

Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518
NEC 11 1989

WBS 1.2.9.3 QA

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

ISSUANCE OF STANDARD DEFICIENCY REPORTS (SDRs) 460 THROUGH 471, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 89-07 OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS) (NN1-1990-0661)

Enclosed are SDRs 460 through 471, Revision 0, generated as a result of Project Office QA Audit 89-07 of Los Alamos that was conducted on November 13-17, 1989, at Los Alamos and November 27-28, 1989, at the Las Vegas offices.

Please identify the corrective actions to be taken and implemented to correct the deficiencies by completing blocks 14 through 18, as appropriate, on each SDR.

Responses to the SDRs are due within 20 working days of the date of this letter. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send the original of your responses to Juanita J. Brogan, Science Applications International Corporation (SAIC), 101 Convention Center Drive, Las Vegas, Nevada 89109, and a copy to Ralph W. Gray, U.S. Department of Energy, P.O. Box 98518, Las Vegas, Nevada 89193-8518.

Your cooperation and timely response is appreciated. If you have any questions, please contact James Blaylock of my staff at (702) 794-7913 or FTS 544-7913, or Stephen R. Dana of SAIC at (702) 794-7176 or FTS 544-7176.

Donald G. Horton, Director Quality Assurance Division

Yucca Mountain Project Office

YMP:JB-1088

Enclosure: SDRs 460 thru 471, Revision 0

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8 Requirement (continued)

activities affecting quality shall be clearly established and delineated in writing. These activities affecting quality include both the performing functions of attaining quality objectives and the QA functions."

LANL QAPP, Rev. 4.4, Para. 1.4, states "When more than one LANL subcontractor organization is involved in activities affecting quality, the responsibility and authority of each organization for interface, as well as changes thereto, shall be clearly established and documented and any shared responsibilities shall be defined and documented. To support these interfaces, required interface documentation shall be defined in the administrative procedures. The YMP administrative procedures (APs) shall provide the implementing interface controls used by LANL. A LANL QP shall describe the methods of conducting and documenting interorganizational interfaces."

9 Deficiency (continued)

cient details describing the methods of conducting and documenting interorganizational interfaces.

10 Recommended Actions (continued) prevent recurrence.

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	5 Organization Los Alamos Nat'l Lab	6 Person(s) Contact K. Foster	ted	7 Response Due Date is 20 Working Days from Date of Transmittal			
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8 Requirement (continued)

certification acknowledging receipt and understanding of indoctrination and training. Step 19 requires the individual's supervisor to sign the certification accepting the indoctrination and training for the individual's qualification.

9 Deficiency (continued)

TWS-QAS-QP-03.10

TWS-QAS-QP-03.11

TWS-QAS-QP-03.12

TWS-QAS-QP-03.13

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 recurrance.

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8 Requirement (continued)

position."

TWS-QAS-QP-02.1, Rev. 1, Para. 6.2, Step 9, requires "Supervisors are responsible for determining and documenting that the personnel selected have relevant experience commensurate with the minimum requirements specified in the position description." Para. 6.3, Step 10, requires supervisors to "...verify resumes of employees or potential employees for accuracy and conformance to position description requirements, by reviewing the Project resume against the position description, and document verification of relevant education and experience by signing and dating the Project Resume Form...."

9 Deficiency (continued)

"equivalent experience" in lieu of the stated formal education requirements.

o Project Leader (EES-13)

Required: MS or equivalent

Actual: BS ChE

o Lab Technician (LS-2)

Required: BS or equivalent

Actual: No degree

10 Recommended Actions (continued)

to 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 recurrance.

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þ	9 Deficiency 1. The FRD, as reviewed, and subsequently, as issued (10/04/89, TWS-EES-13-10-89-004) contained numerous errors and inconsistent structure in the logic elements of the IDS that was not identified by the					
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8 Requirement (continued)

per QP-03.15, para. 6.3. The transmitted letter requested the reviewers to assure:

- 1. The FRD is correct.
- 2. The FRD is consistent with the ESF SDRD.
- 3. The FRD is concisely and logically structured.
- 4. The FRD fulfils its purpose adequately to start Title II design.
- 5. The FRD complies with the LANL QA plan.
- 9 Deficiency (continued)

design review process. (See attached List of Discrepancies)

- 2. The FRD referenced the design input source as the ESF SDRD, Benchmark #5 draft. Although, that was the issued version at the time of FRD preparation, Benchmark #6 changes had been approved by DOE/HQ (02/21/89) issued by YMPO (08/07/89) for incorporation into the SDRD. The changes of Benchmark #6 impacted the list of DOE orders in para. 2.2 of the FRD.
- 3. It is noted that QP-03.15, Rev. 0, was the correct procedure for design review at the time of FRD review; subsequently, QP-03.15, Rev. 1, 10/12/89 directs design reviews to be performed in accordance with QP-03.16, Rev. 0, 10/12/89.
- 10 Recommended Actions (continued) prevent recurrence.

LANL AUDIT 89-7

LIST OF DISCREPANCIES INTEGRATED DATA SYSTEM (IDS) FUNCTIONAL REQUIREMENTS DOCUMENT (FRD)

	PAGE	REFERENCE	DISCREPANCY
1.	2	para 2.2	DOE Order 1330 Draft is 1330.1B Draft per SDRD BM6.
2.	2	para 2.2	DOE Order 1450.1C, listed in SDRD BM5 and BM6, is not listed in the FRD.
3.	2	para 2.2	DOE Order 5310.1A is not listed in SDRD BM5 or BM6 and DOE Order 5300.1B, listed in SDRD BM6, is not listed in the FRD.
4.	11	fig. 3.2.1	Element 1.1.1.5 is identified as "IDS Installation Tests" on logic tree, but "IDS Installation Checks" on page 12.
5.	13	fig.3.2.1	Element 1.1.1.6 and 1.1.1.7 are identified as "System Configuration" and "Instrument Configuration" on logic tree, but "System Configuration Input" and "Instrument Configuration Input" on page 11 (fig. 3.2.1) and page 12.
6.	17	fig. 3.2.4	Element 1.2.1.2 is identified as "Verify" on logic tree, but "Protect" on page 15 (fig. 3.2.3) and page 16.
7.	19	fig. 3.2.5	Element 1.2.1.2 is identified as "Verify" on logic tree; same as comment 6 above.
8.	20	para 3.2.5	"Test Controls" is identified as element 1.1.3, a part of element 1.1, "ACQUIRE"; fig. 3.1.2 (page 5) and fig. 3.2.5 (page 19) show the elements as 1.2 "PROCESS" and 1.2.3 "Test Controls."
9.	22	para. 3.2.6	Paragraph "Store" is a 2nd level element; previous paragraphs and figures are 3rd level elements. The paragraph title should be "IDS Data Archive". A new paragraph 3.2.7, "On-Line" should be inserted.
10.	22	para. 3.2.6	"STORE" is identified as element 1; the correct element designation is 1.3.
11.	24	para. 3.2.7	Paragraph "Distribute" is a 2nd level element; same as comment 9.

12.	25	fig. 3.2.8	Figure does not include 5th level elements 1.5.1.1.1, 1.5.1.1.2, 1.5.1.2.1, 1.5.1.2.2, 1.5.1.2.3; 5th level elements are presented on fig. 3.2.3 (page 15), fig. 3.2.4 (page 17), and fig. 3.2.5 (page 19).
13.	26	para. 3.2.8	"Malfunction Alarm" and subelements are identified as 1.5.1.4, 1.5.1.4.1, etc. The correct elements designations are 1.5.1.2, 1.5.1.2.1, etc.
14.	27	fig. 3.2.9	Figure does not include 5th level elements 1.5.2.3.1, 1.5.2.3.2; same as comment 12 above.
15.	28	para. 3.2.9	"Instrument Malfunction Alarm" subelements are identified as 1.5.2.4.1 and 1.5.2.4.2; the correct element designations are 1.5.2.3.1 and 1.5.2.3.2
16.	29	fig. 3.2.10	Element 1.6.3.2 is identified as "Provide Data I/O Terminals"; para. 3.2.10 (page 30) identifies the element title as "Provide Data I/O Terminals and Remote Access."
17.	30	para. 3.2.10	Paragraph "Operate" is a 2nd level element; same as comment 9 above.
18.	30	para. 3.2.10	"Maintenance and Operations" and subelements are identified as 1.6.4, 1.6.4.1, etc. The correct element designations are 1.6.3, 1.6.3.1, etc. Also "Maintenance and Operations" should be italicized.
19.	49	Appdx. B	"National Bureau of Standards" (NBS) should be "National Institute of Standards and Technology" (NIST). NIST was correctly identified on pages 12 and 16.
20.	52	Appdx. E	"NBS" should be "NIST"; same as comment 19 above.

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ρ	effective date	plans, submitted to the of AP-1.10Q, had been an the version actuall	technically review	ed in a different form			
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8 Requirement (continued)

requires study plans to be "...reviewed technically according to QPS-3.02..."

9 Deficiency (continued)

check or review was documented to assure that changes occurring between the technical review and submission to the Project Office either did not impact technical content of the study plan or that an additional review of the changes for technical adequacy was performed.

It is noted that all study plans having technical reviews performed prior to AP-1.10Q (and prior to QP-03.3) have already been submitted to the Project Office. Only three (3) LANL study plans remain to be submitted.

10 Recommended Actions (continued) prevent recurrance.

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ρ	applicability	9 Deficiency Many DPs do not address acceptance and rejection criteria or limits or the applicability of this subject to the work covered by the DP. Examples of this condition include:					
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- 8 Requirement (continued)
 - o Acceptance and rejection limits and criteria, including required levels of precision and accuracy."

TWS-QAS-QP-05.2, Rev. 2, Para. 6.3.7.6 states in part "Include criteria (eg., postrequisites and final conditions) for ensuring that DPs have been performed correctly."

9 Deficiency (continued)

TWS-EES-DP-54, Rev. 1 TWS-EES-DP-102, Rev. 1 TWS-EES-DP-114, Rev. 1 TWS-EES-DP-124, Rev. 0 TWS-INC-DP-27, Rev. 0

10 Recommended Actions (continued)

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

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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 "superceded," "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.

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8 Requirement (continued)

and to help identify root causes of nonconformances. Results shall be reported to upper management for review and assessment. TWS-QAS-QP-16.2, Rev. 0, Para. 5.2, states "The Quality Assurance Support group generates trending data on a quarterly basis, beginning in January, and delivers these data to the QAPL. TWS-QAS-QP-16.2, Rev. 0, Para. 8.0, states "An approved quarterly trending report is the criterion that demonstrates satisfactory compliance with this QP."

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Organization	3 Discovered During Audit 89-7	3 Discovered During Audit 89-7 3a Identified By A. I. Arceo						
	5 Organization Los Alamos Nat'l La	6 Person(s) P. Goulding			7 Response Due Date is 20 Working Days from Date of Transmittal			
Originating QA	8 Requirement (Audit (Checklist Item Para. 1.0, and Action System s	ns 16-1, 16-2, 16 LANL-YMP-QAPP, R	5-3, and 16-4) N Rev. 4.4, Para.	16.1, state	Rev. 2, Section XVI, The corrective entally adverse to			
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8 Requirement (continued)

quality are identified promptly and corrected as soon as practical. NNWSI/88-9, Rev. 2, Section XVI, Para. 1.1, and LANL-YMP-QAPP, Rev. 4.4, Para. 16.2, state "For significant conditions adverse to quality, the identification, cause, and corrective action taken to prevent recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment... Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, each NNWSI Project Participant shall ensure that:

- o Immediate actions have been taken to remedy the specific condition(s).
- o Causative factors have been determined.
- o Controls have been reviewed, implemented, monitored, and revised, if necessary.
- o Affected managers at all levels have been notified of adverse condition(s) and of lessons to be learned to improve conditions or avoid similar occurrences.*

NNWSI/88-9, Rev. 2, Section XVI, Para. 1.2, and LANL-YMP-QAPP, Rev. 4.4, Para. 16.3, state "The QA organization shall document concurrence of the adequacy of proposed corrective actions to assure that QA requirements will be satisfied. Follow-up action shall be taken by the QA organization to verify proper implementation of this corrective action and to close out the corrective action. The organization responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner." NNWSI/88-9, Rev. 2, Sec. XVI, Para, 1.3, and LANL-YMP-QAP Rev. 4.4, Para. 16.4, state "The QA organization shall periodically analyze corrective action reports to establish quality trends. The results shall be reported to the TPO and QAPL for review and assessment." TWS-QAS-QP-16.1, Rev. 1, Para. 6.3, states "A copy of the CAR Log is sent to the RPC annually in the first quarter of the calendar year."

9 Deficiency (continued)

indicated on the CARs reviewed (CAR Nos. 043; 043, Rev. 1; 044; 046; 055, and 055, Rev 1).

- Verification of corrective action implementation was not documentated on the CAR other than the signature of the person who performed the verification. There were no references as to what was performed (survey, desk survey, or audit) or documents reviewed to verify corrective action implementation.
- 3. CARs were revised; however QP-16.1, Rev. 1, does not provide for revisions to CARs.
- 4. CARs and CAR Log do not provide information as to why the CARs were revised. The CAR Log showed that the CARs were voided, but in reality,

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9 Deficiency (continued)

the CARs were revised (CAR No. 043, 046, and 055).

- 5. The CAR Log was not sent to the RPC as required by QP-16.1, Rev. 1.
- 6. The form used for CAR does not reflect all the information required by the example form in QP-16.1, Rev. 1.
- 7. Some CARs (043, 044, and 055) were not completed in a timely manner.
- 8. CARs were not analyzed to establish quality trends.
- 9. Corrective Action Reports were issued to identify procedural noncompliance instead of "...significant breakdown in the QA Program or repeated nonconformances." Procedural noncompliance should be identified in another deficiency reporting system and when it becomes repetitive, then a CAR should be written.
- 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 recurrance.

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niza	Audit 89-7	5142		469 Rev. <u>0</u>			
\ Organization	5 Organization 6 Person(s) Contacted 7 Response 20 Worki Date of						
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 18-5-1) TWS-QAS-QP-18.1, Rev. 1, Para. 6.6.1, states in part "If any findings have been identified, a response is sent to the audit team leader within 20 working						
by	9 Deficiency Contrary to th the following	e requirements cited a deficiencies:	bove, audit report L	ANL-YMP-89-02 contains			
aldı	10 Recommended Ad	ction(s): X Remedial X I	nvestigative X Correct	tive			
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8 Requirement (continued)

days of the audit report. Para. 6.7.1 states in part The status of audit findings for the current year shall be updated monthly by the QAS and reported to the QAPL. LANL-YMP-QAPP, Rev. 4.4, Para. 16.1, states in part The corrective action system shall ensure that conditions adverse to quality shall be identified promptly, documented on corrective action reports, and corrected soon as practical.

- 9 Deficiency (continued)
 - 1. The audit report was issued on July 11, 1989. However, a response was not issued until October 6, 1989, 63 days after the due date.
 - 2. Status of the audit findings was not reported to the QAPL as required.
 - 3. A corrective action report was never issued. However, the affected audit team leader was aware of the situation but did not take any action to identify it nor to document it.
- 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.

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niza	Audit 89-7 470 R								
A Organization	5 Organization Los Alamos Nat'l Lab	6 Person(s) Contact E. Cole/P. Tiller		7 Response Due Date is 20 Working Days from Date of Transmitta!					
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable)								
by Orig	9 Deficiency Contrary to the requirements cited above:								
	1. Audit plans do not identify organizations to be notified and the appli-								
Completed	10 Recommended Action(s): A Remedial A Investigative A 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								
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8 Requirement (continued)

TWS-QAS-QP-18.1, Rev. 1, Para. 6.4.2, states in part "Auditors document their investigations, observations, and names of personnel interviewed on the audit checklist." NNWSI/88-9, Rev. 2, Section XVIII, Para. 1.4, states in part "Objective evidence shall be examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively."

- 9 Deficiency (continued)
 - cable documents to be used during the audit.
 - 2. Numerous audit checklists do not contain the documented evidence reviewed during the audit.
 - 3. Checklists do not contain qualitative or quantitative criteria to determine whether or not the objective evidence examined during the audit is acceptable to the scope and requirements of the audit.
- 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.



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A Organization	3 Discovered During Audit 89-7	3a Identified By S.L. Crawford			SDR No. Rev. 0			
	5 Organization Los Alamos Nat'l I	6 Person(s) (K. Foster	Contacted		7 Response Due Date is 20 Working Days from Date of Transmittal			
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) (Q #2-2) LANL-YMP-QAPP, Rev. 4.4, para. 2.5 provides "Position descriptions shall establish minimum personnel qualifications and the necessary indoctrination or training or both before a person starts work on activities							
Completed by Oric	position descriptions to identify needed indoctrination or training. Position							
	10 Recommended Action(s): Remedial Investigative Investi							
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8 Requirement (continued)
 that affect quality."

9 Deficiency (continued)

requirements; training matrices, per QP-02.2 are not attached to certifications, resumes, or position descriptions, to show required training prior to annual certification.

10 Recommended Actions (continued) prevent recurrance.

cc w/encl:

Ralph Stein, HQ (RW-30) FORS

D. E. Shelor, HQ (RW-3) FORS

H. P. Nunes, LANL, Los Alamos, NM

J. J. Brogan, SAIC, Las Vegas, NV, 517/T-12

S. R. Dana, SAIC, Las Vegas, NV, 517/T-06

K. A. Hodges, SAIC, Las Vegas, NV, 517/T-06

K. W. Moore, SAIC, Las Vegas, NV, 517/T-31

J. H. Nelson, SAIC, Las Vegas, NV, 517/T-04

S. W. Zimmerman, NWPO, Carson City, NV

J. E. Kennedy, NRC, Washington, De

cc w/o encl:

H. E. Valencia, LAAO

J. W. Hines, NWQA, AL

A. R. Chernoff, MSD, AL

A. L. Temple, SAIC, Las Vegas, NV, 517/T-38

J. W. Gilray, NRC, Las Vegas, NV