

February 20, 2001

Mr. Robert Clark
Acting Director
Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585

SUBJECT: MINUTES OF THE DECEMBER 19, 2000, QUALITY ASSURANCE BREAKOUT SESSION MEETING

Dear Mr. Clark:

Enclosed are the minutes of the December 19, 2000, Quality Assurance (QA) Breakout Session meeting between the staff of the U.S. Nuclear Regulatory Commission (NRC) and representatives of the U.S. Department of Energy (DOE).

The purpose of the December 19, 2000, meeting was to discuss items of mutual interest about QA and those areas contributing to the resolution of QA problems. The meeting was a video conference between the DOE office in Las Vegas, Nevada, The Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas, and NRC headquarters in Rockville, Maryland.

If you have any questions regarding this letter, please contact Kien Chang of my staff at (301) 415-6612.

Sincerely,

/RA/

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: Meeting minutes

cc: See attached list

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OFFICE	HLWB	HLWB	HLWB	HLWB
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DATE	02/12/01	02/2/01	02/15/01	02/16/01

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 20, 2001

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Acting Director
Office of Quality Assurance
Office of Civilian Radioactive Waste Management
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1000 Independence Avenue, S.W.
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Sincerely,

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: Meeting minutes

cc: See attached list

Letter to R. Clark from C.W. Reamer dated: February 20, 2001

cc:

R. Loux, State of Nevada	R. Massey, Lander County, NV
S. Frishman, State of Nevada	J. Pitts, Lincoln County, NV
L. Barrett, DOE/Washington, DC	M. Baughman, Lincoln County, NV
A. Brownstein, DOE/Washington, DC	A. Funk, Mineral County, NV
S. Hanauer, DOE/Washington, DC	J. Shankle, Mineral County, NV
C. Einberg, DOE/Washington, DC	L. Bradshaw, Nye County, NV
J. Carlson, DOE/Washington, DC	M. Murphy, Nye County, NV
N. Slater, DOE/Washington, DC	J. McKnight, Nye County, NV
A. Gil, YMPO	D. Weigel, GAO
R. Dyer, YMPO	W. Barnard, NWTRB
S. Brocoum, YMPO	R. Holden, NCAI
R. Clark, YMPO	A. Collins, NIEC
S. Mellington, YMPO	R. Arnold, Pahrump County, NV
C. Hanlon, YMPO	J. Larson, White Pine County
T. Gunter, YMPO	R. Clark, EPA
K. Hess, BSC	F. Marcinowski, EPA
D. Krisha, BSC	R. Anderson, NEI
S. Cereghino, BSC	R. McCullum, NEI
M. Voegele, BSC/SAIC	S. Kraft, NEI
S. Echols, Winston & Strawn	J. Kessler, EPRI
B. Price, Nevada Legislative Committee	D. Duncan, USGS
J. Meder, Nevada Legislative Counsel Bureau	R. Craig, USGS
D. Bechtel, Clark County, NV	W. Booth, Engineering Svcs, LTD
E. von Tiesenhausen, Clark County, NV	J. Curtiss, Winston & Strawn
A. Kalt, Churchill County, NV	N. Rice, NV Congressional Delegation
G. McCorkell, Esmeralda County, NV	T. Story, NV Congressional Delegation
L. Fiorenzi, Eureka County, NV	J. Reynoldson, NV Congressional Delegation
A. Johnson, Eureka County, NV	S. Joya, NV Congressional Delegation
A. Remus, Inyo County, CA	J. Pegues, City of Las Vegas, NV
M. Yarbro, Lander County, NV	L. Lehman, T-Reg, Inc.

2001-02-12

**MINUTES OF THE DECEMBER 19, 2000
U.S. NUCLEAR REGULATORY COMMISSION /U.S. DEPARTMENT OF ENERGY
QUALITY ASSURANCE BREAKOUT SESSION MEETING**

On December 19, 2000, staff of the U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Energy (DOE) met at NRC headquarters in Rockville, Maryland, with video conference with the DOE office in Las Vegas, Nevada, and the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas. The purpose of the meeting was to discuss items of mutual interest about quality assurance (QA).

Attendees

Attachment 1 provides the name, affiliation, and telephone number of the attendees.

Agenda

Attachment 2 provides the agenda.

Opening Remarks

The meeting opened with the introduction of attendees. John Greeves provides remarks regarding the progress DOE has made in correcting its QA problems and the need for DOE to continue to improve the implementation of its QA program.

Presentations

The NRC staff presented a brief discussion on the following topics: 1) guidance contained in NRC Regulatory Issue Summary (RIS) 2000-18, GUIDANCE ON MANAGING QUALITY ASSURANCE RECORDS IN ELECTRONIC MEDIA; 2) Graded QA; and the development of the NRC Inspection Program for the proposed high-level waste repository at Yucca Mountain, should DOE submit an license application for this repository.

Larry Campbell provided copies of RIS 2000-18 and a paper on graded QA and discussed that these two documents identify one method the NRC accepts for managing records in electronic media and for implementing a graded QA program, respectively.

Ted Carter discussed that the NRC staff is starting to prepare its inspection program for the proposed high-level waste repository, and will be making presentations in future meetings on progress being made.

The DOE presented discussion on the following topics: 1) progress made in verifying/qualifying data and software; 2) the status of Deficiency Report (DR) LVMO-00-D-39; 3) the Fiscal Year 2001 DOE audit schedule; and 4) Transition of QA functions to the new DOE Management and Operating Contractor, Bechtel-SAIC, LLC.

Progress Made in Verifying/Qualifying Data and Software

Bob Wemheuer made a presentation on progress made in verifying/qualifying data and software. He confirmed that plans are in place to qualify 100% of data and software that support SR by June 2001. There was discussion and acknowledgement that the amount, particularly with respect to data, is a moving target as new and revised work is completed by the Project. Mr. Greeves urged the Onsite Representatives to continue with interactions in this area.

Status of Deficiency Report LVMO-00-D-39

Bob Clark discussed the status, provided a brief description of the DR, significance, further actions required, and anticipated corrective action completion date. The approach taken to categorize the issues into 4 bins, based on significance, was discussed. It was noted that DOE was confident that the M&O conclusion regarding "no impact" for bins 1 and 2 was accurate and DOE would review and approve this when the M&O formally transmitted the DR amended response. DOE indicated that for Bin 3, category 2 and for Bin 4 evaluations that proved to be more than "documentation or reproducibility" issues, if any, DOE would determine if any of these should be categorized as "unqualified" software and revise the reporting percentages accordingly. Larry Campbell made a request for the number of routines and which PMRs they supported.

FY 2001 Audit Schedule

Bob Clark handed out the FY 2001 OQA internal and supplier audit schedule. Larry Campbell indicated that one of the audit dates had changed and the correct date was announced.

Transition of QA Functions to the New DOE M&O

Bob Clark briefly presented those QA functions to be transitioned to the new M&O and those to be retained by the DOE QA support contractor.

Attachments 3, 4, 5, and 6, RIS 2000-18, Graded QA Presentation, Status of Data and Software Qualification, and Quality Assurance, respectively provides the presentation handouts.

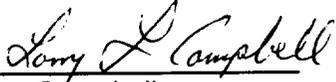
Action Items

DOE agreed to provide the staff information on the number of software routines affected by DR. This was presented the next day during the DOE/NRC Management Meeting.

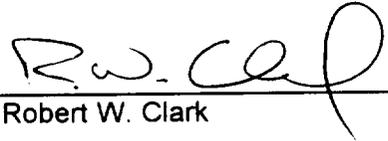
DOE agreed to provide the staff information on the status of model validation activities in the near future.

Closing Remarks

The NRC and DOE believed that the QA Breakout Session meetings were beneficial and should continue. The NRC stressed the fact that the staff would continue the progress that DOE is making in effectively implementing its QA program.



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



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

ATTACHMENT 1

ATTENDANCE LIST
 NRC/DOE Quality Assurance
 December 19, 2000
 Rockville, MD

Name	Organization	Phone	E-Mail
Alex C Chang	NRC/DWM	301 415 6612	kcc @ NRC . GOV
LEO CATER	NRC /DWM	201-415-6684	lhc1@nrc.gov
Bob Gamble	MTS/BAH	702-794-1440	robert_gamble@ymp.gov.
April Gil	DOE/YMP	702 794-5578	april-gill@YMP.gov
Chuck Sharrocks	BSC	240-988-8896	Charles.s.sharrocks@SAIC.COM
Stan Echols	Winston + Strawn	202-371-5777	f echols @ winston . com
Rod McCullen	NEI	202-739-8082	rxm @ nei . org
ROB Mc DONALD	SKRA	202-473-2122	Robert McDonald M/D/RV/DOE-SKRA US
ROBERT WEMMEWEZ	meo/YMP/DOE	702-295-3966	
Bret Leslie	NRC/DWM	301 415-6652	bwL@nrc.gov
TANTRA BLOOMER	NRC/DWM	301 415-6626	TEB@NRC.gov
N. King Stoltz	NRC/DWM		
TIM GUNTER	DOE/YMSCO	702-794-1843	timothy-gunter@ymp.gov
WILKINS SMITH	NRC/FCSS	301-415-5788	WRS@NRC.GOV
Bill Reamer	NRC/DWM	301-415-6537	cbf@nrc.gov

List of Attendees
December 19, 2000
DOE/NRC Quality Assurance Meeting
Location: LAS VEGAS - HILL SHIRE (ATRIUM)
 (city, state / organization - building)

Name	Organization	Phone
Les Kellum	MDO LIC	295-1326
Walt Whittingly	Nye County	360-948-5610
Marty Bryan	Mald Co	295-6273
SUSAN ZIMMERMAN	State of NV	775-687-3744
Sam Horton	OQA/QATSS	794-1497
Robb Keele	OQA/QATSS	295-8808
Steve Dana	QATSS	295-2749
ROBERT HOWARD	NEP PERFORMANCE ASSESS	295-3097
DEANIS R. WILLIAMS	DOE/YM/DOE	794-5326
Barbara McKinnon	MTS/BAIT	794-5482
George Hellstrom	DOE/YM	794-1559
MICHAEL ESTLEMAN	MTS/OIM	794-1360
STEPHEN B. SPRAWN	MIO/IT/SCM	295-3831
FRANK J. KRATZINGER	MTS	794-5057
LEW ROBERTSON	MTS	794-5077
ROBERT P. HANSON	OQA/QATSS	794-5023
Kristi A. Hodges	OQA/QATSS	794-1464
Jean Younger	MDO ART	295-5497
ROBERT M. LATTA	US NRC	794-5048
RAM B. MURTHY	US DOE/OQA	794-5509
Lyle C. Southworth	MFO/DOE/DOE	295-3282
DONALD L. HILL	MFO/DOE/DOE	295-7331
SAMUELE ARCHULETA	OQA/QATSS	794-1476
Reina Pawning	Nye Co	(775) 727-7727
Rosalee Sweeney	MFO/DOE/DOE	795-6248052

ATTACHMENT 2

TENTATIVE EXTERNAL AGENDA
NRC/DOE Quarterly Quality Assurance Meeting
December 19, 2000
1:30 PM to 3:00 PM EST
10:30 AM to 12:00 PM PST
NRC White Flint (Room T2B5) Rockville, MD
Audio Bridge to SW Research Center (Room B232) San Antonio, TX
V-Tel to DOE Headquarters (Room 7F-034) Washington, D.C.
V-Tel to DOE-Hillshire (Room 516) Las Vegas, NV

Recent Guidance on Managing QA Records in Electronic Media	NRC
Graded QA	NRC
NRC Inspections	NRC
Progress Made Qualifying Data and Software	DOE
Model Validation Status	DOE
DR LVMO-00-D-39	DOE
CY 2001 Internal and External Audit Schedule	DOE
OQA Functions After Transition vs. M&O QA Functions	DOE

ATTACHMENT 3

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, D.C. 20555-0001

October 23, 2000

**NRC REGULATORY ISSUE SUMMARY 2000-18
GUIDANCE ON MANAGING QUALITY ASSURANCE RECORDS
IN ELECTRONIC MEDIA**

ADDRESSEES

All holders of operating licenses for nuclear power plants, including licensees that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel. In addition, those materials licensees, including certificate holders and vendors, that are required to have an NRC approved quality assurance program.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide guidance on managing quality assurance (QA) records in electronic media. This RIS does not supersede or revise existing guidance or abrogate the guidance in Regulatory Guide (RG) 1.88, Revision 2, or RG 1.28, Revision 3. It does not provide guidance on submitting electronic records to the NRC as required by Section 50.4(c) of Title 10 of the *Code of Federal Regulations* (10 CFR 50.4(c)).

The guidance in this RIS is intended to provide, for those licensees with QA programs, a way to satisfy the requirements for the maintenance of QA records. However, the guidance can also be applied to the record keeping and maintenance requirements present in other parts of the regulations that specify that storing records in the form of electronic media is acceptable.

This RIS does not create any new or changed NRC requirements or staff positions, and it requires no specific action or written response. Any action on the part of addressees to use electronic media for managing QA records is strictly voluntary.

BACKGROUND

For nuclear power plants, Criterion VI, "Document Control," and Criterion XVII, "Quality Assurance Records," of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," establish requirements for issuing, identifying, and retrieving QA records. For other types of licensees, 10 CFR 40.61; 10 CFR 60.150, 60.151, 60.152; 10 CFR 71.1, 71.91, 71.135; 10 CFR 72.48, 72.72, 72.80, 72.150, 72.174, 72.212, and 72.234; and 10 CFR 76.70 and 76.93 establish requirements for QA records.

NRC-accepted practices for the collection, storage, and maintenance of QA records for nuclear power plants, independent storage of spent nuclear fuel and high-level radioactive waste

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facilities, special nuclear materials, packaging and transportation of radioactive materials, and gaseous diffusion plants are described in the following documents:

- American National Standards Institute (ANSI) N45.2.9-1974, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants," as endorsed by RG 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records," Revision 2.
- ANSI/American Society of Mechanical Engineers, ANSI/ASME-NQA-1, 1983 edition, "Quality Assurance Program Requirements for Nuclear Facilities," as endorsed by RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3.

On October 20, 1988, the NRC staff issued GL 88-18, "Plant Record Storage on Optical Disks," to provide guidance on quality controls for an optical disk document-imaging system. GL 88-18 expanded the guidance of RGs 1.88 and 1.28 to describe an acceptable method for storing QA documents in optical media in accordance with the criteria in Appendix B to 10 CFR Part 50.

DISCUSSION

Although the guidance in GL 88-18, RG 1.88, and RG 1.28 remains relevant and acceptable, licensees and nuclear steam system suppliers have suggested that additional guidance on the acceptability of new information management technologies is needed. NRC regulations already recognize the acceptability of storing and maintaining licensee records in electronic media. Specifically, 10 CFR 50.71(d)(1), "Maintenance of Records, Making of Reports," states that records that must be maintained pursuant to 10 CFR Part 50 "may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period." In addition, various other parts of the regulations, such as in Part 20, Parts 30-39, and Parts 40 and 70 for example, indicate that electronic media are acceptable for use when the requirements for authentication, reproduction, and storage are met. This RIS provides the additional guidance requested by the nuclear industry on storing and maintaining QA records in electronic media. The guidance applies to QA records that are subject to the requirements of Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76, and that are noted in a licensee's QA program description. In addition, this guidance may be followed to satisfy the record keeping and maintenance requirements found in other parts of the regulations that specify that electronic media are acceptable for storing documents.

Since addressees are responsible for ensuring the integrity of QA records, Attachment 1 to this RIS provides a list of guidance documents on establishing an electronic recordkeeping system to maintain the integrity, authenticity, and acceptability of QA records during their required retention period in accordance with the requirements of Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76. These guidance documents also describe methods to authenticate electronic records, prevent their alteration or falsification, protect them from or recover them following a disaster, and manage their software configuration. Although the complete set of guidance documents referenced in Attachment 1 constitutes an acceptable method for satisfying the provisions of Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76 with regard to the storage of QA records in electronic media, this guidance does not supersede

current QA record commitments in the addressees' QA program descriptions. These guidelines are intended only for use in meeting recordkeeping requirements and no other requirements.

This RIS does not provide guidance pursuant to other regulations, such as 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

In accordance with 10 CFR 50.54(a), 10 CFR 50.71(e), 10 CFR 71.37, 10 CFR 72.11(a), 10 CFR 72.140(c), 10 CFR 76.9(a) or 10 CFR 76.68(b), as appropriate, addressees choosing to use electronic media for managing QA records should include this information in their new or updated QA program descriptions. The new or updated QA program description should describe the addressee's implementation of the guidance in this RIS or otherwise describe how the relevant criteria in Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76 continue to be satisfied when electronic media are used for managing QA records. The addressee should specify the media in which records will be kept (optical disk, magnetic tape, and so on), and whether GL 88-18 or this RIS is being implemented.

RELATED GENERIC COMMUNICATION

GL 88-18, "Plant Record Storage on Optical Disks," issued October 20, 1988.

BACKFIT DISCUSSION

Backfitting is defined in 10 CFR 50.109 as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position." In addition, 10 CFR 72.62 and 10 CFR 76.76 contain a similar backfitting definition.

This RIS imposes no new requirements and imposes no new regulatory staff positions, nor does it provide a new interpretation of a previously applicable staff position and, as such, does not constitute a backfit as defined in 10 CFR 50.109, 10 CFR 72.62, or 10 CFR 76.76. Furthermore, this RIS requires no action or written response. Any action on the part of addressees to use electronic media for managing QA records is strictly voluntary. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment was published in the *Federal Register* (63 FR 64) on April 3, 1998, seeking comment on a draft supplement to GL 88-18. Comments were received from 11 respondents, including 8 power reactor licensees, 2 industry groups, and 1 consulting firm. The NRC staff's evaluation of the comments is available from the NRC Public Document Room. After considering the comments received, the NRC staff appropriately revised the text of the generic communication. Additionally, the generic letter supplement was reformatted as a regulatory issue summary in keeping with recent actions taken by the staff to improve the agency's generic communications program and its implementation; this is described more fully in RIS 99-01, "Revisions to the Generic Communications Program."

PAPERWORK REDUCTION ACT STATEMENT

The information collections contained in this RIS are covered by the requirements of 10 CFR Part 50, 10 CFR Part 60, 10 CFR Part 71, and 10 CFR Part 72, which were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011, 3150-0127, 3150-0008, and 3150-0132, respectively. Pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), OMB clearance is not required for 10 CFR Part 76.

PUBLIC PROTECTION NOTIFICATION

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

If you have any questions about this matter, please contact the technical contacts listed below, the appropriate Office of Nuclear Reactor Regulation (NRR) or the appropriate Office of Nuclear Material Safety and Safeguards (NMSS) project manager.

RA/Charles E. Ader FOR

David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Technical contacts: Michael T. Bugg, NRR
301-415-3221
E-mail: mtb@nrc.gov

RA/Patricia K. Holahan FOR

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

James J. Pearson, NMSS
301-415-1985
E-mail: jjp@nrc.gov

Mark A. Sitek, NMSS
301-415-5799
E-mail: mas3@nrc.gov

Attachments:

1. Guidance on Managing Quality Assurance Records in Electronic Media
2. References
3. List of Recently Issued NRC Regulatory Issue Summaries

**GUIDANCE ON MANAGING QUALITY ASSURANCE
RECORDS IN ELECTRONIC MEDIA**

Industry Guidelines

The Electronic Recordkeeping Subcommittee of the Regulations Committee of the Nuclear Information and Records Management Association, Inc. (NIRMA) has prepared a set of four guidelines¹ on collecting, storing, and maintaining electronic quality assurance (QA) records for nuclear power plants and other facilities subject to the regulations identified in this generic letter.

1. NIRMA Technical Guide (TG) 11-1998, "Authentication of Records and Media"
2. NIRMA TG 15-1998, "Management of Electronic Records"
3. NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance"
4. NIRMA TG 21-1998, "Electronic Records Protection and Restoration"

When implemented together, these guidelines provide an acceptable basis for complying with the recordkeeping requirements of 10 CFR Part 31, Part 32, Part 34, Part 40, Appendix B to 10 CFR Part 50, Part 60², Part 70, Part 71, Part 72, or Part 76. The scope of the NRC's acceptance of these four NIRMA technical guidelines is only for managing electronic quality assurance records.

Supplemental Industry Guidelines

The NRC does not prohibit a licensee from using additional guidance documents. Licensees may use the following Institute of Electrical and Electronics Engineers (IEEE) standards³ to supplement the NIRMA guidelines.

- IEEE Std. 610.12-1990, "Standard Glossary of Software Engineering Terminology"
- IEEE Std. 730-1989, "Standard for Software Engineering Quality Assurance Plans"
- IEEE Std. 828-1990, "Standard for Software Configuration Management Plans"
- IEEE Std. 1008-1987 (R1993), "Standard for Software Unit Testing"

¹NIRMA publications may be obtained from the Nuclear Information and Records Management Association, Inc., 210 Fifth Avenue, New York, NY 10010.

²Pages 8640 through 8679 of Federal Register Volume 64, No. 34, dated February 22, 1999, contains proposed rulemaking that would provide requirements for disposal of high-level radioactive wastes in a geologic repository at Yucca Mountain, Nevada (proposed 10 CFR Part 63). The guidance provided in this RIS is acceptable for the QA program requirements proposed in the 10 CFR Part 63 rulemaking.

³IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

- IEEE Std. 1012-1986 (R1992), "Standard for Software Verification and Validation Plans"
- IEEE Std. 1028-1988 (R1993), "Standard for Software Reviews and Audits"
- IEEE Std. 1062-1993, "Recommended Practice for Software Acquisitions"
- IEEE Std. 1219-1992, "Standard for Software Maintenance"
- IEEE Std. 1228-1994, "Standard for Software Safety Plans"

However, implementation of these IEEE standards does not imply or ensure compliance with any NRC requirements.

REFERENCES

1. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50).
2. Section 50.71, "Maintenance of Records, Making of Reports," of Title 10 of the *Code of Federal Regulations* (10 CFR 50.71).
3. Part 70, "Domestic Licensing of Special Nuclear Material," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 70).
4. Part 71, "Packaging and Transportation of Radioactive Material," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 71).
5. Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 72).
6. Part 76, "Certification of Gaseous Diffusion Plants," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 76).
7. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3.
8. Regulatory Guide 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records," Revision 2.
9. Generic Letter 88-18, "Plant Record Storage on Optical Disks," October 20, 1988.
10. American National Standards Institute (ANSI) N45.2.9-1974, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants."
11. American National Standards Institute/American Society of Mechanical Engineers, (ANSI/ASME) NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," 1983 edition.
12. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 11-1998, "Authentication of Records and Media."
13. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 15-1998, "Management of Electronic Records."
14. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 16-1998, "

Software Configuration Management and Quality Assurance."

15. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 21-1998, "Electronic Records Protection and Restoration."

From: BJS3@nrc.gov
To: Multiple recipients of list <gc-nrr@nrc.gov>
Date: Mon, Oct 23, 2000 3:40 PM
Subject: NRC REGULATORY ISSUE SUMMARY 00-18

Recently Issued Generic Communications are listed below, also attached in WordPerfect 8.0 is file:

NRC Regulatory Issue Summary 00-18, "Guidance on Managing quality Assurance Records in Electronic Media," issued October 23, 2000.

To subscribe or unsubscribe send an email to listproc@nrc.gov, no subject, and one of the following commands in the message portion:

subscribe gc-nrr (first and last name)
unsubscribe gc-nrr (no name please)

The URL for Web access to generic communication files on the NRC Homepage is:
<http://www.nrc.gov/NRC/GENACT/GC/index.html>

LIST OF RECENT NRC GENERIC COMMUNICATIONS

NRC Regulatory Issue Summary 00-18, "Guidance on Managing quality Assurance Records in Electronic Media," issued October 23, 2000.

NRC Information Notice 00-17, "Crack in Weld Area of Reactor Coolant System Hot Leg Piping at V. C. Summer," issued October 18, 2000.

NRC Information Notice 00-16, "Potential Hazards Due to Volatilization of Radionuclides," issued October 5, 2000.

NRC Information Notice 00-15, "Recent Events Resulting in Whole Body Exposures Exceeding Regulatory Limits," issued September 29, 2000.

NRC Information Notice 00-14, "Non-Vital Bus Fault Leads to Fire and Loss of Offsite Power," issued September 27, 2000.

NRC Information Notice 00-13, "Review of Refueling Outage Risk," issued September 27, 2000.

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ATTACHMENT 4

Graded Quality Assurance in a Risk-Informed and Performance-Based Regulatory Environment

By Larry Campbell and Timothy Kobetz

Introduction

Several U.S. Nuclear Regulatory Commission (NRC) regulations contain requirements that permit applicable NRC quality assurance (QA) requirements to be applied to systems, structures, and components (SSCs) to an extent consistent with their importance to safety. It is important to note that the regulations also require that the licensee's QA program describe how the QA requirements, contained in the regulations, will be satisfied.

In the mid-1990s, the NRC began to transition its regulatory focus from being compliance-based to being risk-informed and performance-based. This resulted in many changes to the way both the Agency and the nuclear industry assessed nuclear facility performance in an effort to focus the appropriate attention on safety/risk-significant systems and operations. As such, QA programs also have begun to focus more attention on safety/risk-significant issues and less attention on issues with low safety consequences.

A graded QA program is structured to apply QA measures and controls to all items and activities in proportion to the significance of their safety functions. Depending on the type of facility, the QA program applies to items and activities that are important to safety, important to waste isolation, or safety-related. A graded QA program should also describe the process used to establish the degree of importance based on the safety/risk significance of each of the items or activities.

This paper presents one method the NRC accepts for applying QA requirements to SSCs, consistent with their importance to safety.

Work Description

All NRC licensees may choose to implement a graded QA program. Although licensees will adjust their QA programs to accommodate their individual needs, all graded QA programs should have the following four essential elements:

1. Categorization of SSCs

The QA program should adequately describe, at a high tier, the safety/risk-significant categorization process. This is, for the most part, an engineering analysis, using both probabilistic and deterministic considerations appropriate to the analysis. This should involve the consideration of quantitative and qualitative probabilistic risk assessment results in conjunction with engineering evaluations and plant experience to make an integrated assessment of the safety significance of the SSCs. Each type of facility is unique; therefore, the basis and methodology used for categorization are based on specific facility activities, design, and safety considerations. The licensee may select two or more safety/risk-significance categories (e.g., high, low, or medium). The QA Program should contain provisions for

reassessing the safety/risk-significance categorization when new information becomes available.

2. QA Controls for Categories

The selection of graded QA controls to be applied to each safety/risk-significant category must be described in adequate detail. Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decision-Making: Graded Quality Assurance," Section 3.2, "Potential Areas for Implementing GQA Program Controls," provides guidance on acceptable application of graded QA controls. In proposing reduced QA controls, the following two basic objectives should be kept in mind:

- The graded QA program should be sufficient to reasonably ensure the design integrity and ability of the SSC to successfully perform its intended safety function; and
- The graded QA program should include processes that support an effective corrective action program.

The goal is to allow licensees flexibility to define acceptable QA controls that provide reasonable confidence that the SSCs will perform their intended functions. The assignment of QA controls is dynamic and it is necessary to consider feedback information, from the monitoring and corrective-action elements, that may lead to reinstatement of controls that had previously been relaxed.

Graded QA controls may be applied to any element of the QA program. The following paragraphs discuss four of the potential elements where graded QA may be applied to low-risk/safety-significant SSCs and related activities. Reference 1 addresses additional areas.

a. Procurement

A licensee may choose to reduce commitments regarding source verifications and procurement program audits. However, for low-safety/risk-significant items, licensee practices for receipt inspections, post-installation testing, and a component-level monitoring program for plant operations should provide feedback to identify any necessary corrective actions. Overviews of suppliers will be based on performance monitoring and trending of this feedback.

b. Inspections

The licensee may choose to reduce inspection activities by monitoring or performing surveillance oversight to ensure that components perform their intended functions. Verifications by peer personnel may be implemented if the licensee uses individuals qualified to do inspections and independent from the actual performance of the work activity, as discussed above. However, these changes cannot conflict with other inspections and examinations specified in NRC regulations (e.g., use of the Authorized Nuclear Inspector services or inspections and examinations required by the American Society of Mechanical Engineers Boiler and Pressure Vessel Code).

Licensees may propose to reduce training and qualification for personnel who perform inspections on low-safety/risk-significant items. The QA organization will need to provide periodic oversight of these inspectors. Because of the unique industry standards for special processes, the application of graded QA controls should not be applied to the training and qualification of staff who perform nondestructive examinations.

c. Audits

Processes and work may be audited less thoroughly and less frequently than high-safety/risk-significant activities. Surveillance, performance monitoring, self-assessments, trend data, or other activities may in some cases replace formal audits.

d. Use of Reduced Sampling

The use of reduced sampling plans for low-safety/risk significant SSCs and related activities may be appropriate. The basis, including any supporting analyses, for the use of sampling plans should be documented. The following apply to the use of sampling plans: (a) sampling plans used for high-safety/risk-significant items and activities are expected to use criteria that provide a high level of confidence such as a 95 percent confidence that there are only 5 percent defective items in a lot (95/5); (b) reduced sampling plans may be used for low-safety/risk significant items and activities; and (c) activities and items sampled at the reduced level are essentially homogenous.

3. Feedback Mechanisms

The QA program must contain provisions for a feedback process to adjust graded QA controls and provisions to reassess the QA controls when new information becomes available through adverse trends or nonconformance reporting. The licensee QA program description should discuss elements specifically related to effective corrective actions and causal analysis.

It is important that the licensee have an effective process in place so that adjustments can be made in the graded QA program on the basis of industry experiences. The licensee process controls should have the capability to determine whether SSCs have been treated properly in the graded QA program. Failures, or performance degradations, of low-safety/risk significant SSCs should be identified in accordance with the licensee corrective action programs so that the licensee can ascertain whether the reduction of the QA controls has resulted in excessive nonconformances and an unacceptable decrease in performance of SSCs and barriers.

The licensee should employ techniques such as monitoring, surveillance, and trend analysis to identify when an SSC is found to be unacceptable or the reliability of low-safety/risk significant SSCs are trending toward unacceptable levels. SSC monitoring approaches should be used to accomplish this goal.

4. Reassessment Methods

Provisions for an effective root-cause analysis and corrective action, as a result of the feedback process, should be described. Provisions should also be described for evaluating common-cause/mode failures. The licensee corrective action efforts should determine, at a minimum,

the apparent cause of repetitive failures of SSCs under the graded QA controls, so that it can be decided whether graded QA controls should be adjusted. In some instances, a failure may result in an unanticipated event and may cause the categorization of the SSC to be changed.

Results

The NRC has initiated rulemaking to implement new regulations for a repository at Yucca Mountain. Part 63 of Title 10 of the U.S. Code of Federal Regulations is the latest risk-informed regulation to be proposed by NRC. As such, NRC is currently preparing a risk-informed review plan for a license application for a repository at Yucca Mountain if Yucca Mountain is found to be acceptable for a high-level waste repository.

The review plan is being written to accommodate the potential use of graded QA controls. High-safety/risk significant items and activities should have a high level, or full application, of QA control, and less-safety/risk significant items and activities may have reduced QA controls.

Additional information on the use of graded QA practices that the staff has found acceptable for low-safety/risk-significant items is described in the references.

Conclusions and Discussion

Graded QA is intended to provide a safety benefit by allowing licensees and the NRC to preferentially allocate resources based on the safety significance of an item or activities related thereto. Licensees developing graded QA programs should adjust their programs to accommodate their individual needs.

The licensee's QA program must describe the graded QA process and how the applicable NRC regulatory requirements will be satisfied. The graded QA program should contain high-tier descriptions of the essential elements of the graded QA process, including an adequate description of the graded QA controls to be applied to low-safety/risk significant SSCs.

References

1. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decision-Making: Graded Quality Assurance,"
2. U.S. Nuclear Regulatory Commission, SECY-97-229, "Graded Quality Assurance/Probabilistic Risk Assessment Implementation Plan for the South Texas Project Electric Generating Station."
3. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.174, "An approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," July 1998.
4. U.S. Nuclear Regulatory Commission, NRC Inspection Manual, Inspection Procedure 35703, "Graded Quality Assurance," June 1999.

DISCLAIMER: The contents of this paper were based on the authors' interpretation of the above listed references and may not necessarily represent the position of the U.S. Nuclear Regulatory Commission.

ATTACHMENT 5



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

Status of Data and Software Qualification

Presented to:
NRC/DOE Quality Assurance Meeting

Presented by:
Dr. Robert F. Wemheuer
Management and Operating Contractor

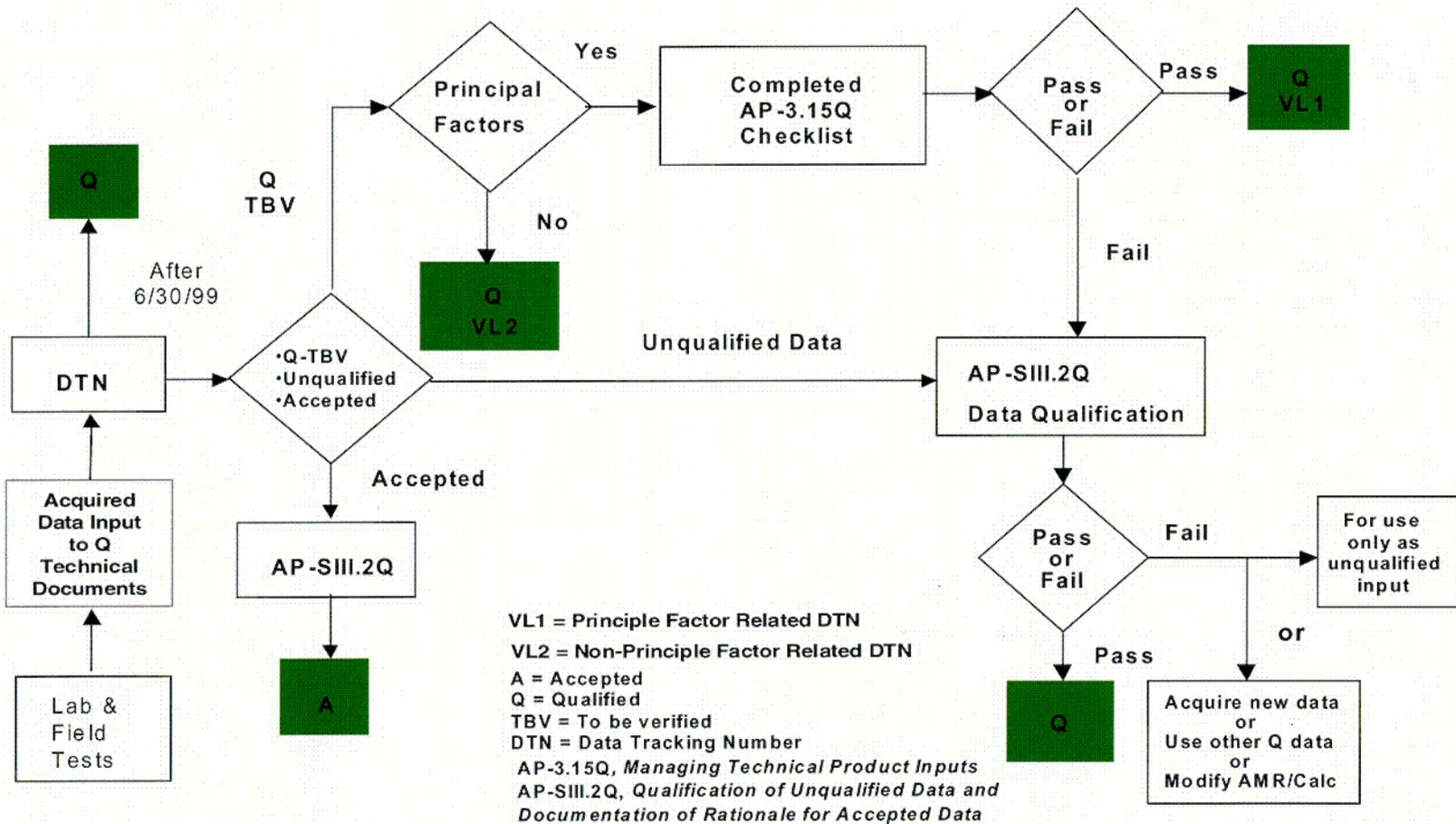
December 19, 2000

**YUCCA
MOUNTAIN
PROJECT**

Objectives and Focus

- **Conduct verification and qualification activities for data and software used in AMRs**
- **Focus continues to be on data supporting the SRCR and SR**
- **Control and ensure the integrity of the verification and qualification processes using approved quality procedures**
- **Ensure supporting software used to support technical products is qualified**
- **The overall objective is to assure the integrity, fidelity and confidence in data, software and process procedures that provide the foundation for the development of the SRCR, SR and LA**

Data Verification and Qualification Process



PMR Status vs. 12/22/00 Goals

PMR	% Data Qualified	% Data Verified	% Software Qualified
Biosphere	89	100	100
Disruptive Events	92	100	100
EBS	82	93	96
ISM	74	93	100
Near Field	87	100	98
SZ F&T	80	100	85
UZ F&T	81	93	97
Waste Form	71	92	100
Waste Package	86	92	100
December 22, 2000 Goals	80	90	80

Data status as of 12/15/2000

Software status as of 12/15/2000

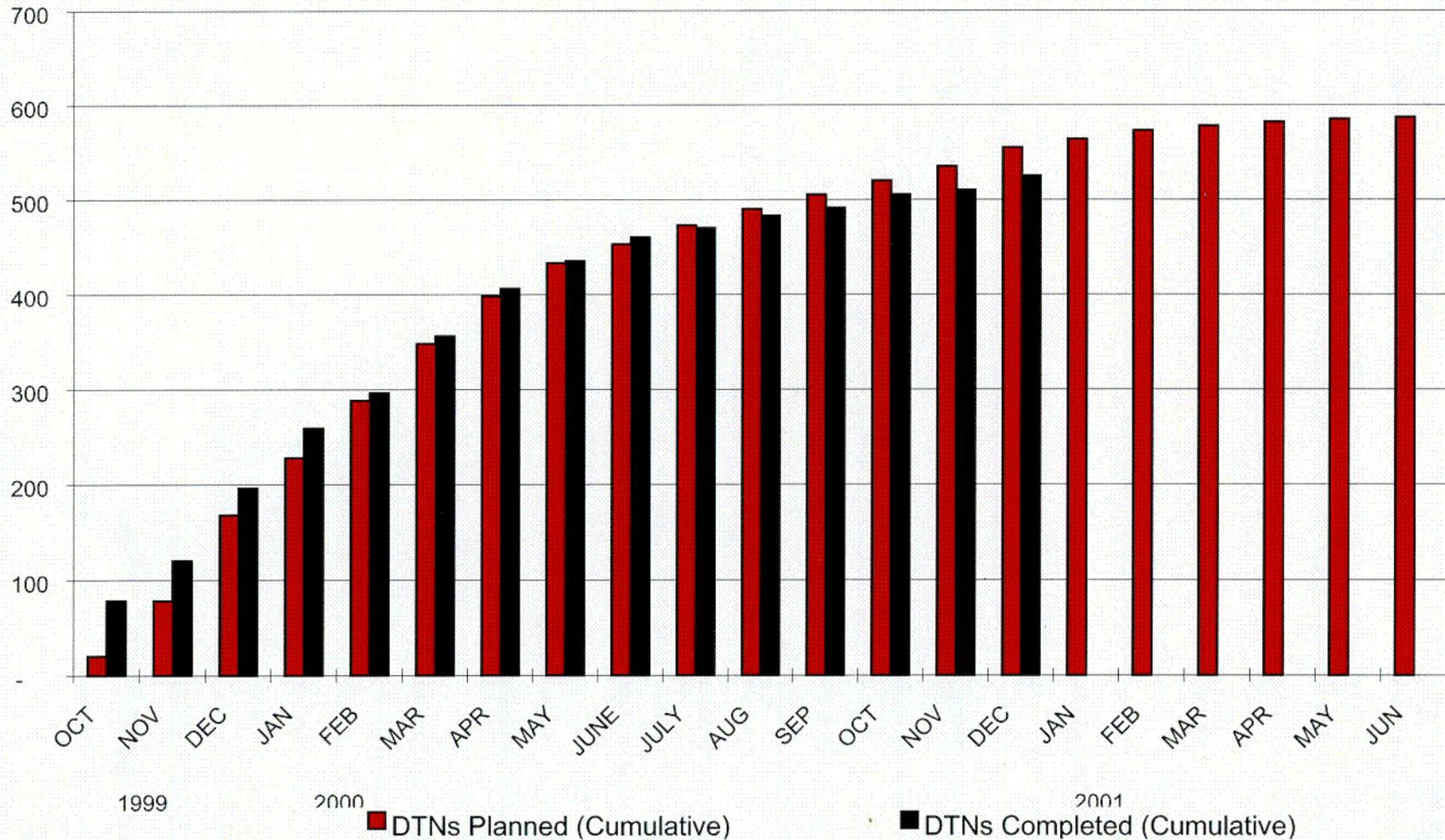
Green = Meets or above December 22, 2000 Goal

Yellow = Below December 22, 2000 Goal

C-2

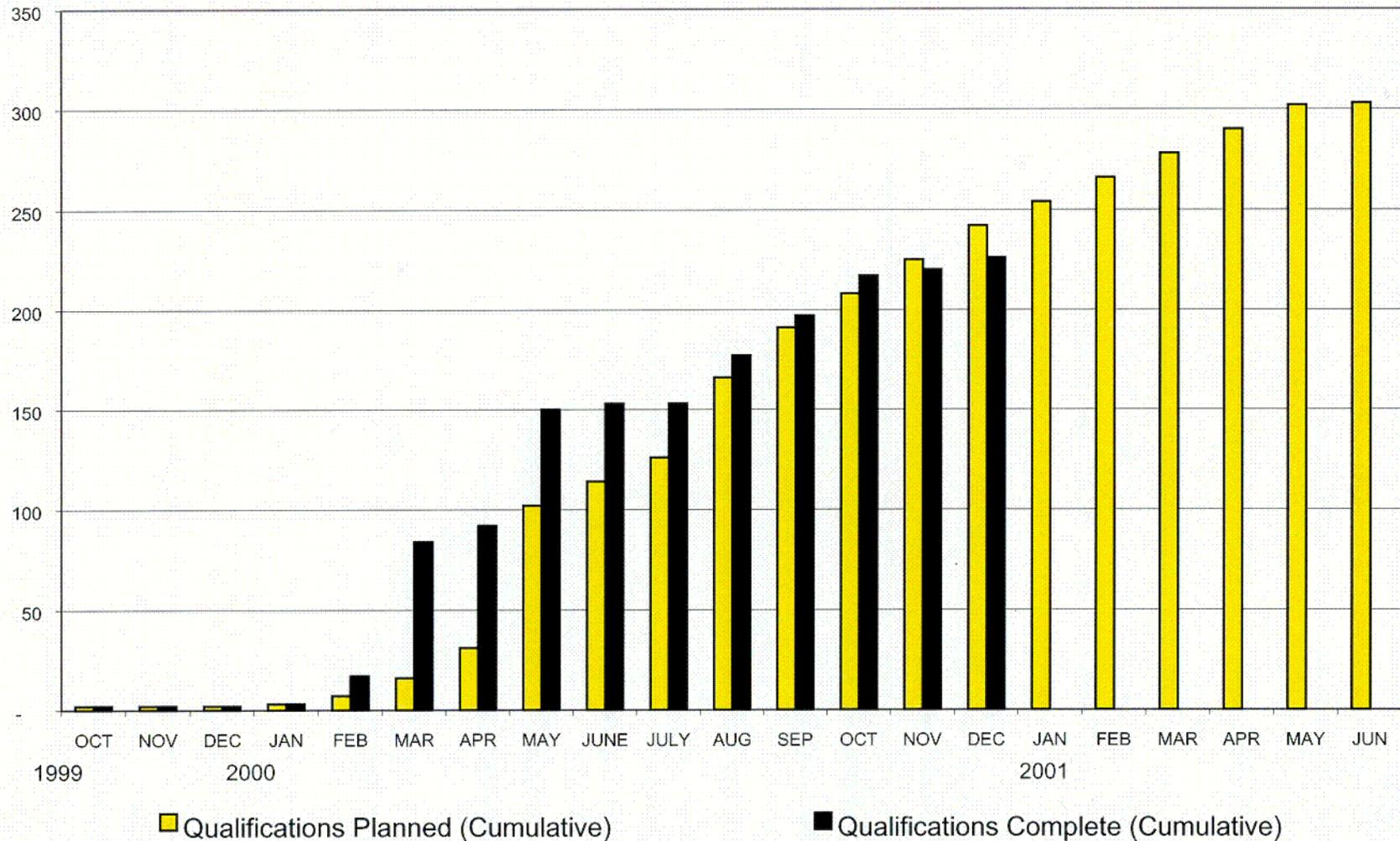
M&O DTN Verifications

Planned vs. Completed as of 12/15/2000



6-3

M&O DTN Qualifications Planned vs. Completed as of 12/15/2000



Handwritten initials

Verification/Qualification Status as of 12/15/00

	<u>Total</u>	<u>Completed</u>	<u>To-Go</u>	
VL1 DIRS (Verif. Checklists)	238	214	24	(Q-TBV) ("actual citations")
VL1 Sources (Verif. Checklists)	349	311	38	(Q-TBV) ("daughters")
VL2 (No Verification Checklists)	167	167	0	(Q-TBV)
Accepted Data (Fact)	88	88	0	(e.g., handbooks, textbooks)
Accepted Data approved by Assistant Manager, Office of Project Execution	53	28	25	(e.g., journal articles)
Qualified by procedures established after 6/30/99	15	15	0	
Unqualified DTNs	<u>333</u>	<u>226</u>	<u>107</u>	
Totals	1243	1049	194	
% of Total Data Citations		84%	16%	

Note: Document Input Reference System VL1+VL2+AP-SIII.2Q+Accepted (894) + Source VL1 (349) = Total Data Citations (1243)

DTNs Qualified Post 6/30/99

DTN

LA0002JF831222.001
LA0003JC831341.001
LA0003JC831341.002
LA0003JC831341.003
LB000121123142.003
LL000112051023.004
LL000112105924.111
LL000123351021.117
LL000201405924.121
LL991208205924.096
LL000210551021.120
LL000316205924.142
MO0003RIB00071.000
MO0005PORWATER.000
MO9804MWDGFM03.001

AMR

S0040, U0085
U0100
U0100
U0100
N0120
F0095
W0035, W0040
F0110
W0085
W0035, W0070
F0060
W0095
W0045, W0055, W0095
E0100
I0035

Software Qualification Status as of 12/15/00

	<u>Unqualified</u>	<u>Qualified</u>	<u>Total</u>	<u>%UnQ</u>	<u>%Qual</u>
Codes	9	52	61	15%	85%
Routines	0	333	333	0%	100%
Macros	<u>0</u>	<u>14</u>	<u>14</u>	<u>0%</u>	<u>100%</u>
Total	9	399	408	2%	98%

Unique Unqualified Software Codes

<u>CODE NAME</u>	<u>AMR</u>	<u>SOFTWARE DESCRIPTION</u>
ERMASITEGEOLOGIST V6.0.1	S0000	Used for subsurface studies Code can create, attribute, and manipulate 2-D and 3-D cross sections, post data with attribute symbology, generate boring logs and post screen horizons to map.
FEHM V.210 (SUN)	U0065 U0160 U0070 S0045 S0025 S0055	Used for parameter studies in the design and specification of field tracer & flow experiments & their interpretation. Will also be used for field-scale simulations of radionuclide migration in saturated/unsaturated zones below Yucca Mountain.
INFIL V2.0	U0010	Used as a numerical simulation code for determining fieldwater balance between precipitation, runoff, evapotranspiration, change in soil water storage and drainage.
INFIL VA2.a1	U0095	Used as a modification of INFIL V2.0 which allows this code to accept input from a pre-processing software program and allow the infiltration model software code to output to a post-processing software.

Unique Unqualified Software Codes

(Continued)

<u>CODE NAME</u>	<u>AMR</u>	<u>SOFTWARE DESCRIPTION</u>
LAGRIT V1.0	S0045 U0100	Used for 3-D finite element and finite volume mesh generation for saturated and unsaturated zone flow and transport calculations.
MSTHAC V6.2	E0120	Software develops time histories of variables of interest at various locations within the Engineered Barrier System.
NETPATH V2.13	S0040 S0045	Used to correct groundwater C14 ages in field data used to support the saturated zone.
PEST V2.0	S0045	Used to assist in data interpretation, model calibration and predictive analysis.
PETROSYS V7.60d	S0000	Used to create grids of data representing irregular spaced data points. Grids can be exported to ASCII format and/or contoured.

Data Confirmation Results as of 12/15/00

<u>ORG</u>	<u>Completed Checklists</u>	<u>Verified Q</u>	<u>Verified UQ</u>	<u>Failure Rate**</u>
USGS	267	254	13	4.9%
LANL	94	94	0	0%
LBNL	3	2	1	33%
LLNL	17	17	0	0%
M&O*	50	48	2	4.0%
SNL	79	78	1	1.3%
Total	510	493	17	3.3%

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

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

Impact and Significance of Unqualified Data

- **Overall verification reject rate for Q-TBVs continues to be low ~ 3.3%**
- **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**
- **Effects of unqualified data are captured in parameter uncertainties; TSPA sensitivity results identify the parameters important to performance**
- **Data and input management process controls are in place to evaluate specific impacts should any data sets fail the qualification process**
- **Will include impact and significance discussion in SRCR transmittal letter**

Challenges

- **Qualification production continues to be greatly dependent on early identification of new or additional unqualified data or software requiring qualification**
- **Due to AMR changes, RSS Rev 4, and Principle Factors, scope fluctuations in UnQ- & Q-TBV DTNs and software requiring qualification have been experienced**
- **There is increasing complexity in the remaining unqualified DTNs that require more processing time**
- **Despite the challenges, there is commitment by M&O, Labs & USGS to improve the integration of activities and timeliness of products to support data and qualification schedules**

Summary

- **The qualification of data and software will meet the schedule to support SRCR submittal providing:**
 - **90% of data verified by 12/22/00**
 - **80% of data qualified by 12/22/00**
 - **80% of software qualified by 12/22/00**
- **The above percentages are predicated on documents that are specifically referenced in the SRCR, plus revisions or ICNs**

Summary

(Continued)

- **Coordination and integration, between the authors, regulatory and qualification groups, and other affected parties, has become increasingly more effective and is supported by senior management**
- **DSQD expects to meet all activities supporting SRCR and the transmittal of required data and software qualification information**

Backup

Key Process Procedures

- Initial verification activities were performed to a project-wide Development Plan per AP-2.13Q, *Technical Product Development Planning*
- AP-2.13Q was superseded by AP-2.21Q, *Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities*
- Data verification checklists are prepared per AP-3.15Q, *Managing Technical Product Inputs*
- Data qualification is performed per AP-SIII.2Q, *Qualification of Unqualified Data and Documentation of rationale for Accepted Data*
- Software qualification is performed per AP-SI.1Q, *Software Management*

Model Validation Status

AMRs Describing Models	AMR ID	AMR/PMR Document Control ID	Version	Open Validation Issues	Remarks
Aging and Phase Stability of WP Outer Barrier	W0020	ANL-EBS-MD-000002	Rev 00		
General and Localized Corrosion of WP Outer Barrier	W0035	ANL-EBS-MD-000003	Rev 00		
Generalized & Localized Corrosion on Drip Shield	W0085	ANL-EBS-MD-000004	Rev 00		
SCC of DS,WP Outer Barrier & SS Struct Material	W0095	ANL-EBS-MD-000005	Rev 00		
Hydrogen Induced Cracking of Drip Shield	W0105	ANL-EBS-MD-000006	Rev 00		
Degradation of Stainless Steel Structural Material	W0115	ANL-EBS-MD-000007	Rev 00		
Clad Degradation- Local Corrosion Zirc and its Alloys	F0035	ANL-EBS-MD-000012	Rev 00		
Clad Degradation - Dry Unzipping	F0030	ANL-EBS-MD-000013	Rev 00		
Clad Degradation -Wet Unzipping	F0025	ANL-EBS-MD-000014	Rev 00		
CSNF Waste Form Degradation: Summary Abstract	F0055	ANL-EBS-MD-000015	Rev 00		
Defense HLW Glass Degradation	F0060	ANL-EBS-MD-000016	Rev 00		
In-Drift Thermal-Hydrological-Chemical Model	E0065	ANL-EBS-MD-000026	Rev 00 ICN 01		
Water Diversion Model	E0085	ANL-EBS-MD-000028	Rev 00	DR 119 EOC	Model not used in TSPA, no impact
Water Drainage Model	E0070	ANL-EBS-MD-000029	Rev 00 ICN 01	DR 119 EOC	Model not used in TSPA, no impact
Ventilation Model	E0075	ANL-EBS-MD-000030	Rev 00		
Invert Diffusion Properties Model	E0000	ANL-EBS-MD-000031	Rev 01		
Water Distribution and Removal Model	E0090	ANL-EBS-MD-000032	Rev 00		
EBS: Physical & Chemical Environment Model	E0100	ANL-EBS-MD-000033	Rev 00 ICN 01		
EBS Radionuclide Transport Model	E0050	ANL-EBS-MD-000034	Rev 00 ICN 01		
In-Package Chemistry Abstraction	F0170	ANL-EBS-MD-000037	Rev 00		
In Drift Microbial Communities	E0040	ANL-EBS-MD-000038	Rev 00		
Seepage/Backfill Interactions	E0030	ANL-EBS-MD-000039	Rev 00	DR 119 EOC	No longer relevant, backfill not in current design.
In Drift Corrosion Products	E0020	ANL-EBS-MD-000041	Rev 00		
In-Drift Colloids and Concentration	E0045	ANL-EBS-MD-000042	Rev 00		
Seepage/Invert Interactions	E0060	ANL-EBS-MD-000044	Rev 00	DR 119 EOC	Model not directly used in TSPA. (See Note 1)
In-Drift Precipitates/Salts Analysis	E0105	ANL-EBS-MD-000045	Rev 00		
Physical & Chemical Environmental Abstraction Model	E0010	ANL-EBS-MD-000046	Rev 00		
Multiscale Thermohydrologic Model	E0120	ANL-EBS-MD-000049	Rev 00		
WAPDEG Analysis of WP and Drip Shield Degradation	W0050	ANL-EBS-PA-000001	Rev 00	DR 119	Model has been revised.
Abst Mdls Pitting & Crevice Corrosion DripShield/WP	W0040	ANL-EBS-PA-000003	Rev 00		
SCC of Drip Shield & WP Outer Barrier & H2 Induced	W0045	ANL-EBS-PA-000004	Rev 00		
Abstraction of Models for SS Structural Material Degradation	W0120	ANL-EBS-PA-000005	Rev 00		
Evaluation of Applicability of Biosphere-Related FEPs	B0000	ANL-MGR-MD-000011	Rev 00		
Development of Numerical Grids for UZ F&T Modeling	U0000	ANL-NBS-HS-000015	Rev 00		
UZ & SZ Transport Properties	U0100	ANL-NBS-HS-000019	Rev 00	DR 119	Validation issues will be addressed as part of DR.
Modeling SubGridblock Scale Dispersion in 3D Hetero	S0015	ANL-NBS-HS-000022	Rev 00	DR 119 EOC	Model not used in TSPA, no impact
Particle Tracking Model/Abstr of Transport Process	U0065	ANL-NBS-HS-000026	Rev 00	DR 119	Validation issues will be addressed as part of DR.
UZ Colloid Transport Model	U0070	ANL-NBS-HS-000028	Rev 00		
Input & Results Base Case SZ F&T Model TSPA	S0055	ANL-NBS-HS-000030	Rev 00		
SZ Colloid-Facilitated Transport	S0035	ANL-NBS-HS-000031	Rev 00		
Simulation of Net Infiltration for M & P Climate	U0010	ANL-NBS-HS-000032	Rev 00		

Model Validation Status

AMRs Describing Models	AMR/ID	AMR/RMR Document Control ID	Version	Open Validation Issues	Remarks
Hydrogeologic Framework Model	S0000	ANL-NBS-HS-000033	Rev 00		
Abstraction of Drift Seepage	U0120	ANL-NBS-MD-000005	Rev 00		
Thermal Tests Thermal-Hydrological Analysis/Model Report	N0000	ANL-NBS-TH-000001	Rev 00		
DSNF and Other WF Degradation Abstraction	F0065	ANL-WIS-MD-000004	Rev 01		
Summary of Dissolved Concentration Limits	F0095	ANL-WIS-MD-000010	Rev 00	DR 119	Validation will be addressed in Rev 01.
WF Colloid-Assoc Concentration Limits : Abst & Sum	F0115	ANL-WIS-MD-000012	Rev 00		
Igneous Consequence Modeling for TSPA-SR	T0070	ANL-WIS-MD-000017	Rev 00		
EBS Radionuclide Transport Abstraction	E0095	ANL-WIS-PA-000001	Rev 00		
Geologic Framework Model 3.1	I0035	MDL-NBS-GS-000002	Rev 00, ICN 01		
Mineralogical Model	I0045	MDL-NBS-GS-000003	Rev 00, ICN 01		
Rock Properties Model	I0040	MDL-NBS-GS-000004	Rev 00, ICN 01		
Drift Scale Coupled Processes (DST & THC Seepage) Models	N0120	MDL-NBS-HS-000001	Rev 00		
Calibrated Properties Model	U0035	MDL-NBS-HS-000003	Rev 00		
Seepage Calibration Model & Testing Data	U0080	MDL-NBS-HS-000004	Rev 00		
Conceptual & Numerical Models for UZ F&T	U0030	MDL-NBS-HS-000005	Rev 00		
UZ Flow Models and Submodels	U0050	MDL-NBS-HS-000006	Rev 00		
Mtn-Scale Coupled Process (TH) Model	U0105	MDL-NBS-HS-000007	Rev 00		
Radionuclide Transport Models under Ambient Cond	U0060	MDL-NBS-HS-000008	Rev 00		
SZ Transport Method and Component Integration	S0025	MDL-NBS-HS-000010	Rev 00		
Calibration of the Site-Scale SZ Flow Model	S0045	MDL-NBS-HS-000011	Rev 00		

General Notes:

Models are validated as suitable for their intended use using the process specified in procedure AP-3.10Q.

"DR 119" refers to the originally identified validation issues in Deficiency Report LVMO-00-D-119.

"DR 119 EOC" refers to the validation issues identified as part of the "Extent of Condition" section in Deficiency Report LVMO-00-D-119.

Notes:

1. Model not directly used in TSPA; validation will be addressed either in next ICN or merged with the Physical and Chemical Abstraction Model.

Single Use Software Routines in DR-39 Bins

PMR	Bin 1	Bin 2	Bin 3	Bin 4
BIO	0	3	3	1
DE	0	5	0	12
EBS	0	5	1	76
ISM	0	0	0	0
NFE	0	4	1	4
SZ	0	2	0	24
UZ	0	42	0	21
WF	0	7	1	0
WP	0	4	0	2
Totals	0	72	6	140

ATTACHMENT 6



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

Quality Assurance

Presented to:
NRC/DOE Quality Assurance Meeting

Presented by:
Robert W. Clark
Department of Energy
Yucca Mountain Site Characterization Project

December 19, 2000

**YUCCA
MOUNTAIN
PROJECT**

DR LVMO-00-D-39

Brief Description

- **Inaccurate documentation and validation of software routines and macros**
- **Identified via:**
 - **OQA Audits M&O-ARP-00-06 and M&O-ARP-00-08**
 - **Phase 3 Verification of CAR-LVMO-98-C-006**

DR-LVMO-00-D-39

Significance of DR to Software Qualification Status Summary

- **A comprehensive review of the 122 AMRs that support the 9 PMRs was conducted**
 - **The review was performed to evaluate the use of single and multiple use routines**
 - **Review results indicate there are 280 single use and 90 multiple use software routines**
 - **The 90 multiple use routines were reviewed - all discrepancies corrected. No further action required**

DR-LVMO-00-D-39

(Continued)

Significance of DR to Software Qualification Status Summary (Continued)

The 280 single use software routines were classified into 4 Bins

Bin # 1

- **38 AMRs - no impact. No single use routines/macros subject to the requirements of AP-SI.1Q were used in the AMR. No further action required**

Bin # 2

- **31 AMRs - no impact. Software adequately documented inside the AMR. No further action required**

DR-LVMO-00-D-39

(Continued)

Significance of DR to Software Qualification Status Summary (Continued)

Bin # 3

- **33 AMRs - Impact Indeterminate, the use of commercial software (i.e. Built in- functions, math operators, or formulas) were not adequately documented inside the AMR**

Bin # 4

- **20 AMRs - Impact Indeterminate. Developed software (i.e. routines developed in C, FORTRAN, BASIC) including some commercial software were not adequately documented in the AMRs**

DR-LVMO-00-D-39

(Continued)

Required further actions to resolution

BIN # 3

- **Evaluate each use of commercial software, separate into two categories as appropriate**

Category 1

- **The calculation used internal built-in functions. If use of commercial software has no impact, provide rationale**

Category 2

- **The calculation is an algorithm that is a string of arithmetic functions or other user-written application to obtain results**
- **Calculation, input, algorithm or process steps used, and the output need to be documented and impacts addressed**

DR-LVMO-00-D-39

(Continued)

Required further actions to resolution (Continued)

BIN # 4

- **The commercial software contained inside the AMRS will be documented as noted in BIN # 3, (previous page)**
- **User developed software routines**
 - **A detailed checklist is being provided to appropriate AMR authors**
 - **Specific information is being solicited to adequately document the single use routine inside the AMR**
 - **The completed checklist with the impacts addressed will be attached to the associated AMR**

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(Continued)

Anticipated completion of corrective action

- **Corrective action scheduled to be complete 03/30/01**
- **Verification of corrective action to be completed 04/15/01**

U.S. Department of Energy Office of Quality Assurance

Audit Schedule

- **Internal Audit Schedule - (See Handout)**
- **External Audit Schedule - (See Handout)**

Office of Quality Assurance Functions (After Transition)

OQA Direct Support Contractor Scope

- **Development and maintenance of the QARD**
- **Quality Assurance Program Management & Policy**
- **Quality Systems support to YMSCO Federal Staff**
- **Conduct of all independent QA program audits and surveillances at all major participant locations**
- **Trending of all quality assurance program deficiencies**

QAMA Contractor Scope

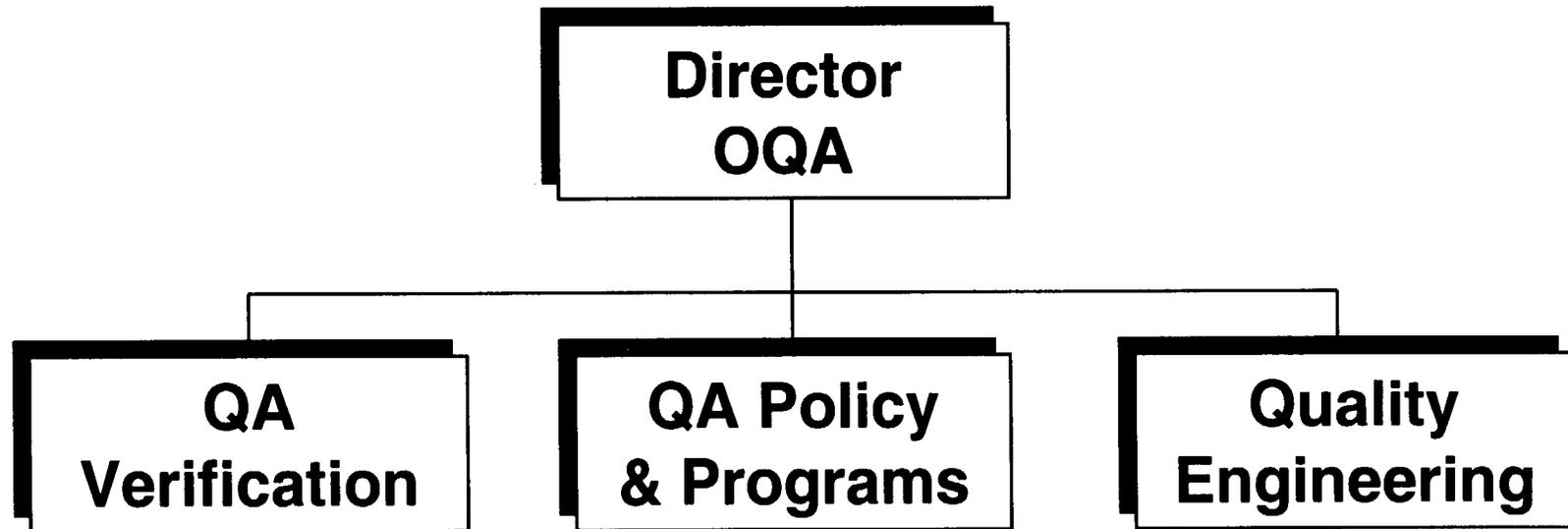
- **Perform QA management assessments of Affected Organizations**

Management and Operations QA Functions

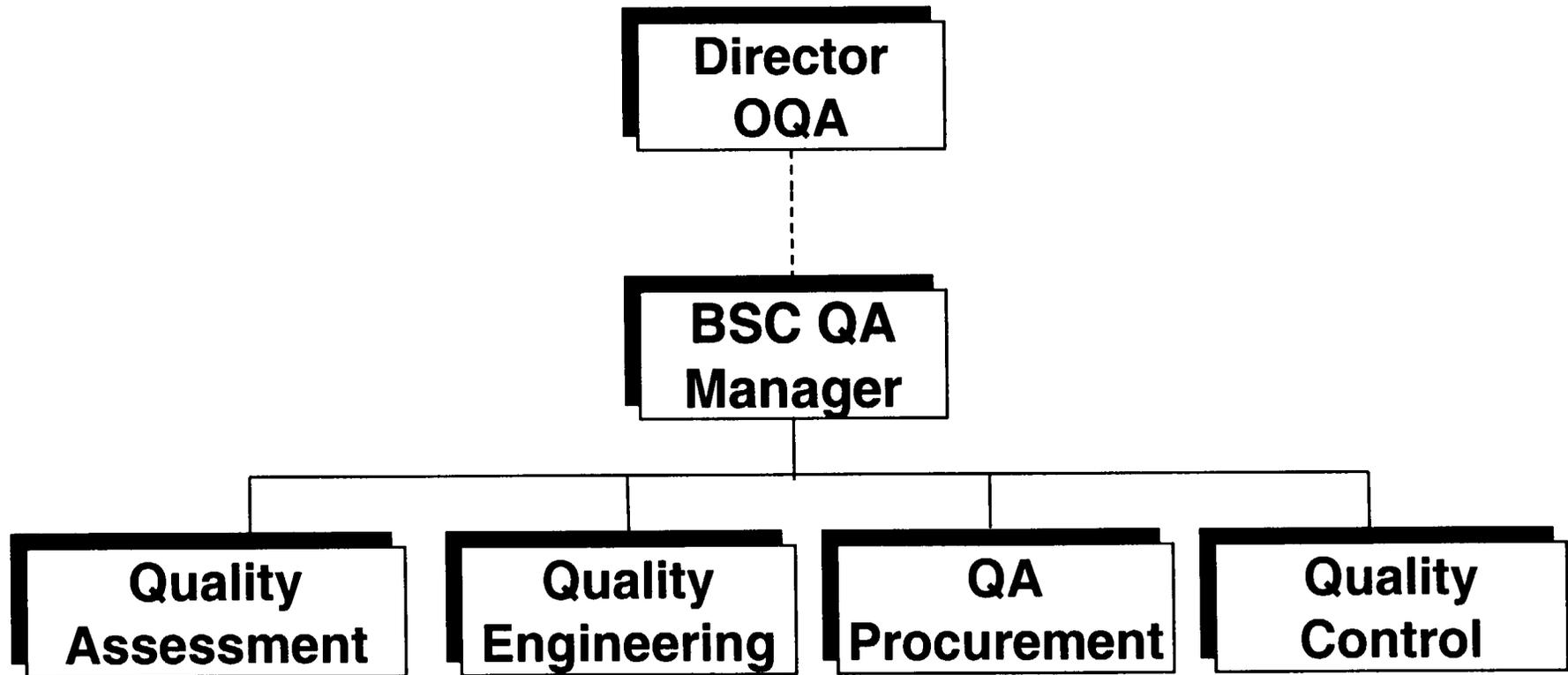
M&O QA Scope

- **Quality Engineering Functions**
 - Review of M&O procedures & procurement documents
 - In-process review of M&O technical & design documents
 - Providing advice to M&O Line regarding QA matters
 - Review & concurrence of M&O generated deficiencies
 - Maintenance of M&O QSL/Supplier Verification
- **Quality Control Functions**
 - Independent inspection of facility items
 - Receipt inspection of procured items
 - Non destructive Examination
- **On Site QA Representation of National Lab/USGS**
 - Perform Quality Engineering functions

Office of Quality Assurance and Direct Support Organization



M&O Organization (Tentative)



OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
 FY-01 QUALITY ASSURANCE INTERNAL AUDIT SCHEDULE, REVISION WIP

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ORGANIZATION	LOCATION	NUMBER	TEAM LEADER	DATES	QA CRITERIA
M&O	LAS VEGAS, NV	M&O-ARC- 1-003	V. Barish	01/16/01-01/19/01	C 1
M&O	LAS VEGAS, NV	M&O-ARP- 1-001	D. Harris	02/09/01-02/09/01	PB 2
M&O	LAS VEGAS, NV	M&O-ARP- 1-002	R. Hartstern	02/05/01-02/09/01	PB 3
M&O	LAS VEGAS, NV	M&O-ARC- 1-005	J. Voigt	02/26/01-03/02/01	C 4
M&O	LAS VEGAS, NV	M&O-ARC- 1-006	TBD	MAR 2001	C 5
M&O	LAS VEGAS, NV	M&O-ARP- 1-004	K. Hodges	APR 2001	PB 6
M&O	LAS VEGAS, NV	M&O-ARC- 1-007	TBD	APR 2001	C 7
EM	GERMANTOWN, MD	EM-ARC- 1-009	TBD	MAY 2001	C 8
M&O	LAS VEGAS, NV	M&O-ARC- 1-012	TBD	MAY 2001	C 9
M&O	LAS VEGAS, NV	M&O-ARC- 1-010	TBD	JUN 2001	C 10
USGS	DENVER, CO	USGS-ARC- 1-011	TBD	JUN 2001	C 11
M&O	LAS VEGAS, NV	M&O-ARC- 1-008	TBD	JUL 2001	C 12

See Scope/Notes Attached

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
FY-01 QUALITY ASSURANCE INTERNAL AUDIT SCHEDULE, REVISION WIP

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ORGANIZATION	LOCATION	NUMBER	TEAM LEADER	DATES	QA CRITERIA
EM	IDAHO FALLS, ID	EM-ARC- 1-013	TBD	AUG 2001	C 13
YMSCO	LAS VEGAS, NV	YMSCO-ARC- 1-014	TBD	AUG 2001	C 14
OQA	LAS VEGAS, NV	OQA-ARC- 1-015	TBD	SEP 2001	C 15

See Scope/Notes Attached

SCOPE/NOTES

- 1 Compliance with elements 4* & 7* of DOE/RW-0333P. *=Include appendices A and C as part of this audit, as applicable.
- 2 WBS 1.2.21.3 Process Model Report - EBS Degradation Flow & Transport, plus compliance with applicable elements of DOE/RW-0333P. Audit rescheduled at the request of the CRWMS M&O Waste Management and Repository Facilities Director.
- 3 WBS 1.2.21.3 Process Model Report - Unsaturated Zone Flow and Transport, plus compliance with applicable elements of DOE/RW-0333P. Audit rescheduled at the request of the CRWMS M&O ARTS Manager and the LBNL Lab Lead.
- 4 Compliance with supplements II & IV of DOE/RW-0333P.
- 5 Compliance with elements 8, 9*, 10*, 11, 12, 13 & 14 of DOE/RW-0333P. *=Include appendices A and C as part of the audit, as applicable.
- 6 WBS 1.2.21.3.2 - Total System Performance Assessment-Site Recommendation, plus compliance with applicable elements of DOE/RW-0333P.
- 7 Compliance with element 3, supplement III* & appendix B of DOE/RW-0333P. *=Include appendices A and C as part of the audit, as applicable.
- 8 Compliance with all applicable elements of DOE/RW-0333P.
- 9 Compliance with elements 1, 2*, 5 & 6 of DOE/RW-0333P. *=Include appendices A and C as part of the audit, as applicable.
- 10 Compliance with supplements I and V of DOE/RW-0333P.
- 11 Compliance with all applicable elements of DOE/RW-0333P.
- 12 Compliance with elements 15*, 16 & 17 of DOE/RW-0333P. *=Include appendices A and C as part of the audit, as applicable.
- 13 Compliance with all applicable elements of DOE/RW-0333P.
- 14 Compliance with all applicable elements of DOE/RW-0333P.
- 15 Compliance with all applicable elements of DOE/RW-0333P.