



Department of Energy
 Yucca Mountain Site Characterization
 Project Office
 P. O. Box 98608
 Las Vegas, NV 89193-8608

WBS 1.2.9.3
 QA

JAN 04 1991

Richard J. Herbst
 Technical Project Officer
 for Yucca Mountain
 Site Characterization Project
 Los Alamos National Laboratory
 University of California
 N-5, Mail Stop J521
 P.O. Box 1663
 Los Alamos, NM 87545

CLOSURE OF STANDARD DEFICIENCY REPORT (SDR) 222, REVISION 0, RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION AUDIT 88-08 OF LOS ALAMOS NATIONAL LABORATORY

SDR 222, Revision 0, has been closed based on satisfactory verification of completed corrective actions. A copy of the SDR is enclosed for your files.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973, or Neil D. Cox of Science Applications International Corporation at (702) 794-7236 or FTS 544-7236.

Catherine Hampton
 Donald G. Horton, Director
 Yucca Mountain Quality Assurance Division

YMQAD:CEH-1426

Enclosure:
 SDR 222, Revision 0

cc w/encl:
 K. R. Hooks, NRC, Washington, DC
 S. W. Zimmerman, NWPO, Carson City, NV
 J. L. Day, LATA, Los Alamos, NM
 H. P. Nunes, LANL, Los Alamos, NM
 N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:
 J. H. Hines, OQD, AL
 A. R. Chernoff, MSD, AL
 H. E. Valencia, LAAO
 J. W. Gilray, NRC, Las Vegas, NV
 R. A. Morley, LANL, Los Alamos, NM

9101150134 910104
 PDR WASTE
 WM-11 FDR

FULL TEXT ASCII SCAN

YMP-5
 142123

102.7
 WM-11
 NAD3

YMPQ STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completec by Originating QA Organization	1 Date 10/6/88		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 46
	3 Discovered During Audit 88-08		3a Identified By K. Schwartztrauber		3b Branch Chief Concurrence Date
	5 Organization LANL		6 Person(s) Contacted M. McGowan/K. Eggert		4 SDR No. 222 Rev. 0
	7 Response Due Date is 20 Working Days from Date of Transmittal				
Completec by Originating QA Organization	8 Requirement (Audit Checklist Reference, if Applicable) LANL QAPP, R2 Sections 5.1 and 3.3.1 state that activities and software used to support a license application are documented and controlled according to LANL implementing procedures.				
	9 Deficiency Contrary to the above requirement, the quality of software development documentation activities prior to the implementation of LANL procedure TWS-QAS-QP-3.1, RO, dated 21-Sept-88 cannot be assured. The following				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Modify LANL procedure TWS-MSTQA-QP-14 or TWS-QAS-QP-3.1 to include criteria				
Completec by Originating QA Organization	11 QAE/Lead Auditor Date William H. Camp 11/4/88		12 Branch Manager Date A. J. Caldwell 4 Mar 89		13 Project Quality Mgr. Date James Blaylock 11/15/88
	14 Remedial/Investigative Action(s) Refer to Page 5 of 6				
Completec by Originating QA Organization	15 Effective Date				2/28/89
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 6 of 6				
Completec by Originating QA Organization	17 Effective Date				
	18 Signature/Date James 12/21/88				
Comp. by Orig. QA Org.	19 Response <input type="checkbox"/> Accept <input checked="" type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date W.H. Camp 3-9-89		Branch Manager/Date A.J. Caldwell 9 Mar 89
	20 Amended Response <input checked="" type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date William H. Camp 4-21-89		Branch Manager/Date A.J. Caldwell 21 Apr 89
	21 Veri-fication <input checked="" type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date Neil D. Cox 12/20/90		Branch Manager/Date James Blaylock 12/21/90
	22 Remarks 1. TELECON: N.D. COX TO H. NUNES EXTENSION REQUEST TO BE PREPARED JAN 2-12, 1990. DATE: 12/22/89 2. TELECON: N.D. COX TO H. NUNES, JAN. 18, 1990, REPEATED EXTENSION REQUEST DATED 11 JAN. 90. LETTER NO. TWS-13 01 9096, HERBST TO HORTON 3. LETTER HERBST TO HORTON, dated 1/11/90, No. TWS-13-01-90-066, REQUESTED CLOSURE. (RCD 1/23/90) 4. LETTER HORTON TO HERBST, dated 2/7/90, YMP:RBC-1916, REQUEST DENIED, NEW COMPLETION DATE REQUESTED.				
23 QA CLOSURE					
QAE/Lead Auditor/Date Neil D. Cox 12/21/90		Branch Manager/Date N/A		PQM/Date James Blaylock 12/21/90	

It is dated 12/22/88 - TWS-13-01-90-066

ENCLOSURE

WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-GA-038
10/86

SDR No. 222

Rev. 0

Page 2 of 6

8 Requirement (continued)

The LANL NNWSI QAPP, R2, Sections 5.1 and 5.2 require that activities affecting quality be performed in accordance with documented procedures (i.e., QP's or DPs). Section 3.3.1 of the QAPP also states that computer software used to support a license application is documented and controlled according to LANL implementing procedures. Section 3.1.6 of the LANL NNWSI QAPP, R2 also requires that LANL establish procedures for review, approval and release of documents transmitting (software) information or items across scientific investigation interfaces.

LANL NNWSI QAPP, R2 states that, LANL will institute a software configuration management program through implementing procedures and will provide documentation of this program to the Records Management System (RMS).

9 Deficiency (continued)

objective evidence was examined to support this finding:

- o LANL procedures do not specify appropriate quantitative or qualitative criteria for determining satisfactory work performance and compliance with QA requirements for scientific notebook documentation of software development activities.
- o CAR 045 does not specify that a determination be made of the impact on quality resulting from the software development work performed prior to the date LANL procedural guidance was in effect.
- o CAR 045 does not specify the action necessary to preclude the issuance of LANL reports and or publications containing data/results generated from computer codes which are not baselined, controlled and fully verified and validated as defined by NUREG-0856.
- o LANL procedure TWS-QAS-QP-3.1, R0 and LANL NNWSI QAPP, R2 does not state that computer programs developed and/or modified for the YMP shall be documented and controlled in accordance with the applicable elements of NUREG-0856.
- o LANL procedure TWS-QAS-QP-3.2, R0 does not state that the minimum requirements for software configuration management include a chronology of versions and description of changes made between versions.
- o LANL procedure TWS-QAS-QP-3.1, R0 does not specify how software verification, test and validation interface controls are coordinated among project participants. However, LANL is participating in Computer Code Verification Efforts (called COVE) with SNL, USGS, LLNL, LBL and PNL under Subtask D, titled "Computer Code Benchmarking Activities", of LANL

YMP O STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 222

Rev. 0

Page 3 of 46

9 Deficiency (continued)

SIP 87/4.1.7, RO (WBS 2.3.4.1.7/A) without interface procedural control.
Software interface controls are not addressed in LANL CAR 045.

DISCUSSION

LANL is developing Quality Assurance Level I scientific and engineering software and has been involved in this activity for several years to support the Yucca Mountain/NNWSI Project. LANL failed to issue procedural guidance to control software development documentation and to institute a software configuration management program as required by Section 3.3 of the LANL QAPP. LANL has recognized this deficiency in CAR 045, "Software Control", dated 19-Sept-88. On 21-Sept-88 LANL issued procedure TWS-QAS-QP-3.1, RO. The audit team did not have the benefit of reviewing this procedure prior to the audit, however, this procedure contained programmatic deficiencies, as described above, which were discovered during the conduct of the audit.

10 Recommended Actions (continued)

for satisfactory compliance with QA requirements for scientific notebook documentation of software development activities; include model development, mathematical methods, numerical techniques, source code listing references and changes.

2. Determine the impact on quality of software development work performed prior to the effective date of TWS-QAS-QP-3.1, RO. Investigate whether or not all LANL YMP software development documentation is being consistently prepared, reviewed, verified and validated
3. Document by Nonconformance Report all publications and reports containing data/results generated from computer codes which were not baselined, controlled, and fully verified and validated according to LANL procedures. Determine the impact on quality of publication of results based on the use of unqualified data and unverified and unvalidated computer codes. Develop measures to assure the LANL reports and publications are not released which contain data generated by uncontrolled computer codes unless appropriate disclaimers are included.
4. Modify LANL procedure TWS-QAS-QP-3.1 so that a commitment to the documentation requirements of NRUEG-0856 is stated.
5. Modify LANL procedures TWS-QAS-QP-3.1 so that the minimum requirements for configuration management are included.



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 222

Rev. 0

Page 4 of 6

10 Recommended Actions (continued)

6. Modify LANL PROCEDURE TWS-QAS-WP-3.1 or other appropriate procedures to ensure that software interfaces are controlled, coordinated and documented. Document by Nonconformance Report all COVE and other interface information generated from computer codes without appropriate disclaimers stating that the data/results are not based on controlled and fully verified and validated computer codes. Determine the impact on quality of potential use of results based on the use of unqualified data and unverified and unvalidated computer codes. Develop measures to assure that future COVE benchmarking activities are conducted in accordance with LANL interface control procedures.

21. REMARKS (CONTINUED)

- REQUEST FOR EXTENSION RECEIVED 2/26/90, LETTER: HERBST TO HORTON, TWS-EES-13-02-90-048, DATED 2/20/90. EXTENSION REQUESTED DUE DATE: 4/1/90
- EXTENSION REQUEST GRANTED TO 5/21/90 BY LETTER HORTON TO HERBST, YMP:RBC-2327, DATED 3/9/90. LONGER TIME CONSIDERED NECESSARY FOR COMPLETION OF CORR. ACTION.
- Accept Extension 5/23/90 - YMP: ACW-3391
- UNREQUESTED EXTENSION GRANTED TO AUG. 31, 1990, LTR HORTON TO HERBST, DATED 5/23/90; YMP-ACW-3391 (DUPLICATE OF ITEM JUST ABOVE)

Extension Request 8/28/90 - TWS-EES-13-08-90-100
Extension Evaluation 9/26/90 - QA:CEH-5085

VERIFICATION

THE LANL SOFTWARE QA PLAN AND ITS ASSOCIATED IMPLEMENTING PROCEDURES WERE APPROVED BY THE PROJECT OFFICE BY LETTER HORTON TO HERBST, YMQAD:ACW-1257, DATED DEC. 19, 1990. THE PLAN AND IMPLEMENTING PROCEDURES CORRECT THE DEFICIENCIES IN THE SDR.

14. Remedial/Investigative Action(s)

Revisions to Procedures TWS-QAS-QP-03.1, R0 (LANL Computer Software Control) and QP-14 (Research and Development Experimental Procedure) (to be issued as TWS-QAS-QP-03.5, R0) are now in progress, with issuance scheduled for January 1989. These and other procedures, as well as actions already initiated, will address the noted deficiencies as detailed below.

- Criteria for determining satisfactory work performance will be in the revised QP-03.1. QA requirements for notebooks will be in QP-03.5.
- As part of obtaining a fully qualified QA program, Project personnel have been directed to identify computer codes used after June 1984 to generate data used in LANL reports. This information will be used to assess any effects on quality of codes developed before implementation of QP-03.1. At present, it is LANL's intention to use no computer-generated data developed before implementation of the qualified QA plan in pursuing its scope of work.
- QP-03.1 and revisions to that procedure specify that reports using codes that have not been verified must include a disclaimer to that effect. Criteria for reviewing reports, as contained in the technical review procedure (TWS-QAS-QP-03.2), will address this requirement.
- The methods described in QP-03.1 are consistent with, or go beyond, NUREG-0856. LANL procedures reference only the LANL QAPP. The QAPP, in turn, references external source documents. The LANL QAPP, Rev. 4, now in preparation, is expected to cite NUREG-0856 as one of the external reference documents for guidance of software QA control.
- The requirements for a chronology of codes and description of changes between versions occurs in the LANL QAPP, Rev. 2. The software control procedure requires development of that information. The chronology of code version is documented on the Software Summary Form. The procedure requires reissuance of the summary form and all supporting documentation to document changes between versions of a code.

- An interface control procedure (TWS-QAS-QP-01.2) will govern all organizational interface activities, including software related activities.

16. Cause of Condition and Corrective Action to Prevent Recurrence

Cause: Inadequate procedural direction. NUREG-0856 was referenced in the YMP QA Plan as a document for guidance, not as a specific implementing requirement.

Corrective Action: As noted in Section 14. All corrective actions and required training will be completed by 3/31/89.

14. Remedial/Investigative Action(s)

Revisions to Procedures TWS-QAS-QP-03.1, R0 (LANL Computer Software Control) and QP-14 (Research and Development Experimental Procedure) (to be issued as TWS-QAS-QP-03.5, R0) are now in progress, with issuance scheduled for January 1989. These and other procedures, as well as actions already initiated, will address the noted deficiencies as detailed below.

1. Criteria for determining satisfactory work performance will be in the revised QP-03.1. QA requirements for notebooks will be in QP-03.5.
2. The QAPP, R4.3, requires that any computer software and computer-generated data used for licensing must be documented in compliance with methods described in the LANL software quality administrative procedures. This documentation is currently described in QP-03.1. Codes developed before implementation of QP-03.1 will be documented as necessary, consistent with QP-03.1, before they are used for generating licensing information. Data generated by computer software that has not been documented and verified in accordance with the QA methods described in QP-03.1 are unacceptable for use in the licensing process.

As part of developing a fully qualified QA program, Project personnel at LANL have been directed to identify computer codes used after June 1984 to generate data appearing in LANL reports. Any of these data that may be required for licensing will be regenerated after the code and associated documentation have been shown to be in compliance with QP-03.1 or subsequent implementing procedures for software QA. The regeneration of these data will ensure that there is no effect on quality resulting from software developed before implementation of QP-03.1.

Control of computer software and computer-generated data is achieved through the application of the procedure governing the technical review of technical information products (reports), QP-03.2. The procedure stipulates that a quality assurance review be performed of all computer software described in or used to generate data appearing in the report. A disclaimer is

SLC 4/14/89 - TWS-NS-04-89-047

to be inserted in the report identifying any software that is not in full compliance with QA requirements.

Surveys and audits will be used to verify that LANL software is being developed and documented in accordance with QA requirements. All LANL groups currently using or developing computer software will be audited against the applicable software QA requirements.

3. QP-03.1 and revisions to that procedure specify that reports using codes that have not been verified must include a disclaimer to that effect. Criteria for reviewing reports, as contained in the technical review procedure (TWS-QAS-QP-03.2), will address this requirement.
4. The methods described in QP-03.1 are consistent with NUREG-0856. LANL procedures reference only the LANL QAPP. The QAPP, in turn, references external source documents. The LANL QAPP, Rev. 4.3, issued 3/30/89, cites NUREG-0856 as one of the external reference documents for guidance of software QA documentation.
5. The requirements for a chronology of codes and description of changes between versions occurs in the LANL QAPP, Rev. 4.3. The software control procedure explains the development of that information. The chronology of code version is documented on the Software Summary Form. The procedure requires reissuance of the summary form and all supporting documentation to document changes between versions of a code.
6. An interface control procedure (TWS-QAS-QP-01.2) will govern all organizational interface activities, including software related activities.

16. Cause of Condition and Corrective Action to Prevent Recurrence

Cause: Inadequate procedural direction. NUREG-0856 was referenced in the YMP QA Plan as a document for guidance, not as a specific implementing requirement.

Corrective Action: As noted in Section 14. All corrective actions and required training will be completed by 4/30/89.