. Use of ISIs would start in Fiscal Year (FY) 2002. The Yucca Mountain Review Plan will also follow the ISI approach.

DOE proposed an August meeting on use of ISIs to allow preparation of FY 2002 Budget Guidance for Bechtel SAIC Company, LLC based on their understanding of the NRC plans. The NRC indicated that their approach was not finalized, and the process would evolve through discussions with the stakeholders.

DOE also requested a meeting this summer on the Integrated IRSR. DOE also indicated that they would like to see stabilization of the acceptance criteria. The NRC indicated that they were moving toward five generic acceptance criteria, previously used in IRSRs.

DOE requested that a "meeting on meetings" be held to allow agreement on the mix of meetings over the next six months. The NRC indicated that an interaction on OITS should be first. The NRC indicated that the KTI process is working well and recognizes that DOE is working to address issues. The NRC also indicated that the ISI process is the next correct step in the KTI resolution process.

Larry L. Campbell 8/14/00

Larry L. Campbell
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission

R. W. Clark

Robert W. Clark
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

April V. Gil

April V. Gil
Office of Licensing and
Regulatory Compliance
Yucca Mountain Site
Characterization Office
U.S. Department of Energy

ENCLOSURE 2

DOE/NRC Quarterly QA Meeting
Agenda
April 17, 2001
9:00 AM – 11:30 AM PST / 12:00 AM – 2:30 PM EST / 11:00 AM - 1:30 PM CST

DOE, 1551 Hillshire, Atrium, Las Vegas, NV 89134	NRC White Flint O3B4, Rockville, MD
490 L'Enfant Plaza, Washington, DC	SWRI (CNWRA) San Antonio, TX

9:00 AM	Introduction	
9:10 AM	Status of Model Validation	DOE
9:20 AM	Progress Made in Qualifying Data	DOE
9:35 AM	Progress Made in Qualifying Software	DOE
10:05 AM	Corrective Action Status (including DR-039)	DOE
10:30 AM	NRC Interfaces for Observing External Vendor Audits	NRC/DOE
10:45 AM	Status of NRC Inspection Program	NRC
11:00 AM	Results of the UZ and EBS PMR Audits	NRC/DOE
11:30 AM	Adjourn	

DOE/NRC KTI Status Breakout Session
Agenda
April 17, 2001
12:30 PM - 1:30 PM PST / 3:30 PM - 4:30 PM EST / 2:30 PM - 3:30 PM CST

DOE, 1551 Hillshire, Atrium, Las Vegas, NV 89134	NRC White Flint O3B4, Rockville, MD
490 L'Enfant Plaza, Washington, DC	SWRI (CNWRA) San Antonio, TX

12:30 PM	Status of KTI Subissues	NRC
12:40 PM	Status of KTI Agreements	NRC
12:50 PM	NRC Review Process of Documents Received Pertaining to KTI Agreements	NRC
1:00 PM	Plans for an Integrated IRSR, purpose, format and relationship with Sufficiency Review and YMRP	NRC
1:15 PM	Lessons learned (RDTME)	DOE
1:25 PM	NRC Chairman's response to Judy Treichel's letter	NRC
1:30 PM	Adjourn	

ENCLOSURE 3

13

ATTENDEE SIGN-IN
NRC/DOE QA MEETING
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
MYRLE RICE	INTERTECH Lincoln County	702 726 3658
Jim PEGUES	CITY OF LAS VEGAS	229-6862
Judy Treichel	NV NWTF	248-1127
Steve Frishman	NV NWOPO	775-687-3744
Jennivieve Novero	Beckman	29.55331
William J. Glasser	OQA QATSS	702 794 5014
DONALD T. KRISHA	BSC QA	702-295-6242
KENNON HESS	BSC	702-295-0502
William Watson	BSC	702-295-5550
John Kessler	EPRI	650-855-2069
ROBERT HASSON	OQA/QATSS	(702) 794-5023
Kristi A. Hodges	OQA/QATSS	(702) 794-1464

(14)

ATTENDEE SIGN-IN
NRC/DOE QA MEETING
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
E.v. Tiesenhausen	Clark County	702 455-5184
Mal Murphy	Nye County	360 943 5610
Frank Kratzinger	MTS	794-5057
Sam Horton	BSC QA	295-0304
Don Beckman	BSC Licensing	295-4392
George Hellstrom	DOE YMSCO	702-794-5519
Tim Gunter	DOE YMSCO	702-794-1343
April Gil	DOE/YMSCO/ORC	702 794-5578
Bob Clark	DOE-OQA	702 794 5583
Bob Andrews	BSC - Projects	702 295 5549
Robert Wemhauer	BSC - PROJECTS - IMTPI	702-295-3966
Bill Belke	NRC	702-794-5047
Bill Reamer	NRC	301-415-6537
Ri Chang	NRC	301-415-6612
Rod McCullum	NEI	202-739-8082
K M. Latta	NRC	702 794-5048
Judy Gebhart	BSC QA	702 295-4478
Christy Guedry	Sen John Ensign	702 388-6605
John F Pelletier	BSC/Sandia	702-493-2536
S. J. Cereghino	BSC - LA Project	702-295-4251

(15)

ATTENDEE SIGN-IN
NRC/DOE QA MEETING
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
SAM NOLES	BSC / LAP	702 295 6620
Chad Glenn	[redacted] NRC	702-794-5046
MARY McDANIEL	BSC / ENG	702-295-7590
Jim WHITCRAFT	BSC / ENGINEERING	702-295-4464
NANCY WILLIAMS	BSC/MGR. OF PROJ.	702-295-5143
HARVEY DOVE	BSC/QA	702-295-2797
Charles Sherrocks	BSC/CTO	702-295-6193

16

From Rockville

April 17, 2001, QA MEETING

LARRY L. Campbell	USNRC	(301) 415 5000
MANNY COMAR	US NRC	(301) 415-6074
TED CARTER	USNRC	(301) 415-6694
THOMAS MATUCA	US NRC	(301) 415-8563
King Stablein	US NRC	(301)-415-7445
Jim Curtiss	Winston & Strawn	(202) 371-5751
Jim Andersen	USNRC	(301) 415-5717
ROB MACDOUGALL	BSC/JKRA	202.479.2122
Bret Leslie	USNRC	(301) 415-6652

17

From: the Center in San Antonio

ATTENDEE SIGN-IN
NRC/DOE QA MEETING
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
Tom Trbovich	SwRI - CNWRA	210-522-3145
Amos E. Holt	SwRI - Q.A.	210-522-2076
Dow Davidson	Nye County - NWRPO QA	512 257 8128
Asad Chowdhury	CNWRA	210-522-5151
Don Dunavant	SwRI - QA	210-522-2942
Robert Brient	SwRI - QA	210-522-5537
Bruce Mabrito	CNWRA QA	210-522-5149
Wesley C. Patrick	CNWRA	210-522-5158
Ruthi Sofar	CNWRA	210-522-5252

Post-it® Fax Note 7671 | Date 4/17/0 | # of pages ▶ 1
To Marvin Cohen | From Bruce Mabrito
Co./Dept | Co.
Phone # | Phone # (210) 522-5149
Fax # (702) 794-5061 | Fax #

KTI BREAKOUT SESSION
QUARTERLY MANAGEMENT MEETING
NRC HEADQUARTERS
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
LARRY Campbell	NMSS/DWM/HLWB	(301) 415-5000
Bret Leslie	NMSS/DWM/HLWB	(301) 415-6652
Tim McCartin	NMSS/DWM	(301) 415-7285
Mysore(Raj) Nataraja	NMSS/DNM	301-415-6695
MANNY COMAN	NMSS/DWM	301-415-6074
King Stablein	NMSS/DWM/HLWB	301-415-7445
Jeff Ciocco	NMSS/DWM/HLWB	301-415-6391
Banad Jagannath	NMSS/DWM/HLWB	301-415 6653
Jim Andersen	NMSS/DWM/HLWB	301-415-5717

(9)

ATTENDEE SIGN-IN
NRC/DOE KTI STATUS BRIEFING MEETING
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
Evon Hasenyager	Clark County	702 455-5184
Bob Gamble	MTS/BAH	702-794-1440
Bob Bradbury	MTS/S+W	702-794-5424
R.M. Latta	U.S. NRC	702-795-5048
Jim Whitcraft	BSC - Engineering	702-295-4464
Jim Linhart	NSNFP	702 295-0366
Judy Treichel	NV NWTF	248-1127
Steve Frishman	NV NWPO	775-687-3744
Barbara McKinnon	MTS/BAH	7027945480
Jennivieve Nuno	BSC	295-5331
David Lanier	BSC Licensing	(702)-295-5331

10

ATTENDEE SIGN-IN

NRC/DOE KTI STATUS BRIEFING MEETING

APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
MYRLE RICE	INTERTECH Lincoln County	
Mal Murphy	Nye County	360-[illegible]-5610
John Kessler	EPRI	650-855-2069

(11)

ATTENDEE SIGN-IN
NRC/DOE KTI STATUS BRIEFING MEETING
APRIL 17, 2001

NAME	ORGANIZATION	PHONE NUMBER
Sam Hobbs	BSC / LAP	702-295-6620
George Hellstrom	DOE - YMSCO	DOE-794-5519
Dan BECKMAN	BSC/LICENSING	702-295-4392
S.J. CERGHINO	BSC - LA PROJECT	702-295-4251
April Gil	DOE/YMSCO	702 794-5578
TIM GUNTER	DOE/YMSCO	702-794-1343
Bill Reamer	NRC	301-415-6537
Bill Chang	NRC	301-415-6612
Rod McCullin	NEI	202-739-8082

ENCLOSURE 4

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

Model Validation Status

Presented to:
DOE/NRC Quarterly QA Meeting

Presented by:
Robert Andrews, Project Manager
Science and Analysis
Bechtel SAIC Company, LLC

April 17, 2001

Outline

- Background
- Historical Perspective
- Provide current information on model validation status
- Model validation documentation issues
- Summary of causes and path to resolution
- Summary

Background: Models at YMP

- Analysis Model Reports (AMRs)
- AMRs describe the development, testing, and use of models
- Model requirements, including validation, are procedurally controlled

Historical Perspective

- Prior to 1998, models and modeling were not explicitly procedurally controlled
- A Corrective Action Request (CAR) (LVMO-98-C-010) was initiated to place procedural controls on models and modeling
- AP-3.10Q was developed and implemented in 1999
- Initial products (AMRs) were produced using AP-3.10Q in 1999
- Audits performed in 1999 indicated deficiencies in implementation of AP-3.10Q with respect to the distinction between modeling and analysis

Historical Perspective (cont.)

- AP-3.10Q was revised and training conducted in early 2000
- AMR production continued with the completion of 122 AMRs
- Further audits indicated model validation was being inadequately documented and resulted in three DRs
  - DR-119
  - DR-007
  - DR-050
- In addition, a Suspect Trending Investigation Report (STIR) has been initiated (but results are not yet available from that investigation)

Model Validation Documentation Issues

- All issues identified to date are documentation related, not fundamental flaws in the modeling
- Documentation issues include:
  - Some AMRs have no single specific section of the report that contains consolidated model validation information (i.e., information spread across a number of sections) making it difficult to understand how validation was conducted
  - Some AMR validation discussion is unclear or lacking
  - Some model validations were based on methods that were not specifically recognized by the procedure
  - Some model validations are subjective and lack specific validation criteria
  - Some AMRs contain purely conceptual models which do not require validation

Summary of Causes of Deficiencies

- AP-3.10Q does not clearly describe the process of validation
- AP-3.10Q does not distinguish between validation of different types of models (conceptual, process, abstraction, system)
- Criteria for validation are unclear

Path to Resolution

- **Revise Procedure AP-3.10Q**
  - **focus will be entirely on models in scientific investigation**
  - **dedicated section on model validation will be required**
- **Revise AMRs used to support the LA to assure adequate documentation of models**
- **Provide assistance in revising AMRs**
  - **Training on details of requirements**
  - **Assistance teams to support AMR authors, review in process work and assure consistency**

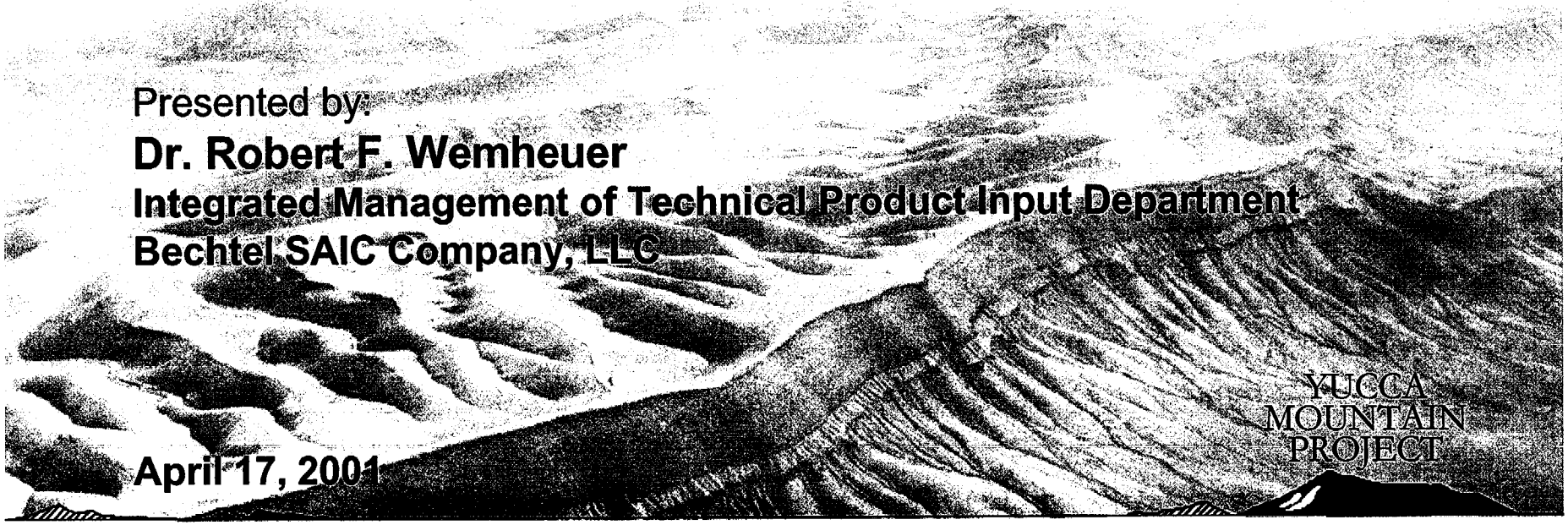
Conclusions

- All model validation concerns identified to date involve documentation and not model suitability or results
- Improvements in process requirements and additional training are being planned for future AMRs

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

Data Qualification Status

Presented to:
NRC/DOE Quality Assurance Meeting



Presented by:
Dr. Robert F. Wemheuer
Integrated Management of Technical Product Input Department
Bechtel SAIC Company, LLC

April 17, 2001

Post-Transition Organization

- Bechtel SAIC Company, LLC (BSC) effected a seamless and smooth transition and assumption of data work
- BSC took a proactive role in facilitating the consolidation, integration, and coordination of data related activities including Document Input Reference System (DIRS), To Be Verified (TBV), Technical Document Management System (TDMS) input, and the administrative process groups by forming the Integrated Management of Technical Product Input Department (IMTPID)
- Core technical and administrative personnel demonstrating data qualification and technical data input processing history were retained
- Personnel are and will continue to be qualified and trained to the Quality Assurance Requirements Description (QARD)

Responsibilities

- **BSC has chartered IMTPID with execution and control of the following functions:**
  - **DIRS**
  - **To Be Determined (TBD)/TBV management**
  - **Reference controls**
  - **Verification of input data**
  - **Qualification of input data**
  - **Technical Product Input (TPI) compliance**
  - **TPI integration, tracking, and status**
  - **Improvement of the data qualification processes**

Process Improvements

- Focus responsibilities and accountabilities for the integrity and flow of TPIs
- Integrate AP-3.14Q and AP-3.15Q processes for TBD/TBV and DIRS
- Centralize the responsibility for assuring consistency of TPI usage, management, statistics, etc. across the project
- Improve communication and clarity of expectations and requirements through procedural efficiencies

Mission Expectations

- Reduced number of unnecessary TBD/TBVs, inventories, and time to resolve them
- Continued satisfaction of U. S. Department of Energy (DOE) and U. S. Nuclear Regulatory Commission (NRC) expectations of reproducibility of data qualification results and accuracy of reporting qualification status, as well as
- Maintain DOE and NRC confidence in our project TPI processes, controls and quality programs
  - The January 31, 2001 Technical Exchange explaining the data verification/qualification processes to NRC reviewers

Qualification Objectives and Focus

- Conduct verification and qualification activities for the data used in Analysis Model Reports (AMRs) that support the Site Recommendation (SR)
- Ensure the integrity of the verification and qualification processes and make continued process improvements
- Support Chief Information Office (CIO) on legacy (prior to 06/30/99) software qualification & documentation issues contained in pre-Process Validation and Reengineering (PVAR) data verification/qualification processes
- Overall objective is to assure the integrity, fidelity and confidence in data and process procedures that provide the foundation for the development of the SR and License Application (LA)

Data Qualification Status by Process Model Report (PMR)

PMR	12/15/00 Percent Data Qualified	12/15/00 Percent Data Verified	03/31/01 Percent Data Qualified	03/31/01 Percent Data Verified
Biosphere	89	100	94	100
Disruptive Events	92	100	91	100
EBS	82	93	87	100
ISM	74	93	83	100
Near Field	87	100	88	100
SZ F&T	80	100	81	91
UZ F&T	81	93	88	94
Waste Form	71	92	93	95
Waste Package	86	92	91	100
Total	81	94	88	96

Percent completion for data figures are based upon Data Tracking Numbers (DTNs) contained in locked DIRS

Verification/Qualification Status as of 3/31/01

	Total	Completed	Remaining	
VL1 DIRS (Verif. Checklists)	253	237	16	(Q-TBV) ("actual citations")
VL1 Sources (Verif. Checklists)	326	314	12	(Q-TBV) ("daughters")
VL2 (No Verification Checklists)	183	183	0	(Q-TBV)
Accepted Data (Fact)	83	83	0	(e.g., handbooks, textbooks)
Accepted Data approved by Assistant Manager, Office of Project Execution	45	31	14	(e.g., journal articles)
Qualified by procedures established after 6/30/99	22	22	0	
Unqualified DTNs	309	243	66	
Totals	1221	1113	108	
Percent of Total Data Citations		91%	9%	

Note: Document Input Reference System VL1+VL2+AP-SIII.2Q+Accepted (895) + Source VL1 (326) = Total Data Citations (1221)

VL1 = Principal Factor Related DTN

VL2 = Non-Principal Factor Related DTN

Data Confirmation Results as of 4/10/01

Organization	Completed Checklists	Verified Q	Verified UQ	Failure Rate**
USGS (U.S. Geological Survey)	280	267	13	4.6%
LANL (Los Alamos National Laboratory	103	103	0	0%
LBNL (LawrenceBerkeley National Laboratory)	5	4	1	20%
LLNL (Lawrence Livermore National Laboratory)	33	33	0	0%
BSC* (Bechtel SAIC Company, LLC)	53	51	2	3.8%
SNL (Sandia National Laboratories)	79	78	1	1.3%
Total	553	536	17	3.1%

* Data generated by previous Yucca Mountain Site Characterization Project (YMP) organizations (i.e., Raytheon Services Nevada and Technical and Management Support Services) are now considered BSC data, and the results for these data are included in the BSC totals.

** Failure is defined as a determination that the data submitted under the associated DTN cannot be qualified. There are two principal causes for failure. Either the data acquisition/development process did not meet QARD requirements or data/record-related issues discovered during checklist preparation could not be resolved.

LBNL Challenge

- LBNL DTNs are typically large and tend to be more complex by nature
- Traceability evaluation thoroughly traces data from raw records to the TDMS
- Approximately 60% of LBNL DTNs have over 5,000 rows of data
- DTN LB960500834244.001 (Hydrological Data, Permeability in ESF Area)
  - 49 data tables
  - 10,929 rows of data
  - more than 45 pieces of Measuring & Test Equipment (M&TE)
  - 2 intermediate processing steps from raw records to final data
  - 7 scientific notebooks

Impact and Significance of Unqualified Data

- Overall verification reject rate for Q-TBVs continues to be low ~ 3.1%
- Individual rejects are either qualified per AP-SIII.2Q, or replaced, having the authors rely on an alternative qualified data set(s), or only use the data as corroborative information
- Data and input management process controls are in place to evaluate specific impacts should any data sets fail the qualification process

Challenges

- Qualification production continues to be dependent upon early identification of new or additional unqualified data requiring qualification
- Due to policy and AMR changes for SR, fluctuations in scope of UQ- & Q-TBV DTNs requiring qualification are being experienced
- There continues to be complexity in the remaining unqualified DTNs resulting in greater than average processing time
- Despite the challenges, there is commitment by BSC, Labs, and USGS to improve integration of activities and timeliness of products to support data and qualification schedules

Summary

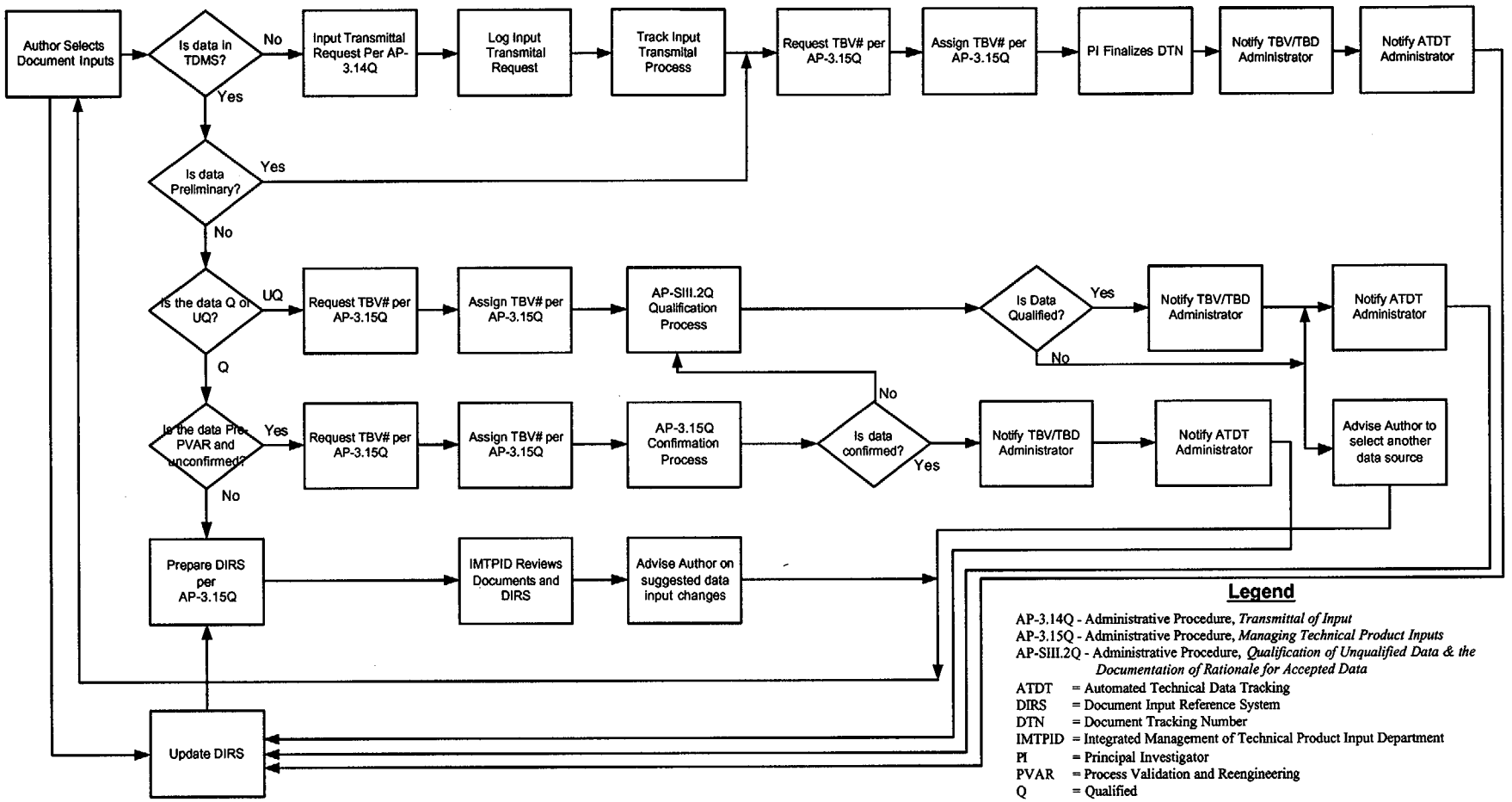
- The qualification of 100% of the data used to support AMR/PMR documents contained in the technical products baseline is on track for completion prior to SR submittal
- Based on current set of AMRs, efforts stand at:
  - 96% of data verified
  - 88% of data qualified
- Coordination and integration, between the authors, regulatory, qualification, and process groups has become increasingly more effective and is supported by BSC management
- New organization and integration of process functions will enhance overall coordination and performance
- Activities and schedules are being managed to support SR

Backup

Key Process Procedures

- Data Verification and Qualification activities are controlled by AP-2.21Q, *Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities*
- Requests, control, receipt, and transmittal of inputs required to be from controlled sources are managed per AP-3.14Q, *Transmittal of Input*
- Data verification checklists are prepared per AP-3.15Q, *Managing Technical Product Inputs*
- Qualification activities affecting software are worked in concert with requirements in AP-SI.1Q, *Software Management*
- Data qualification is performed per AP-SIII.2Q, *Qualification of Unqualified Data and Documentation of Rationale for Accepted Data*

Technical Product Input Process

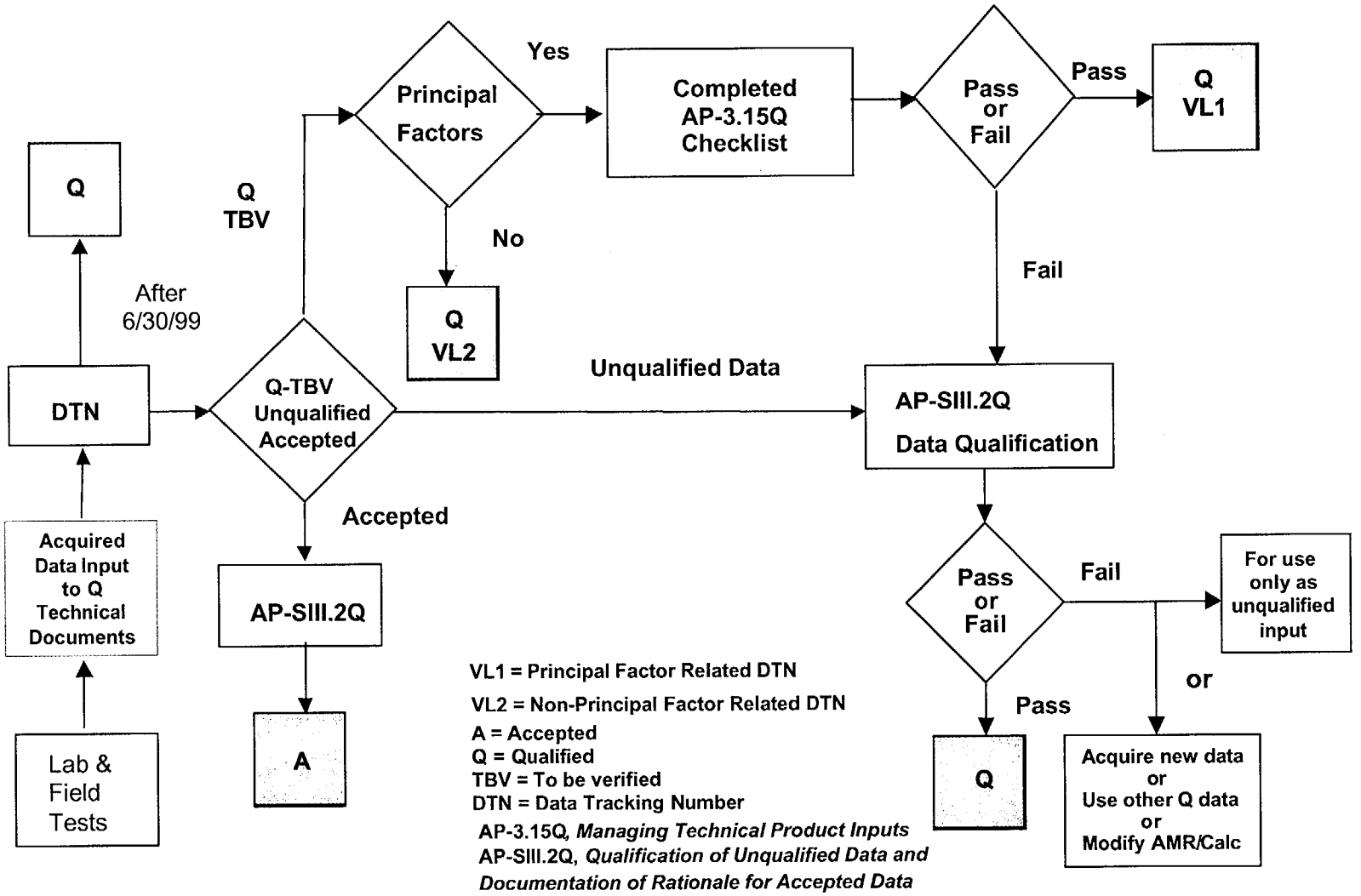


Legend

AP-3.14Q - Administrative Procedure, *Transmittal of Input*
AP-3.15Q - Administrative Procedure, *Managing Technical Product Inputs*
AP-SIII.2Q - Administrative Procedure, *Qualification of Unqualified Data & the Documentation of Rationale for Accepted Data*

ATDT = Automated Technical Data Tracking
DIRS = Document Input Reference System
DTN = Document Tracking Number
IMTPID = Integrated Management of Technical Product Input Department
PI = Principal Investigator
PVAR = Process Validation and Reengineering
Q = Qualified
TBD = To Be Determined
TBV = To Be Verified
TDMS = Technical Data Management System

Data Verification and Qualification Process



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

Software Qualification Status

Presented to:
DOE/NRC Quarterly QA Meeting

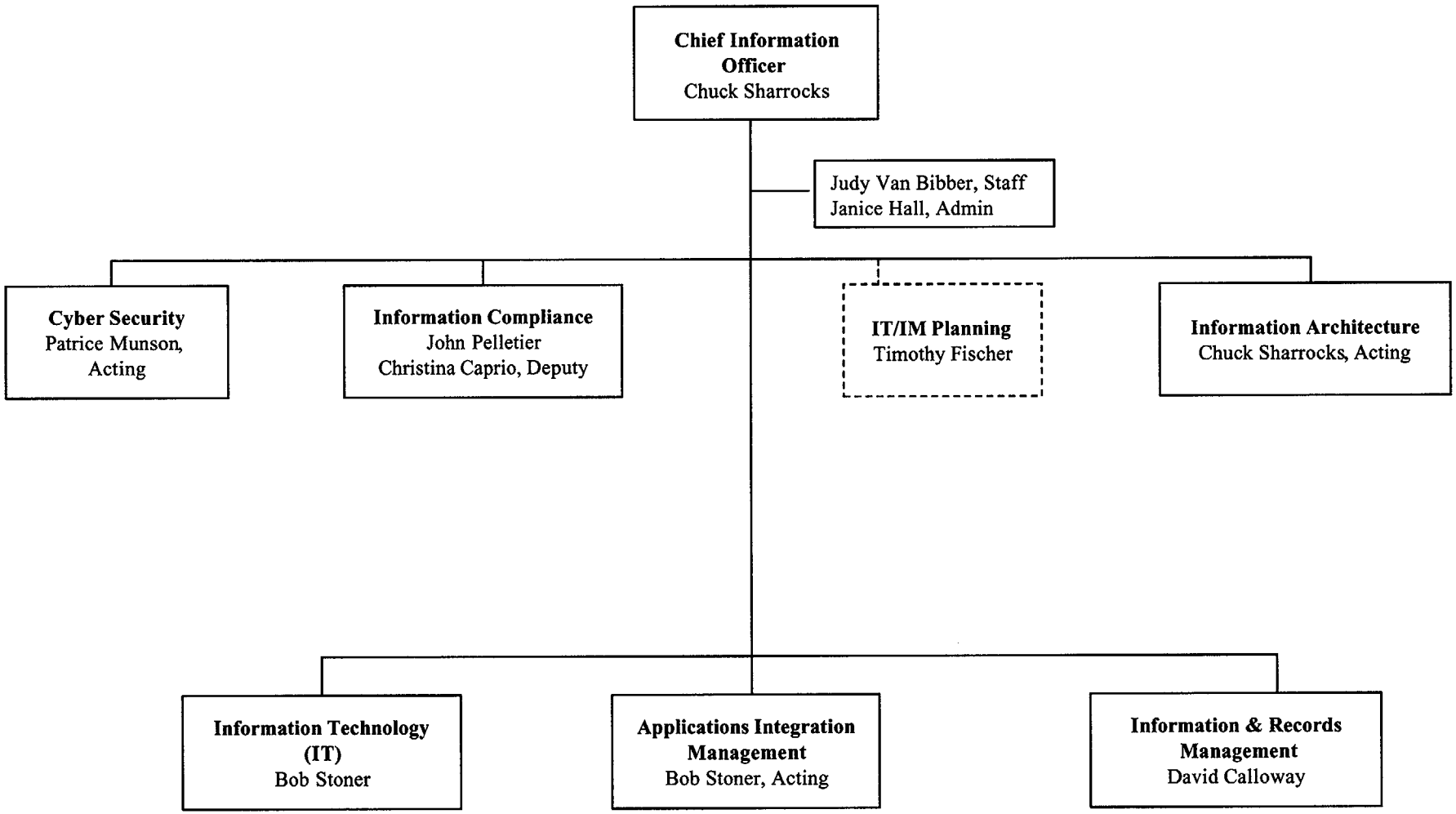
Presented by:
John F. Pelletier
Information Compliance
Bechtel SAIC Company, LLC

April 17, 2001

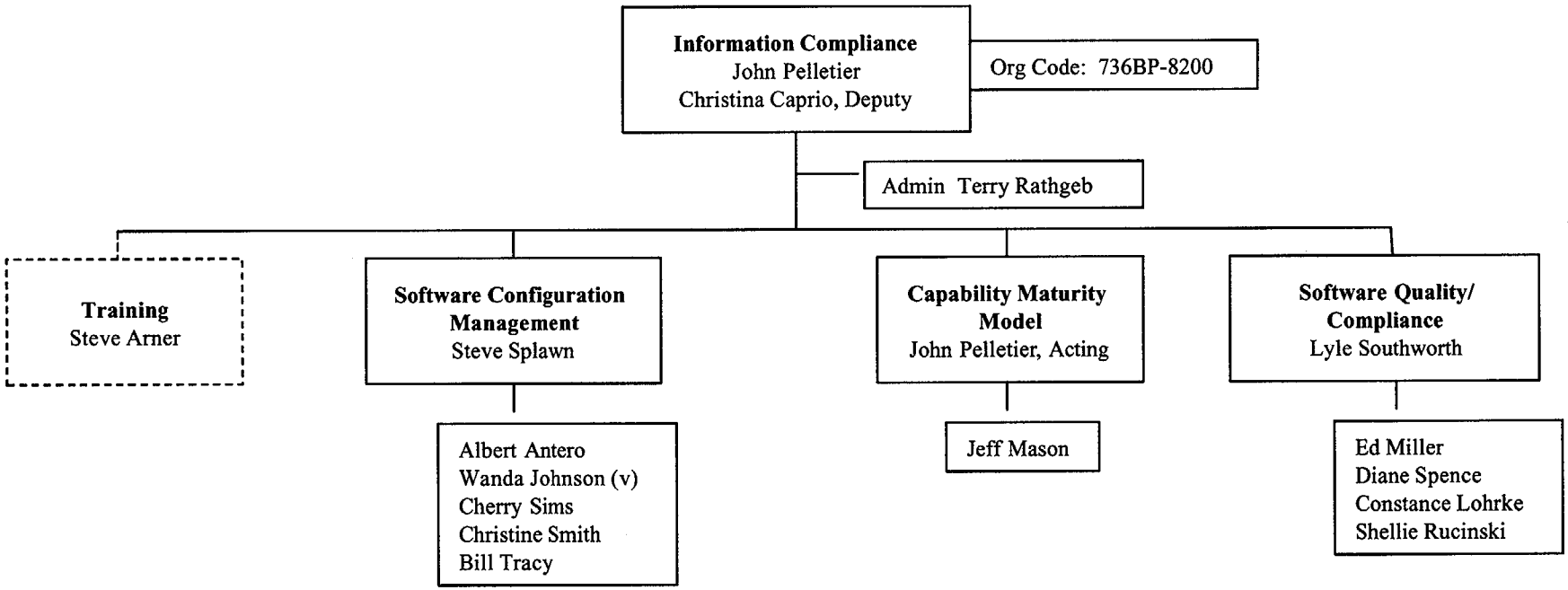
Software Topics

- Organization
- AP-SI.1Q Revision
- Software Qualification Percentage by PMR
- Software Qualified by PMR
- Unique Unqualified Software Codes
- DR-039 on Software Routines

New CIO Organization Effective 2/12/2001



New IC Organization Effective 2/12/2001



AP-SI.1Q Revision 3, ICN 0

- Improved process flow and rigor
- Provides for 3 levels of Software Classification
- Line Management Accountability
- Focused document Review and Testing
- Submission of Software Media with Baseline Documentation
- Documentation flow and approval has been streamlined
- Discontinued the use of Single Use Routines/Macro
- Effective Date 4/01/2001

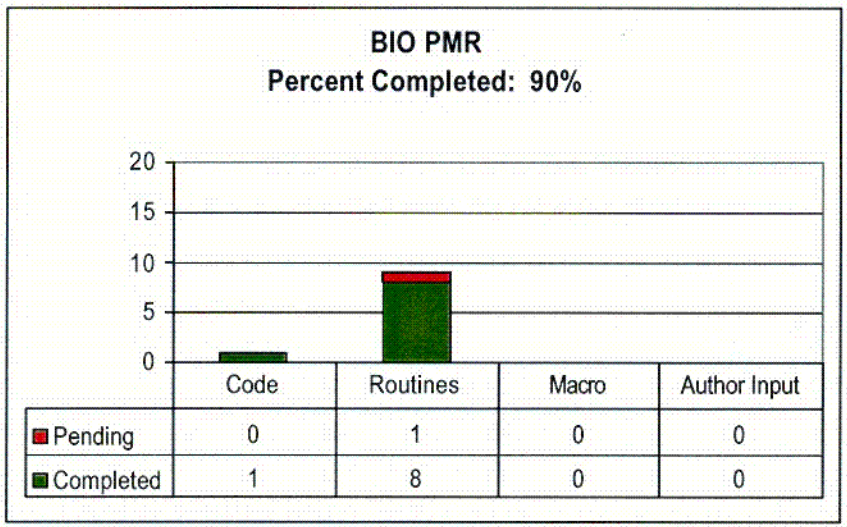
Software Qualification Percent By PMR

- **BIO 90%**
- **DE 100%**
- **EBS 96%**
- **ISM 100%**
- **NFE 99%**
- **SZ 89%**
- **UZ 98%**
- **WF 100%**
- **WP 100%**

Note: The number of software packages varies as analyses mature and are revised.

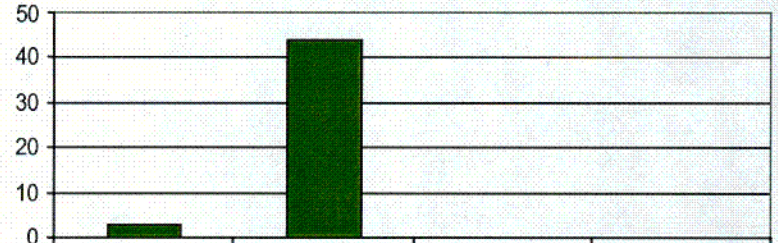
Software Qualified by PMR

BIO PMR
Percent Completed: 90%



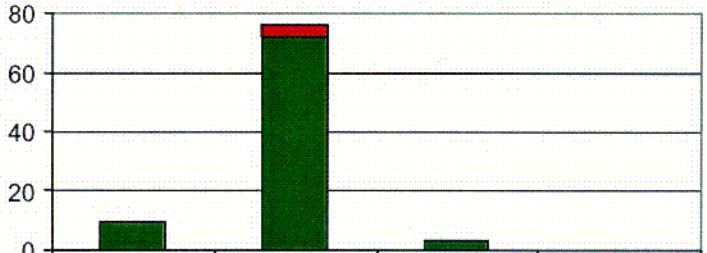
	Code	Routines	Macro	Author Input
Pending	0	1	0	0
Completed	1	8	0	0

DE PMR
Percent Completed: 100%



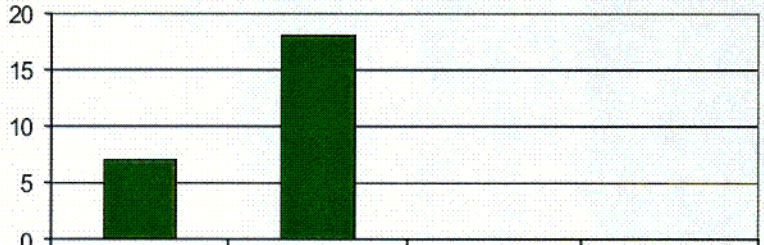
	Code	Routines	Macro	Author Input
Pending	0	0	0	0
Completed	3	44	0	0

EBS PMR
Percent Completed: 96%



	Code	Routines	Macro	Author Input
Pending	0	4	0	0
Completed	10	72	3	0

ISM PMR
Percent Completed: 100%

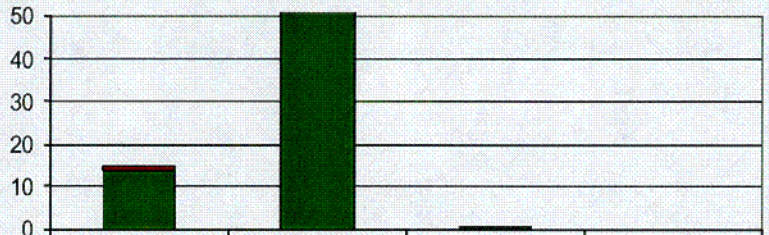


	Code	Routines	Macro	Author Input
Pending	0	0	0	0
Completed	7	18	0	0

C01

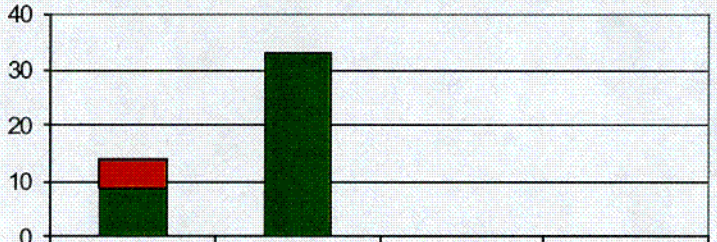
Software Qualified by PMR (Continued)

NFE PMR
Percent Completed: 99%



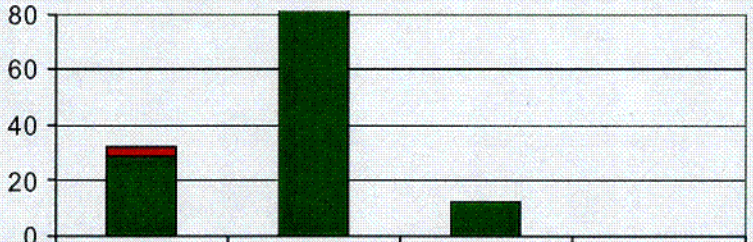
	Code	Routines	Macro	Author Input
Pending	1	0	0	0
Completed	14	58	1	0

SZ PMR
Percent Completed: 89%



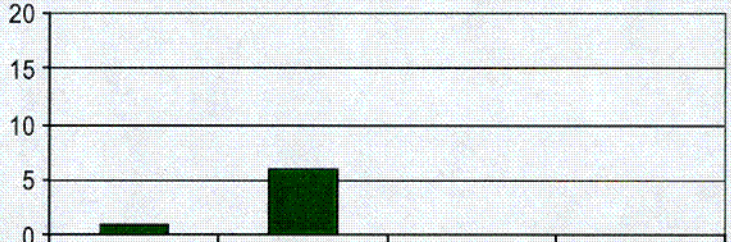
	Code	Routines	Macro	Author Input
Pending	5	0	0	0
Completed	9	33	0	0

UZ PMR
Percent Completed: 98%



	Code	Routines	Macro	Author Input Needed
Pending	3	0	0	0
Completed	29	86	12	0

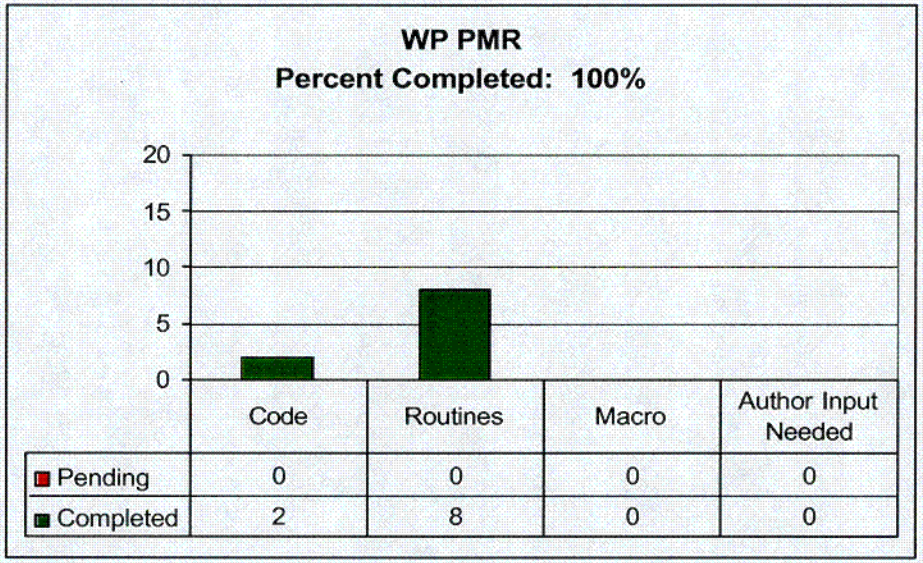
WF PMR
Percent Completed: 100%



	Code	Routines	Macro	Author Input Needed
Pending	0	0	0	0
Completed	1	6	0	0

C02

Software Qualified by PMR (Continued)



	Code	Routines	Macro	Author Input Needed
Pending	0	0	0	0
Completed	2	8	0	0

C03

Unique Unqualified Software Codes

- **There are currently fourteen codes being managed in accordance with AP-SI.1Q Revision 3, Section 5.10 "Interim Use of Unqualified Software...".**

ERMA SITEGEOLOGIST	Version 6.0.1
FEHM	Version 1.99
FEHM	Version 2.10
INFIL	Version 2.0
INFIL	Version A2.a1
LAGRIT	Version 1.0
NETPATH	Version 2.13
PEST	Version 2.0
PETROSYS	Version 7.60d
STO-UNSAT	Version 1.0LV
TOUGH2	Version 1.3
TOUGH2	Version 3.4.3
TOUGHREACT	Version 2.3
UDEC	Version 3.0

DR-039 Status KEY POINTS

- Extent of deficiency was more than anticipated based on information obtained from the ongoing investigation
- Re-evaluated extent of condition and significantly broadened the corrective actions
- To date, corrective actions involve only documentation and similar problems, but no impact on the integrity of the software output or on the technical products
- New Commitment to close DR on or before 9/18/01

Open Deficiency Report - DR-039

- **LVMO-00-D-039: Issued 02/15/2000**
- **Brief Description:**
  - Inaccurate documentation and validation of software routines and macros
- **Issue:**
  - Some software routines documented as part of the Analysis Model Reports (AMRs) are not adequately documented per AP-SI.1Q. Issues include missing test information, missing source code, and lack of version control
- **Solution:**
  - Correct/Amend AMR documentation to ensure reproducibility and defensibility of software routines. AMRs that are not revised will have their record packages appended to include missing information
  - Issue new Software Management Procedure
  - Raise Management Awareness

Open Deficiency Report - DR-039 (Continued)

- Based on information emerging from the extent of condition and corrective action DR-039 has expanded to include documents with software routines other than AMRs (e.g., engineering documents)
- The Document Input Reference System (DIRS) for the technical bases documents supporting a potential Site Recommendation were reviewed to identify additional documents that might contain software routines
- Based on the expanded extent, additional time was requested and approved to complete the additional corrective actions
- Significant progress is being made to ensure that software routine documentation for technical bases documents is reproducible and defensible

DR 39 Status 04/09/01 - Software routines have been classified and placed in Bins

- **A comprehensive review of 123 AMRs that support the 9 PMRs was conducted. AMR software routine documentation was classified into bins.**
- **Definition of Bins:**
  - Bin 1: No single use routines/macros developed in AMR (Current Status: 31 AMRs).
  - Bin 2: All software used in AMR were adequately documented in the AMR (Current Status: 31 AMRs).
  - Bin 3: Commercial software (i.e. Built in-functions, math operators, or formulas) were not adequately documented inside the AMR (Current Status: 41 AMRs).
  - Bin 4: Developed software (i.e. routines developed in C, FORTRAN, BASIC) including some use of commercial software were not adequately documented in the AMR (Current Status: 20 AMRs).
- **BSC is working with authors/developers to resolve issues.**
- **Required corrections/additions are being made to AMRs or AMR Record Packages.**

DR -039 Status 04/09/01
Current BSC Status

- **Item 1 –Total affected AMRs: 61, Bin 3: 41, Bin 4: 20 -- working with Author/Developer to resolve issues**
  - 25 Complete No issues
  - 30 working with Author/Developer to resolve issues
  - 6 Being packaged for OQA review
  - 61 Total AMRs
- **Item 2 - Multi-Use Software Routines and Macros**
  - Software Routine(s) Total 179 as of 3/30 per SCM
  - Complete No issues 101
  - SRRs Completed with Issues 44, being Re-worked
  - SRRs Not yet reviewed 34
  - 179 Total SRRs
- **Item 3 – Ongoing reviews for DIRS items supporting potential SR technical bases documents and SDDs**

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

Corrective Action Status

Presented to:
NRC/DOE Quality Assurance Meeting

Presented by:
Robert Clark, Director
Office of Quality Assurance
Yucca Mountain Site Characterization Office

April 17, 2001

OQA INTERIM ACTION TO VERIFY DEFICIENCY REPORT (DR-039)

- **Verification Approach:**
  - Review analyses and model reports (AMR) and other technical bases documentation packages
  - Ensure documentation meets requirements
  - Ensure completeness/accuracy of documentation
  - Resolve any issues prior to acceptance
  - 100% verification is planned
  - Verification is conducted as reviews are completed by Software Configuration Management (SCM)

OQA INTERIM ACTION TO VERIFY DEFICIENCY REPORT (DR-039)

(Continued)

- **Verification Results:**
  - **BIN 1: (31 AMRs) 100% verified/accepted**
    - ✓ **Resulted in moving 8 AMRs to BIN 3**
  - **BIN 2: (31 AMRs) 100% verified/accepted**
  - **BIN 3 and 4: (25 of 61) 40% verified/accepted**
  - **Software Routine Reports (SRRs): (179) 0% verified**
  - **Document Input Reference System (DIRS) for technical bases documents for potential Site Recommendation: 0% verified**
  - **No open issues in any of the completed verifications**
  - **Numbers and percentages are subject to change as verification of the SRRs and technical bases documents begin**

DEFICIENCY REPORTS STATUS AND PATH FORWARD

- **Current Status:**
  - **As of 04/04/00, total number of Deficiency Reports (DRs) open = 42**
  - **Majority are being managed within goal to close within 100 days**
  - **Current total number of DRs open > 100 days = 15**

DEFICIENCY REPORTS STATUS AND PATH FORWARD

(Continued)

- **Path Forward:**
  - **Sustaining our goal for effective and timely resolution of deficiencies is an OCRWM and BSC Management top priority**
  - **Responsibilities, corrective actions and completion dates have been reviewed and confirmed or changed for each transitioned BSC deficiency document**

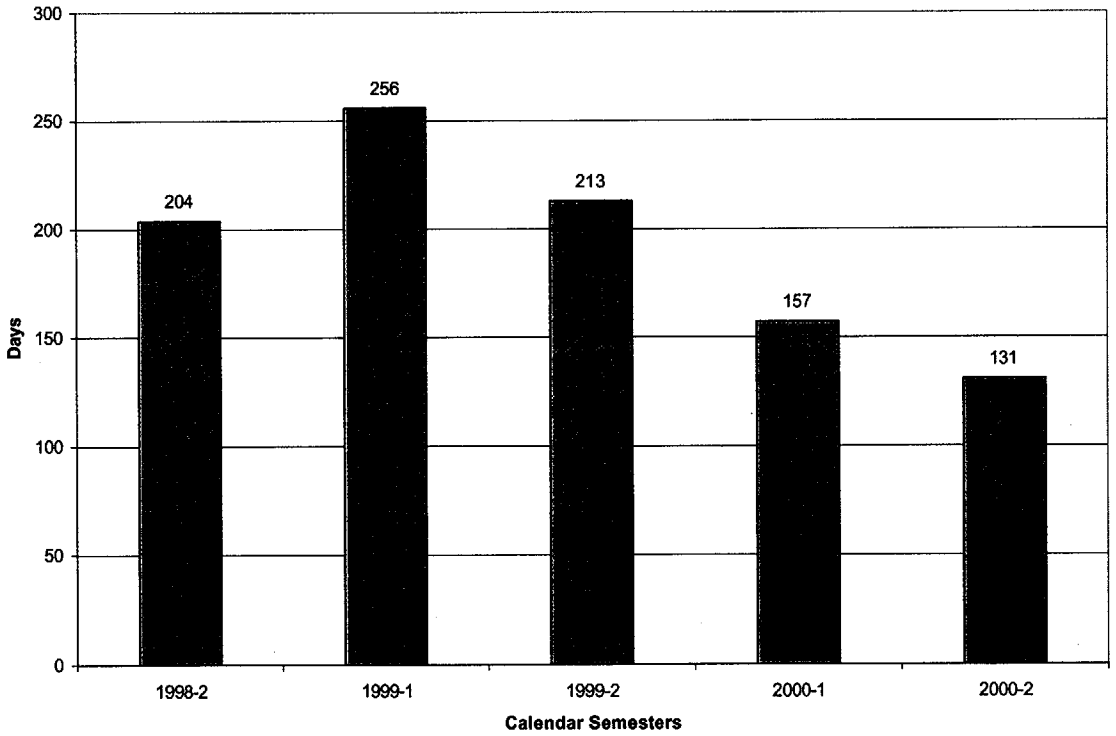
DEFICIENCY REPORTS STATUS AND PATH FORWARD

(Continued)

- **Path Forward:**
  - **OQA has reassigned Quality Assurance Representative (QAR) responsibilities for some prioritized DRs; e.g., DR-039, which will facilitate resolution/closure**
  - **BSC will re-assess DRs that are over 100 days old to ensure that adequate resources are applied**
  - **OCRWM and BSC Senior Management will monitor resolution process**

CORRECTIVE ACTION TIMELINESS

- **Average Days to Close DR/CARs**



Trend Analysis for last two years continues to show improvement.

Corrective Action Board (CAB)

- The CAB function is in operation
- The BSC General Manager has enhanced the CAB function by holding biweekly Open Items meetings
- DRs, NCRs, and CIRS items are discussed at the meeting
- Responsible managers provide the status of overdue items, i.e., why they are late, and what is being done to resolve the issue(s)
- DOE and NRC representatives have a standing invitation to attend the Open Items meeting

AUDIT M&O-ARP-01-02
UNSATURATED ZONE FLOW AND TRANSPORT PROCESS MODEL REPORT
FEBRUARY 5-9, 2001

- Overall Results - critical process steps were effectively implemented
- Audit revealed significant improvement in area of software
- Previous audit recommendations were incorporated
- One DR issued:
  - LVMO-01-D-044, relating to the processing and closure of AP-3.14Q Input Transmittals
- Twelve previously issued DRs were evaluated for effectiveness of corrective action taken, with satisfactory results

AUDIT M&O-ARP-01-01
ENGINEERED BARRIER SYSTEM
PROCESS MODEL REPORT
FEBRUARY 20-23, 2001

- **Overall Results - critical process steps were effectively implemented**
- **Three conditions adverse to quality were identified:**
  - **DR BSC-01-D-050, relating to model validation. Due to the potentially repeatable nature of this issue, Suspect Trend Investigation Report (STIR) BSC-01-004 was issued to evaluate overall effectiveness of corrective actions on traceability and transparency.**

AUDIT M&O-ARP-01-01
ENGINEERED BARRIER SYSTEM
PROCESS MODEL REPORT
FEBRUARY 20-23, 2001
(Continued)

- DR BSC-01-D-051, relating to traceability, transparency and calculation problems in one AMR. Due to the potentially repeatable nature of this issue, STIR BSC-01-003 was issued to evaluate overall effectiveness of corrective actions on traceability and transparency
- Deficiency Identification and Referral 01-01 to DR LVMO-01-D-044, relating to the processing and closure of AP-3.14Q Input Transmittals

- Eleven previously issued DRs were evaluated for effectiveness of corrective actions taken, with satisfactory results

REPETITIVE DEFICIENCY EVALUATION

- Trend data and audit deficiencies exhibit need for OQA to further investigate the potential for recurring deficiencies
- STIRs initiated for the following:
  - LVMO-01-001 Implementation of the DIRS described in AP-3.15Q - No adverse quality trend, current corrective action plans adequate
  - BSC-01-002 Inadequate usage of Scientific Notebooks as required by AP-SIII.1Q - Although STIR evaluation not yet completed, no apparent adverse trend has been identified
  - BSC-01-003 Documentation of traceability and transparency errors - STIR evaluation is in progress
  - BSC-01-004 Models are not validated in accordance with AP-3.10Q - STIR evaluation is in progress

AUDIT OBSERVER INQUIRIES UNSATURATED ZONE (UZ) AND ENGINEERED BARRIER SYSTEM (EBS) AUDITS

UZ PMR Audit

4 Technical NRC Inquiries

Status: Responses in progress

EBS PMR Audit

2 NRC Inquiries

(1 QA, 1 Technical)

Status: Responses in progress

Note: Technical inquiries are processed by DOE Office of Licensing and Regulatory Compliance (contact: Tim Gunter); QA inquiries are processed by OQA (contact: Kristi Hodges)

DOE OQA AUDIT RECOMMENDATIONS

- FY01 OQA & future audit recommendations input to and tracked through the CIRS
  - Recommendations input by the OQA Lead Auditor
  - CIRS number for each recommendation included in the Audit Report
  - Any action assignment or commitments tracked through CIRS
  - OQA follow-up at next audit
- FY00 PMR Audit Technical Recommendations (backlog) tracked by OQA
  - OQA database established to track PMR recommendations for only 10 audits
  - Tracking only 175 items to closure
  - Approximately 113 items either closed or ready for closure verification
  - Used in lieu of CIRS to ensure timely OQA involvement

NRC INTERFACES FOR OBSERVING VENDOR AUDITS

- **BSC Vendors:**
  - Robert Hartstern, Procurement Quality Manager (Acting), 702-295-2675
  - James Blaylock, DOE/OQA, 702-794-1420
- **DOE Vendors:**
  - Robert Hasson, QATSS QA Verification Manager, 702-794-5023
  - James Blaylock, DOE/OQA, 702-794-1420

Vendor Audit Schedule, Revision 1 available on OCRWM Home Page or hard copy

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

Improvements to the Key Technical Issue (KTI) Meeting Process

Presented to:
NRC/DOE KTI Status Meeting

Presented by:
Timothy Gunter
Office of Licensing & Regulatory Compliance
Yucca Mountain Site Characterization Office

April 17, 2001

KTI Meetings To Date

- KTI Meetings have been productive and have resulted in improved interactions with the NRC
- Lessons from meetings to date will allow improvements and enhancements for future meetings

Potential Enhancement Areas

- Resources
- Schedule
- Logistics
- Presentations
- Delivery
- Preparation