



Department of Energy

Nevada Operations Office

P. O. Box 98518

Las Vegas, NV 89193-8518

WBS 1.2.9.3

QA

MAR 06 1990


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

ACCEPTANCE OF RESPONSES TO 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)

The Project Office QA staff has evaluated and accepted your responses to SDRs 460 through 471, Revision 0, generated as a result of Project Office QA Audit 89-07 of Los Alamos. The SDRs will be closed after verification of satisfactory completion of the specified corrective actions. Copies of the SDRs are enclosed for your information.

Verification of completion of your corrective action will be performed after the effective dates that were provided. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send copies of the extension request to Nita J. Brogan, Science Applications International Corporation (SAIC), 101 Convention Center Drive, Las Vegas, Nevada 89109, and Ralph W. Gray, U.S. Department of Energy, P.O. Box 98518, Las Vegas, Nevada 89193.

If you have any questions, please contact Robert B. Constable of my staff at (702) 794-7945 or FTS 544-7945, 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:REC-2245

Enclosure: *See jacket* *Audit 89-7*
11/17/89
SDRs 460 thru 471, Revision 0

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Richard J. Herbst

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MAR 06 1990

cc w/encl:

Ralph Stein, HQ (RW-30) FORS
D. E. Shelor, HQ (RW-3) FORS
P. R. Guthals, LANL, Los Alamos, NM
H. P. Nunes, LANL, Los Alamos, NM
S. R. Dana, SAIC, Las Vegas, NV, 517/T-06
S. W. Zimmerman, NWPO, Carson City, NV
J. E. Kennedy, NRC, Washington, DC 

cc w/o encl:

H. E. Valencia, LAAO
J. W. Hines, NWQA, AL
A. R. Chernoff, MSD, AL
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06
J. W. Gilray, NRC, Las Vegas, NV

YMPO STANDARD DEFICIENCY REPORT

N-QA-038

Received w/Ltr Dated 3/6/90

1 Date 11/17/89	2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Page 1 of 2
3 Discovered During Audit 89-7	3a Identified By M. Diaz	4 SDR No. 460 Rev. 0

5 Organization Los Alamos Nat'l Lab	6 Person(s) Contacted R. Herbst, H. Nunes	7 Response Due Date is 20 Working Days from Date of Transmittal
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8 Requirement (Audit Checklist Reference, If Applicable)
(Checklist Item 1-1)
NNWSI/88-9, Rev. 2, Para. 1.0, states "The organizational structure, lines of communication, authority, and duties of persons and organizations performing

9 Deficiency
Contrary to the requirements in Item 8 above, the responsibility and authority of each subcontractor for interface controls are not defined and documented in a procedure. Additionally, TWS-QAS-QP-01.1, Rev. 0, does not provide suffi-

10 Recommended Action(s): ☒ Remedial ☐ Investigative ☒ Corrective
Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to

11 QAE/Lead Auditor/Date S. Dana 11/30/89	12 Division Manager/Date 11/30/89	13 Project Quality Mgr./Date 12/1/89
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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

17 Effective Date 2/16/90

18 Signature/Date
H. Nunes 11/2/90

19 Response Accepted	QAE/Lead Auditor/Date S. Dana 2/21/90	Division Manager/Date S. Dana 2/21/90	Project Quality Mgr./Date 12/21/90
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date

21 Remarks Response letter TWS-EES-13-01-90-065 PLUS AMENDED RESPONSE letter TWS-EES-13-02-90-033.

22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date
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102.7

Rec'd. w/ltr. dtd. 3/6/90
Accession No. 9003130645

LA dtd. 11/1/90 - TWS-EES-13-01-90-065

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

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12/88

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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.

14 Remedial/Investigative Action(s)

Remedial actions: Revise the QAPP, Section 1.4, Interface Between Organizations, and the administrative implementing procedure, QP-01.1, R1, Procedure for Interface Control, to eliminate ambiguity.

Investigative actions: None Required.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause: An ambiguous QAPP requirements statement and further, inadequate direction in the implementing procedure over how to identify an interface and establish the appropriate controls.

Corrective Action to Prevent Recurrence: Refer to the remedial action stated above.

ATTACHMENT

Responses to the below listed SDRs are amended or clarified as indicated.

SDR 460-Amendment

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

"Remedial Action-QP01.1 will be revised to detail the methods for conducting and documenting organizational interfaces and to define responsibilities and authority for subcontractor interface controls. In addition, Figure 1-1 of the QAPP will be updated to correctly identify current LANL Subcontractors and Participating Groups."

"Investigative Action-None Required."

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

"Cause-QP01.1, Rev. 0 did not adequately detail methods for conducting and documenting organizational interfaces or define responsibilities and authority for subcontractor interface controls."

" Corrective Action to Prevent Recurrence-See Remedial Action stated above."

SDR 462-Amendment

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

"Remedial Action-A new procedure, QP02.5-Procedure for the Selection of Personnel, will be issued to provide a format for position descriptions to document equivalent education and experience requirements that may be used to evaluate an individuals capabilities in lieu of specified formal education. All LANL position descriptions will be rewritten in compliance with this format. In addition, QP02.5 will provide a method for responsible supervision to further evaluate and document an individuals capabilities and acceptability for any position even though they do not comply with the equivalents specified in position descriptions. In these instances justification for acceptance of the individual must be documented. The two individuals identified in Block 9 will be evaluated in accordance with the requirements of QP02.5 and the status of their acceptability documented."

"Investigative Action-See Remedial Action stated above."

Let. lth 2/2/90 - TWS-EES-13-02-90-083

YMPO STANDARD DEFICIENCY REPORT

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4/89

Completed by Originating QA Organization	1 Date 11/16/89		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 S. L. Crawford		4 SDR No. 461 Rev. 0 <i>HPM</i>
	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) (Q#2-5) TWS-QAS-QP-02.1, Rev. 1, Para. 6.5, step 16, requires a record of personnel indoctrination and training to be entered on a Project Certification Form. Step 17 requires the individual to sign the				
Completed by Organization in Block 5	9 Deficiency An individual (Co-PI, Dynamic Transport Column experiments, and Technical Reviewer, Batch Sorption Studies) was certified 5/26/89 to four (4) Quality Procedures that do not exist:				
	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 <i>S. Jones</i> 11/30/89	12 Division Manager/Date <i>Kate Haden</i> 12-1-89	13 Project Quality Mgr./Date <i>[Signature]</i> 12/1/89		
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				
Completed by Org. QA Org.	15 Effective Date 2/16/90				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				
	17 Effective Date 2/16/90				
Comp. by Org. QA Org.	18 Signature/Date <i>HPM Jones</i> 1/12/90				
	19 Response Accepted	QAE/Lead Auditor/Date <i>[Signature]</i> 2/22/90	Division Manager/Date <i>S. Jones</i> 2/22/90	Project Quality Mgr./Date <i>[Signature]</i> 2/22/90	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks ① Ref. SDR response ltr., Herbst to Haden, dtd. 1/1/90				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

Ltr. dtd. 1/1/90 - TWS-EES-13 20-90-205

1/2/90

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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 recurrence.

14 Remedial/Investigative Action(s)

Remedial Actions: The record of the individual noted in Block #9 will be corrected.

Investigative actions: All LANL personnel files will be reviewed and corrected as necessary for similar and other noted deficiencies.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the condition: The training matrices were prepared by listing procedures that were in preparation, in anticipation of needed training. The procedures in Block #9 were never approved for use. The procedures were incorrectly copied from the matrices.

Corrective Action to Prevent Recurrence: The procedure QP-02.1, Training, will be revised (or change request issued) to replace the YMP Certification form with a new form that does not require the listing of the procedures to which personnel have been trained.

ORIGINAL

YMPO STANDARD DEFICIENCY REPORT

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N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/16/89		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 A. I. Arceo, S. L. Crawford		4 SDR No. 462 Rev. 0	
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted L. Hersman, K. Foster		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Q #2-3). LANL-YMP-QAPP, Rev. 4.4, para. 2.5.1 provides "The initial capabilities of an individual shall be based on an evaluation of his education, experience, and training and compared to those established for the					
Completed by Originating QA Organization	9 Deficiency The qualification record files of the following two individuals did not satisfy the minimum education requirements identified in the applicable position descriptions nor had supervisors documented the basis for accepting					
	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,					
Completed by Organization in Block 5	11 QAE/Lead Auditor/Date S. Dana 11/30/89		12 Division Manager/Date H. H. Hedges 12-1-89		13 Project Quality Mgr./Date 12/1/89	
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				15 Effective Date 2/16/90	
Completed by Organization in Block 5	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				17 Effective Date 2/16/90	
	18 Signature/Date H. H. Hedges 1/12/90					
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date S. Dana 2/22/90		Division Manager/Date S. Dana 2/22/90	
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date	
	21 Remarks ① Ref SDR response, Herbert to Horton, dtd. 1/11/90 and Response Clarifications and Amendments H2., Herbert to Horton, dtd. 2/12/90 (TWS-13-02-9033)		Project Quality Mgr./Date 2/22/90		Project Quality Mgr./Date	
22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date		PQM/Date

Ltr dtd 11/11/90 - TWS-CE-13-01-90-065-

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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 recurrence.

14 Remedial/Investigative Action(s)

Remedial actions: A change request will be issued to QP-02.1, Training, stipulating a format for equivalent education and experience in lieu of the stipulated basic education and experience requirements stated on the position description. The two position descriptions noted in Block #9 of the SDR will be rewritten in this new format to document the basis for accepting the equivalent experience of each individual.

Investigative actions: All LANL position descriptions will be rewritten in the revised format to record the basis for accepting the equivalent experience.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: The procedure, QP-02.1, as written did not require any supervisor to record the basis for acceptance of equivalent experience in lieu of stated formal education. The supervisor simply stated his acceptance of the qualifications of the LANL staff member by signing the YMP Resume Forms.

Corrective Action to Prevent Recurrence: The procedure change noted in Block #14 will provide the mechanism by which LANL supervisor decisions involving equivalent experience in lieu of formal education will be documented. This will provide uniformity throughout the LANL project for documenting these decisions.

ATTACHMENT

Responses to the below listed SDRs are amended or clarified as indicated.

SDR 460-Amendment

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

"Remedial Action-QP01.1 will be revised to detail the methods for conducting and documenting organizational interfaces and to define responsibilities and authority for subcontractor interface controls. In addition, Figure 1-1 of the QAPP will be updated to correctly identify current LANL Subcontractors and Participating Groups."

"Investigative Action-None Required."

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

"Cause-QP01.1, Rev. 0 did not adequately detail methods for conducting and documenting organizational interfaces or define responsibilities and authority for subcontractor interface controls."

" Corrective Action to Prevent Recurrence-See Remedial Action stated above."

SDR 462-Amendment

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

"Remedial Action-A new procedure, QP02.5-Procedure for the Selection of Personnel, will be issued to provide a format for position descriptions to document equivalent education and experience requirements that may be used to evaluate an individuals capabilities in lieu of specified formal education. All LANL position descriptions will be rewritten in compliance with this format. In addition, QP02.5 will provide a method for responsible supervision to further evaluate and document an individuals capabilities and acceptability for any position even though they do not comply with the equivalents specified in position descriptions. In these instances justification for acceptance of the individual must be documented. The two individuals identified in Block 9 will be evaluated in accordance with the requirements of QP02.5 and the status of their acceptability documented."

"Investigative Action-See Remedial Action stated above."

5/12/90 - TWS-EEs-13-92-90-013

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/27/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 23	
	3 Discovered During LANL Audit 89-7		3a Identified By S. L. Crawford		4 SDR No. 463 Rev. 0	
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted R. Oblad, R. Morley		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 3-7) TWS-QAS-QP-03.15, para. 6.3 and 6.4 provide for review of design documents. LANL letter TWS-EES-1-09-89-16, 9/8/89 transmitted the Integrated Data System (IDS) Functional Requirements Document (FRD) for review					
Completed by Organization in Block 5	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					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to					
	11 QAE/Lead Auditor/Date <i>S. J. Davis</i> 12/1/89		12 Division Manager/Date <i>V. Oblad</i> 12-1-89		13 Project Quality Mgr./Date <i>[Signature]</i> 12/1/89	
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3					
Completed by Org. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3					
	17 Effective Date 2/16/90					
	18 Signature/Date <i>HPH Jones</i> 1/12/90					
Comp. by Org. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date <i>[Signature]</i> 2/22/90		Division Manager/Date <i>S. J. Davis</i> 2/22/90	
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date	
	21 Remarks ① Ref. SDR response, Herbert to Horton, dtd 1/14/90 and Response Clarification and Amendments etc, Herbert to Horton, dtd 2/12/90 (TWS-13-02-90-33)					
	22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date	
				PQM/Date		

Checked 1/14/90 - TWS-EES-13-01-90-065

1/12/90

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 463

Rev. 0

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CRM

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.

14 Remedial/Investigative Action(s)

Remedial Action(s): The current Functional Requirements Document (FRD) will be corrected to reflect the noted discrepancies in the SDR attachment, pages 1 and 2. The text will be amended to reflect current versions of the Department of Energy (DOE) orders, YMP Benchmark #6, that will govern the work. Upon completion of these revisions, the document will be technically reviewed to assure that any corrections do not impact the technical content of the document.

Investigative Action(s): None required.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: In appropriate use of QP-03.16, Procedure for TMO Review of Design Information. Implementing procedure, QP-03.2, Procedure for Preparation and Technical and Policy Review of Technical Information Products, should have been used prior to issue of the FRD.

Corrective Action to Prevent Recurrence: Modify QP-03.16, Procedure for TMO Review of Design Information, to require use of QP-03.2 prior to release of technical information.

LANL AUDIT 89-7

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

	<u>PAGE</u>	<u>REFERENCE</u>	<u>DISCREPANCY</u>
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. |

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:atl 2/12/90-TWS-EES-13-02-90-C33

YMPO STANDARD DEFICIENCY REPORT

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Completed by Originating QA Organization	1 Date 11/14/89		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 S.L. Crawford		4 SDR No. 464 Rev. 0	
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted R. Herbst, various PI's		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Q#3-1, 3-2) YMP AP-1.10Q, Rev. 0, paras. 5.1.2 and 5.1.5 require project participants to perform a technical review of SCP study plans prior to submittal to the Project Office. LANL TWS-QAS-QP-03.3, Rev. 0, para 6.2.1,					
Completed by Organization In Block 5	9 Deficiency Several study plans, submitted to the Project Office subsequent to the effective date of AP-1.10Q, had been technically reviewed in a different form and content than the version actually submitted to the Project Office. No					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to					
	11 QAE/Lead Auditor/Date S. Jones 11/30/89		12 Division Manager/Date S. Jones 12-1-89		13 Project Quality Mgr/Date S. Jones 12/1/89	
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3					
Completed by Org. QA Org.	15 Effective Date 2/16/90					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3					
	17 Effective Date 2/16/90					
	18 Signature/Date H. Jones 1/12/90					
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date S. Jones 2/22/90		Division Manager/Date S. Jones 2/22/90	
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date	
	Project Quality Mgr./Date		Project Quality Mgr./Date		Project Quality Mgr./Date	
	21 Remarks ① Def. SDR response, Herbst to Horton, dtd. 1/11/90 and response clarification and amendments LR, Herbst to Horton (TWS-13-02-90-33)					
22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date		PQM/Date

QAE/Lead Auditor/Date 11/14/89 - TWS-13-01-90-065

11/2/90

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CDM

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 recurrence.

14 Remedial/Investigative Actions

Remedial Action: The Project Office and DOE/Headquarters have already conducted additional reviews. No further remedial action is required.

Investigative Action: The SDR does not specify what the difference in format and content was, but we conclude that the difference was 1) the addition of a QA appendix, and 2) the addition of a brief abstract. For ongoing studies, the appendix includes quality assurance level assignments (QALAs) and a matrix. The QALAs were already reviewed and approved by the Project Office, no additional review was required. The QA appendix does not provide any new information-- it is a summary of information that is readily available from other sources. The abstract is a short (1-3 paragraph) summary of the existing technical content of the study plan and does not change the technical content of the plans.

The subject study plans have all undergone additional screening, technical, management, and quality assurance reviews at both the Project Office and DOE/HQ. Any problems associated with the additions would have been identified during these reviews.

16 Cause of Condition & Corrective Action to Prevent Recurrence

Cause of Condition: Compliance with verbal direction from the Project Office.

Corrective Action to Prevent Recurrence: Require LANL staff to obtain written confirmation of verbal direction from the Project Office.

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

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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 M. J. Mitchell	4 SDR No. 465 Rev. 0
5 Organization Los Alamos Nat'l Lab	6 Person(s) Contacted R. Herbst, H. Nunes	7 Response Due Date is 20 Working Days from Date of Transmittal
8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item N/A) LANL-YMP-QAPP, Rev. 4.4, Para. 3.1.6.1, states in part "DPs used for scientific investigations shall provide for the following as appropriate:		
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:		
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		

Apv.

11 QAE/Lead Auditor/Date <i>S. Dune 11/30/89</i>	12 Division Manager/Date <i>N. Herbst 12-1-89</i>	13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>
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Completed by Organization in Block 5

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	17 Effective Date 2/16/90
18 Signature/Date <i>H. Nunes 1/12/90</i>	

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date <i>S. Dune 2/21/90</i>	Division Manager/Date <i>S. Dune 2/21/90</i>	Project Quality Mgr./Date <i>[Signature] 2/21/90</i>
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks <i>See Ltr. Herbst to Hoston, dtd 2/12/90, SDR Response Clarification & Amendments and SDR response Ltr, Herbst to Hoston, dtd. 1/11/90.</i>			
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date

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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., prerequisites 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 recurrence.

14 Remedial/Investigative Action(s)

Investigative Actions: Review the following Dps for incorporation of accept reject criteria: DP 54, R1; DP102, R1; DP 114, R0; DP 124, R0; DP 27, R1. Of note, two procedures in Block 9 of the SDR reference the wrong revision number: TWS-EES-DP-114, Rev. 1, is actually Rev. 0, and TWS-INC-DP-27, Rev. 0, is actually Rev. 1. Further, review all remaining technical implementing procedures.

Remedial Action: Issue a change request to each of the above five referenced procedures to add an accept reject criteria section.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: The implementing procedure, QP-05.2, Preparation of a Detailed Technical Procedure, failed to adequately instruct the preparer on inclusion of accept/reject criteria limits.

Corrective Action to Prevent Recurrence: Issue a change request to QP-05.2, R1, incorporation the requirement for a specific section stating the accept/rejection criteria and limits. Modify other detailed technical procedures, as necessary, to include accept reject criteria limits.

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

See dtd 2/12/90-TWIS-EE5-13-02-90-033

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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"					
Completed by Originating QA Organization	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 superceded					
	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					
Completed by Originating QA Organization	11 QAE/Lead Auditor/Date <i>S. Dana 11/30/89</i>		12 Division Manager/Date <i>Robert H. Hays 12-1-89</i>		13 Project Quality Mgr./Date <i>W. J. Hays 12/1/89</i>	
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3					
Completed by Originating QA Organization	15 Effective Date <u>2/16/90</u>					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3					
Completed by Originating QA Organization	17 Effective Date <u>2/16/90</u>					
	18 Signature/Date <i>W. J. Hays 1/12/90</i>					
Completed by Originating QA Organization	19 Response Accepted		QAE/Lead Auditor/Date <i>S. Dana 2/21/90</i>		Division Manager/Date <i>S. Dana 2/21/90</i>	
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date	
Completed by Originating QA Organization	21 Remarks See LTR, Hays to Hays, dtd. 2/12/90, SDR Response Clarification & Amendment and SDR response LTR, Hays to Hays, dtd. 1/11/90.					
	22 QA CLOSURE					
Completed by Originating QA Organization	QAE/Lead Auditor/Date		Division Manager/Date		PQM/Date	

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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 "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.

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

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See dtd 2/12/90 - TWS-EE5-13-02-90-033

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."

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Completed by Originating QA Organization	1 Date 11/17/89		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 23
	3 Discovered During Audit 89-7		3a Identified By M. Diaz		4 SDR No. 467 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted P. Goulding		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 15-7) NNWSI/88-9, Rev. 2, Section XV, Para. 3.0, states "Nonconformance reports shall be periodically analyzed by the QAS organization to show quality trends"				
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirements, there is no documentation to show that a trend report has been issued on NCRs since the effective date of 6/20/89 of the procedure.				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective Identify the remedial actions to be taken to correct the deficiency(ies) noted in block 9.				
	11 QAE/Lead Auditor/Date <i>S. Jones</i> 11/30/89		12 Division Manager/Date <i>W. H. Hedges</i> 12-1-89		13 Project Quality Mgr./Date <i>W. H. Hedges</i> 12/1/89
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				
Completed by Organization in Block 5	15 Effective Date 2/16/90				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				
	17 Effective Date 2/16/90				
Comp. by Org. QA Org.	18 Signature/Date <i>AP Jones</i> 1/12/90				
	19 Response Accepted	QAE/Lead Auditor/Date <i>W. H. Hedges</i> 2/21/90	Division Manager/Date <i>S. Jones</i> 2/21/90	Project Quality Mgr./Date <i>W. H. Hedges</i> 2/22/90	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks RESPONSE LETTER TWS-EES-13-01-90-065 PLUS AMENDED RESPONSE LETTER TWS-EES-13-02-90-033.				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

Ltr. dtd. 11/19/89 - TWS-EES-13-01-90-065

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8 Requirement (continued)

QAP

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."

14 Remedial/Investigative Action(s)

Remedial Actions: Issue a final trending report to cover Calendar Year 1989. The report will incorporate data from audit findings, SDRs, CARs and NCRs issued during the calendar year with recommendations for improvements to the quality program based upon the QAPL's review of the Trend Analysis Report.

Investigative actions: None required, the remedial action above covers all issued involved in trending.

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

None required.

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."

See also 2/12/90 - TMS-EIS-13-02-90-003

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Completed by Originating QA Organization

1 Date 11-17-89	2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	Page 1 of 3
3 Discovered During Audit 89-7	3a Identified By A. I. Arceo	4 SDR No. 468 Rev. 0
5 Organization Los Alamos Nat'l Lab	6 Person(s) Contacted P. Goulding/H. Nunes	7 Response Due Date is 20 Working Days from Date of Transmittal
8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Items 16-1, 16-2, 16-3, and 16-4) NNWSI/88-9, Rev. 2, Section XVI, Para. 1.0, and LANL-YMP-QAPP, Rev. 4.4, Para. 16.1, state "The corrective Action System shall ensure that conditions adverse or potentially adverse to		
9 Deficiency Contrary to the requirements stated above: 1. Actions to prevent recurrence of significant conditions were not		
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		

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11 QAE/Lead Auditor/Date <i>S. Jones</i> 11/30/89	12 Division Manager/Date <i>Robert</i> 12-1-89	13 Project Quality Mgr./Date <i>Robert</i> 12/1/89
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Completed by Organization in Block 5

14 Remedial/Investigative Action(s) Refer to Page 4 of 4	15 Effective Date 2/16/90
16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 4 of 4	17 Effective Date 2/16/90
18 Signature/Date <i>H. Jones</i> 1/12/90	

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date <i>A. I. Arceo</i> 2/21/90	Division Manager/Date <i>S. Jones</i> 2/21/90	Project Quality Mgr./Date <i>Robert</i> 2/21/90
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks Response clarification, letter R.J. Herbert to Horton dated 2/12/90 Responses to SDRs, letter R.J. Herbert to Horton dated 1/11/90			
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date

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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).

2. Verification of corrective action implementation was not documented 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 recurrence.

14 Remedial/Investigative Action(s)

Remedial Actions: For the deficiency reported in Block 9, point #9, transmit a copy of the NCR Log for calendar years 1988 and 1989 to the RPC.

Investigative Actions: Each open CAR and NCR will be evaluated against the deficiencies noted in Block 9, points 1 through 9, revised as necessary and written documentation of the review will be placed in the CAR and NCR files.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: Personnel error and procedural inadequacies.

Corrective Action to Prevent Recurrence: Revise the entire deficiency reporting system, QP-15.1 and QP-16.1. Retrain personnel to the revised deficiency reporting system.

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."

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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 M. Diaz		4 SDR No. 469 Rev. 0	
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted E. Cole/P. Tillery		7 Response Due Date is 20 Working Days from Date of Transmittal	
	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					
Completed by Organization in Block 5	9 Deficiency Contrary to the requirements cited above, audit report LANL-YMP-89-02 contains the following deficiencies:					
	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. Davis 11/30/89		12 Division Manager/Date Kale Hedges 12-1-89		13 Project Quality Mgr./Date [Signature] 12/1/89	
Completed by Organization in Block 5	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					17 Effective Date 2/16/90
	18 Signature/Date [Signature] 1/12/90					
Comp. by Orig. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date [Signature] 2/21/90	Division Manager/Date S. Davis 2/21/90	Project Quality Mgr./Date [Signature]		
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
	21 Remarks RESPONSE LETTER TWS-EES-13-01-90-065.					
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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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 as 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.

14 Remedial/Investigative Action(s)

Remedial Action: None required for the deficiencies reported in Block 9, points 1 through 3. The QAPL is now aware of the audit finding status for LANL audit 89-02, and has notified the TPO, reference letter TWS-EES-13-12-89-003.

Investigative Action: Review the past LANL audit reports for calendar year 1988 and 1989 for a similar deficiency and prepare a summary report for the QAPL.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: Follow-up actions were not documented by the audit team leader. Further, personnel did not follow the audit procedure and issue the audit status finding report. Subsequently no CAR was issued due to a lack of written documentation.

Corrective Action to Prevent Recurrence: The LANL audit procedure, QP-18.1, will be revised to provide more explicit instructions regarding follow-up actions undertaken by the audit team leader and issue of a monthly audit finding status report. The LANL audit staff will be retrained to the new procedure upon its issue.

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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 M. Diaz	4 SDR No. 470 Rev. 0	
5 Organization Los Alamos Nat'l Lab	6 Person(s) Contacted E. Cole/P. Tillery	7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Items 18-2, 18-3-1) NNWSI/88-9, Rev. 2, Section XVIII, Para. 1.3.1, states in part "Audit plans shall identify organizations to be notified,...applicable documents."			
9 Deficiency Contrary to the requirements cited above: 1. Audit plans do not identify organizations to be notified and the appli-			
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			

Aprvl.

11 QAE/Lead Auditor/Date <i>S. Davis</i> 11/30/89	12 Division Manager/Date <i>Glenn Hedger</i> 12-1-89	13 Project Quality Mgr/Date <i>[Signature]</i> 12/1/89
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Completed by Organization in Block 5

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	17 Effective Date 2/16/90
18 Signature/Date <i>HP Ames</i> 1/12/90	

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date <i>[Signature]</i> 2/21/90	Division Manager/Date <i>S. Davis</i> 2/2/90	Project Quality Mgr./Date <i>[Signature]</i> 2/2/90
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks RESPONSE LETTER TWS-EES-13-01-90-065 PLUS AMENDED RESPONSE LETTER TWS-EES-13-02-90-033.			
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date

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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.

14 Remedial/Investigative Action(s)

Remedial Actions: Refer to investigative actions stated below.

Investigative Actions: Review the audit records for proper notification, completed checklists, appropriate document references, and qualitative and quantitative statements for acceptance. Results of each audit reviewed will be reported to the QAPL.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition: Audit direction contained within the implementing procedure was inadequate.

Corrective Action to Prevent Recurrence: Revise the audit procedure to incorporate clear guidance on audit documentation. The audit staff will be trained to the revised procedure upon its issue.

SDR 470-Clarification

1. Change the last sentence of the response in Block 14 addressing Investigative Actions to read as follows:

"Results of each audit reviewed will be documented and reported to the QAPL who will initiate needed additional corrective action."

Responses to SDRs 461, 469, and 471 are considered to be acceptable.

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Completed by Originating QA Organization	1 Date 11/16/89		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 S.L. Crawford		4 SDR No. 471 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) (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 Organization in Block 5	9 Deficiency TWS-QAS-QP-02.1, Rev.1, para. 4.2 and para 6.1, step 5, do not require position descriptions to identify needed indoctrination or training. Position descriptions do not generally identify training and indoctrination				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to				
	11 QAE/Lead Auditor/Date S. Jones 11/30/89		12 Division Manager/Date H. H. H. 12-1-89		13 Project Quality Mgr./Date 12/1/89
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				
Completed by Org. QA Org.	15 Effective Date 2/16/90				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				
	17 Effective Date 2/16/90				
Comp. by Orig. QA Org.	18 Signature/Date AP Jones 1/12/90				
	19 Response Accepted	QAE/Lead Auditor/Date S. Jones 2/22/90	Division Manager/Date S. Jones 2/22/90	Project Quality Mgr./Date 2/22/90	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks ① Ref. SDR response LTR, Herbst to Hester, dtd. 1/11/90				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

S. Jones 11/16/89 - TWS-QAS-QP-02.1 - 13-11-90-265

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ADP1

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 recurrence.

14 Remedial/Investigative Action(s)

Remedial actions: Procedure QP-02.1 will be changed to add the indoctrination and training requirements to each position description. All LANL position description will be revised to include this needed information and the files updated in accordance with the change.

Investigative actions: None required, the above actions involve all the LANL personnel files.

16 Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the condition: Implementing procedure did not require the inclusion of indoctrination and training requirements as a part of the position description.

Corrective action to prevent recurrence: A change request to the implementing procedure QP-02.1, Procedure for Personnel Selection, Indoctrination, and Qualification, will be issued requiring that position descriptions include applicable indoctrination and training information.