



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

ACCEPTANCE OF AMENDED RESPONSE AND CLOSURE OF STANDARD DEFICIENCY REPORT
(SDR) 466, REVISION 0, RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT 89-07 OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS)

The YMQAD staff has evaluated and accepted your amended response to SDR 466,
Revision 0, generated as a result of YMQAD Audit 89-07 of Los Alamos.

The SDR has been closed based on satisfactory verification of completed
corrective action. 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 Donald G. Harris of Science Applications
International Corporation at (702) 794-7356 or FTS 544-7356.

Donald G. Horton, Director
Yucca Mountain Quality Assurance Division

YMQAD:CEH-1429

Enclosure:
SDR 466, Revision 0

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

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

FULL TEXT ASCII SCAN

YMP-5

146124

9101150036 910104
PDR WASTE
WM-11 PDR

102.7
WM-11
NH03

ORIGINAL
THIS IS A RED STAMP

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/17/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 23
	3 Discovered During Audit 89-7		3a Identified By F. Ruth/ J. Hadden		4 SDR No. 466 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted K. Foster		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, If Applicable) (Checklist Item 6-4) TWS-QAS-QP-06.1, Rev. 1, Para. 6.5, states "The holder of a controlled document removes and destroys obsolete documents in accordance with directions				
	9 Deficiency A random sample of the 59 controlled manuals were reviewed in accordance with the latest revision of the table of contents, dated October 13, 1989, to determine if all appropriate procedures had been removed or marked superseded				
Completed by Organization in Block 5	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities or documentation, to				
	11 QAE/Lead Auditor/Date S Dana 11/30/89		12 Division Manager/Date Hadden 12-18-89		13 Project Quality Mgr/Date Hadden 12/1/89
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				
	15 Effective Date 2/16/90				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				
Completed by Organization in Block 5	17 Effective Date 2/16/90				
	18 Signature/Date Hadden 1/12/90				
	19 Response Accepted		QAE/Lead Auditor/Date S Dana 2/21/90	Division Manager/Date S Dana 2/21/90	Project Quality Mgr/Date Hadden 2/21/90
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date Hadden 12-18-90	Division Manager/Date N/A	Project Quality Mgr/Date Hadden 2/21/90
	21 Remarks See Ltr. Hadden to Hadden, dtd 2/12/90, SDR Response Clarification & Amendment and SDR response Ltr. Hadden to Hadden, dtd. 1/11/90. Extension Request 2/20/90-TWS-EES-13-02-90-045-accept 3/6/90-YMP-RBC-2281 Accept Response 3/6/90-YMP-RBC-2245 Amended Response Res'd dtd 3/30/90-TWS-EES-13-03-90-111 Accepted extension 5/8/90-YMP-CEH-3112 Extension Request 7/10/90-TWS-EES-13-07-90-038-accepted 8/6/90-YMP-CEH-4414 Extension Request 10/31/90-TWS-EES-13-10-90-080 (Cont'd)				
22 QA CLOSURE		QAE/Lead Auditor/Date Hadden 12-18-90	Division Manager/Date N/A	PQM/Date Hadden 2/21/90	

ENCLOSURE

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 466

Rev. 0

Page 2 of 3

DP4

8 Requirement (continued)

given in the receipt acknowledgement form. If the holder of a controlled document prefers to keep obsolete revisions, he may do so, but he must mark "superseded," "obsolete," or a similar expression on the cover page of the outdated version and note this action on the receipt acknowledgement form."

9 Deficiency (continued)

or obsolete as required. During the review, procedures were found which should have been removed or marked obsolete. In one case (#90), one procedure was missing from the manual.

Note: The following is a list of the controlled manuals that were reviewed and all discrepancies discovered during the review were corrected during the audit:

#4
#5
#27
#40
#48
#50
#85
#86
#90

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

21 Remarks (Cont'd)

Amended Response Acceptable - *W. Harris* 10/20/90
C. Hampton 10/30/90

accept Amended Response 11/6/90 - QA: CEN - 706
Extension Request TWS-EES-13-11-90-038 - 11/13/90 - accept / YMRAD: CEN-1116-12/1/90
amended Response TWS-EES-13-12-90-011-12/13/90

Amended Response Acceptable - *S. Davis* 12/10/90 CH 12/15/90
Block 20, Closure statement attached - *W. Harris* 12/18/90

14 Remedial/Investigative Action(s)

Remedial Actions: No action is required because the manuals referenced in Block 9 of the SDR were corrected during the audit.

Investigative Actions: All controlled manual holders will be directed to review their controlled copies and verify in writing that it is complete and up to date with the correct revisions and change requests.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: Failure of the copy holders to update their manuals as instructed by the controlled distribution system.

Corrective Action to Prevent Recurrence: All manual holders will be retrained in QP-06.1, Document Control. The LANL QAS will verify a random sample of QA Manuals each calendar quarter to achieve a 95% confidence level.

SDR 463-Clarification

1. Add the following to Block 16-Cause of Condition & Corrective Action to Prevent Recurrence:

"Training will be provided to reviewers to identify the relationship of QP03.2 and QP03.16 and emphasize appropriate use of these procedures during the review process."

SDR 464-Amendment

1. Change Block 16-Cause of Condition and Corrective Action to Prevent Recurrence to read as follows:

"Cause-Study plans were not checked after changes(additions) were made to ensure changes did not impact technical content. These changes were made at the verbal direction of the Project Office."

"Corrective Action to Prevent Recurrence-Remaining Study Plans will be checked by Technical Reviewers to ensure any changes or additions do not impact technical content of the Study Plans prior to submittal to the Project Office."

SDR 465-Amendment

1. Change Block 14-Remedial\Investigative Action(s) to read as follows:

"Remedial Action-The DPs listed in Block 9 of the SDR will be reviewed and corrected as necessary to address acceptance and reject criteria or limits."

"Investigative Action-All remaining DPs will be reviewed to ensure that acceptance and reject criteria or limits are adequately addressed in these procedures. Corrections to remaining DPs will be made as necessary."

SDR 466-Amendment

1. Change Corrective Action to Prevent Recurrence in Block 16 to read as follows:

"All manual holders will be retrained in QP06.1 document control requirements. During the following quarter, the LANL QAS will verify from a random sample of QA Manuals that a 95% confidence level for the manuals has been achieved. In addition, an overview of QA Manuals for

SL dtl 2/12/90 - TWS-EES-13-02-40-033

proper document control will be performed by the QAS each calendar quarter. The requirements for this overview will be documented in a change to QP06.1."

SDR 467-Clarification

1. Add the following to Block 16-Cause of Condition and Corrective Action to Prevent Recurrence:

"Cause-It was intended to issue semi-annual Trend Reports rather than quarterly Trend Reports as required by QP16.2."

"Corrective Action to Prevent Recurrence-QP16.2 will be revised to specify issuance of semi-annual Trend Reports rather than quarterly reports."

SDR 468-Amendment

Block 14-Remedial/Investigative Action(s)

"Remedial-Review generic deficiencies identified in Block 9 for the corrective action process as well as those identified for specific CARs. The QAPL will then determine what remedial action is appropriate for each identified deficiency."

"Investigative-Review all CARs Issued to date for indication of deficient conditions such as those described in Block 9 of the SDR. Document and report the results of this review to the QAPL so that corrective action determined to be necessary may be initiated."

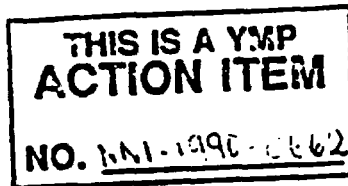
Block 16-Cause of Condition & Corrective Action to Prevent Recurrence

"Cause-Personnel error and procedural inadequacies."

"Corrective Action to Prevent Recurrence-The Corrective Program procedures will be revised to restructure the program. As a result, program requirements not previously addressed will be specified. After revision, training of all personnel involved in the Corrective Action Program will be performed with additional training provided to personnel involved with program implementation and administration."

Los Alamos

Los Alamos National Laboratory
Los Alamos, New Mexico 87545



WBS: 1.2.9.3.A
"QA"

March 30, 1990

TWS-EES-13-03-90-111

Mr. Donald Horton
Yucca Mountain Project Office
U.S. Department of Energy
P. O. Box 98518
Las Vegas, NV 89193-8518

Dear Mr. Horton:

**SUBJECT: AMENDED RESPONSE AND REQUEST FOR EXTENSION TO STANDARD
DEFICIENCY REPORT NO. 466 (ACTION ITEM NO. NN1-1990-0662)**

A survey undertaken by the QA staff showed that controlled distribution manual holders failed to properly maintain their quality assurance manuals (refer to Los Alamos YMP Survey Report No. LANL-02 with accompanying Deficiency Report DR-LANL-01). To continue with our corrective action efforts, I request an extension to June 29 for SDR 466. The following amended response to SDR 466 is submitted for your approval:

Block 16: Cause of Condition & Corrective Action to Prevent Recurrence

Cause of Condition: Manual holders have failed to update their manuals as required in the controlled distribution memorandum.

Corrective Action to Prevent Recurrence: The controlled distribution procedure will be revised to delineate the level of manual control needed, i.e., for quality affecting work and for information only. A new memorandum will be issued containing instructions to alleviate errors in direction and require QA Liaison oversight of the controlled distribution within each work area. The manual holders will be retrained to the new system.

During the quarter following the above actions, the Los Alamos Verification Group will verify a random sample of QA manuals.

If you have any questions, please contact Henry Nunes at (FTS) 843-8039.

Sincerely,

A handwritten signature in dark ink, appearing to read "R.J. Herbst".

R.J. Herbst

QA RECEIVED

APR 05 1990

Mr. Donald Horton
March 30, 1990
TWS-EES-13-03-90-111
Page 2

Cy: J. Blaylock, DOE/YMP, Las Vegas, NV
M. R. Diaz, DOE/YMP, Las Vegas, NV
* J. Brogan, SAIC, Las Vegas, NV
S. R. Dana, SAIC, Las Vegas, NV
A. K. Sacco, DOE/YMP, Las Vegas, NV
S. L. Bolivar, EES-1, MS D462
J. A. Canepa, EES-13, MS J521
M. J. Clevenger, EES-15, MS J495
E. M. Cole, LATA, MS M321
G. P. Cort, EES-13, MS J521
J. L. Day, LATA, MS M321
R. J. Herbst, EES-13, MS J521
T. A. Morgan, INC-7, MS J514
R. A. Morley, EES-1/LV, MS J900/527
H. P. Nunes, EES-13, MS J521
L. W. Schempp, MEE-9, MS J521
S. Sebring, MAT-3, MS P274
K. A. West, EES-13, MS J521
RPC file (2), LATA, MS M321
TWS-EES-13 file, MS J521
QA files, LATA, M321
CRM-4, MS A150

Los Alamos

Los Alamos National Laboratory
Los Alamos, New Mexico 87545

WBS 1.2.9.3
QA

QA RECEIVED

OCT 09 1990

October 3, 1990

TWS-EES-13-10-90-030

Mr. Donald Horton
Yucca Mountain Project Office
U. S. Department of Energy
P. O. Box 98608
Las Vegas, NV 89193-8608

Dear Mr. Horton:

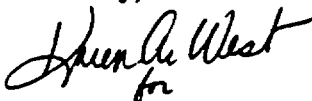
**SUBJECT: AMENDED RESPONSE FOR STANDARD DEFICIENCY REPORT NO. 466,
RESULTING FROM YMP AUDIT NO. 89-7, ACTION ITEM NN1-1990-0662**

Attached for your review and approval is a request for extension to the referenced standard deficiency report (SDR).

SDR No. 466, Request for extension for Corrective Action completion date to November 16. This extension is necessary for us to complete the corrective action to our controlled document distribution procedure. A draft of the Controlled Distribution procedure was completed and reviewed by the QA Liaisons. The final procedure must still be prepared (as required by the recently approved, revised quality implementation procedure for quality procedure preparation) and formally reviewed and approved. The extension will allow us to complete the procedure, conduct needed read-training for those who possess controlled copies of the QA Manual, and implement the procedure.

A copy of the draft quality procedure is attached for your information. If you have any questions, please contact Henry Nunes at (FTS) 843-8039.

Sincerely,



Richard J. Herbst

HPN/kb

Attachments: a/s

Cy: N. Arendt, MAT-3, MS P274
S. L. Bolivar, EES-1, MS D462
N. J. Brogan, SAIC, Las Vegas, NV
J. A. Canepa, EES-13, MS J521
M. J. Clevenger, EES-15, MS J495
E. M. Cole, LATA, MS M321
G. P. Cort, EES-13, MS J521
J. L. Day, LATA, MS M321
R. J. Herbst, EES-13, MS J521

T. L. Morgan, INC-7, MS J514
R. A. Morley, EES-1/LV, MS J900/527
H. P. Nunes, EES-13, MS J521
E. P. Springer, EES-13, MS J521
K. A. West, EES-13, MS J521
RPC file (2), LATA, MS M321
TWS-EES-13 file, MS J521
QA File, LATA, MS M321
CRM-4, w/o attach., MS A150

QA RECEIVED

WBS 1.2.9.3

QA

Los Alamos

DEC 17 1990

Los Alamos National Laboratory
Los Alamos, New Mexico 87545

December 13, 1990

TWS-EES-13-12-90-011

Mr. Donald Horton
Yucca Mountain Project Office
U.S. Department of Energy
P.O. Box 98608
Las Vegas, NV 89193-8608

SUBJECT: AMENDED RESPONSE FOR STANDARD DEFICIENCY REPORT NO. 466,
RESULTING FROM YMP AUDIT NO. 89-7, ACTION ITEM NN1-1990-0662

Dear Mr. Horton:

The following amended response to SDR 466, Revision 0, generated as a result of Project Office QA Audit 89-07 of Los Alamos, is submitted for your approval. Change the Corrective Action to Prevent Recurrence in Block 16 to read as follows:

"All LANL YMP employees and LANL YMP contractor employees on the QA manual controlled distribution list will be retrained to LANL-YMP-QP-06.1, R2, Document Control. During regularly scheduled internal and external audits the LANL YMP verification personnel will examine a random sample of controlled documents issued to LANL YMP employees and LANL YMP contractor employees to assure that the documents comply with the requirements of LANL-YMP-QP-06.1."

All actions necessary to complete the amended response have been completed. The response is amended because the new Revision 2 of LANL-YMP-QP-06.1 (formerly TWS-QAS-QP-06.1, R1) allows for LANL YMP employees and LANL YMP contractor employees to be issued individual controlled working copies of procedures. In addition, the examination of a random sample of controlled documents issued to personnel has been integrated into the LANL YMP audit process for Criterion 6.

If you have any questions, please contact Steve Bolivar at (FTS) 843-1868.

Sincerely,



R. J. Herbst

JLD/jlm

Cy: N. Arendt, MAT-3, MS P274
S. L. Bolivar, EES-13, MS J521
N. J. Brogan, SAIC, Las Vegas, NV
J. A. Canepa, EES-13, MS J521
M. Clevenger, EES-13, MS J495
E. M. Cole, LATA, MS M321
(Continued on reverse side)

SDR 466, Revision 0

LANL amended response letter to Donald Horton from Steve Bolivar, dated December 12, 1990, has been evaluated and accepted.

Block 20, Corrective Action Verification

1. No remedial actions were necessary. The manuals referenced in the SDR were corrected during the course of Audit 89-07.
2. Verified by review of LANL's YMP Reading Acknowledgement Forms, that all LANL YMP employees and contract employees were retrained to LANL-YMP-QP-06.1, Revision 2, Document Control, procedure. (Total of 37 personnel. Forms were dated November 9 thru December 6, 1990.)
3. Verified by review of LANL's Audit Checklist for Criteria 6, Document Control (LANL-YMP-QA 06.1, Revision 2) that the following attributes are contained on the checklist.

Verification that recipients of controlled documents follows the instructions outlined on the Controlled Document Acknowledgement form.

Verified that the recipients of controlled documents sign and return the form by the date indicated.

Verified that the recipient of controlled documents maintain the controlled documents.

4. Verified that LANL audits, AR-90-007, 90-008, 90-009, 90-010, and 90-011 contain attributes on Criteria 6, Document Control, there were two findings (one uncontrolled procedure in a manual and one instance where document control failed to apply a control stamp to a distributed procedure) which occurred prior to the re-training in November and December 1990.

D. J. Harris
12-18-9