

**Department of Energy**  
Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office  
P.O. Box 98608  
Las Vegas, NV 89193-8608

**OCT 18 1996**

L. D. Foust  
Technical Project Officer  
for Yucca Mountain  
Site Characterization Project  
TRW Environmental Safety Systems, Inc.  
Bank of America Center, Suite P-110  
101 Convention Center Drive  
Las Vegas, NV 89109

**EVALUATION OF AMENDED RESPONSES TO DR YM-96-D-080, YM-96-D-083  
THROUGH YM-96-D-085 AND YM-96-D-088 RESULTING FROM YMQA AUDIT  
YM-ARC-96-18 OF SANDIA NATIONAL LABORATORIES**

The Yucca Mountain Quality Assurance staff has evaluated the amended responses to Deficiency Reports YM-96-D-080, YM-96-D-083 through YM-96-D-085 and YM-96-D-088. The amended responses have been determined to be satisfactory. Verification of completion of the corrective actions will be performed after the effective dates provided. Any extension to these dates must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Deborah G. Sult, YMQA/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Donald J. Harris at (702) 794-1467.

*James Blaylock for*  
Richard E. Spence  
Yucca Mountain Quality Assurance

YMQA:MRD-0115

Enclosure:  
DRs YM-96-D-080, YM-96-D-083  
through YM-96-D-085 and  
YM-96-D-088

9610290046 961018  
PDR WASTE  
WM-11 PDR

L. D. Foust

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cc w/encl:

T. A. Wood, DOE/HQ (RW-14) FORS  
J. G. Spraul, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
R. L. Strickler, M&O, Vienna, VA  
B. R. Justice, M&O, Las Vegas, NV  
S. Y. Pickering, M&O/SNL, Albuquerque, NM, M/S 1395  
Records Processing Center

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV  
D. J. Harris, YMOA/QATSS, Las Vegas, NV  
D. G. Sult, YMOA/QATSS, Las Vegas, NV  
D. G. Horton, DOE/OQA, Las Vegas, NV  
M. R. Diaz, DOE/YMSCO, Las Vegas, NV

290008

NH331/  
102.7  
wm-11

recip: Nmss/PAHL

**SANDIA NATIONAL LABORATORIES  
CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)**

**TECHNICAL PROCEDURES**

**Revision 04**

**Effective Date:** June 17, 1996

**Author:**

*[Signature]*

**Date:**

5/31/96

**Concurrence:**

*[Signature]*  
QA Reviewer

**Date:**

6/3/96

**Approval:**

*[Signature]*  
SNL CRWM Lab Lead

**Date:**

6/11/96

**CONTROLLED DOCUMENT**  
(If Numbered in Red Ink)

**Copy Number:** 000003

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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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**BLOCK 14 - REMEDIAL ACTIONS:**

Evaluator had erroneously been given an outdated copy of QAIP 20-1. In fact, Revision 04 to QAIP 20-1 had been approved and issued. As can be seen from the attached copy of QAIP 20-1, Revision 04, Section 4.2, Step 1, Note 2, we have updated our QAIP as suggested by the evaluator and the current revision should be in compliance with QARD, Revision 5, Section 6.2.7. No further remedial action is required.

**BLOCK 15 - EXTENT OF CONDITION:**

Investigation showed that the only other procedure that provided for "expedited changes" is QAIP 1-5 governing Work Agreements. QAIP 1-5, section 4.3, Step 1, does indicate the "level of management" authorized to make expedited changes and the time limit for processing the change through normal change processing channels. QAIP 1-5 also states that work will be evaluated if the normal review process results in a change that is different from the temporary revision. Since the scope of expedited changes is very limited and clearly defined, there is no reason to perform a root cause determination or state action to preclude recurrence.

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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: <b>QARD, Revision 5</b>	2 Related Report No. <sup>3, 5, 11, 14</sup> <b>YM-AR 96-18</b>
3 Responsible Organization: <b>SNL</b>	4 Discussed With: <b>R. Richards, F. Schelling</b>

5 Requirement/Measurement Criteria:

Section 6.2.7, Paragraph B., "Implementing documents shall describe the process to control expedited changes according to the following requirements."

Section 6.2.7, Paragraph B., 1., "The level of management with the authority to make expedited changes shall be identified."

Section 6.2.7, Paragraph B., 2., "The time limits for processing expedited changes through normal change process shall be specified."

6 Description of Condition:

Contrary to the above requirements, QAIP 20-1, Revision 03, "Technical Procedures," Section 4.2, NOTE 2: describes a process for Expedited Changes; however, 1) The level of management with the authority to make expedited changes is not explicitly identified. 2) The time limit for processing expedited changes through the normal change process is not specified. 3) The procedure does not provide the evaluation methodology, when the procedure work activity results in a change that is different from the expedited change. 4) The procedure does not provide the methodology for the PI to notify the author and others, as necessary, of the changes.

7 Initiator <i>Donald J. Harris</i> <b>Donald J. Harris</b> Date <b>8/1/96</b>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Action: (Not required for PR)

Revise appropriate QAIP to incorporate minimum requirements as specified in QARD.

11 QA Review: <i>Donald J. Harris</i> <b>QAR Donald J. Harris</b> Date <b>8/1/96</b>	12 Response Due Date <b>20 working days from issuance</b>
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13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name <b>R.E. SPENCE</b> Signature <i>Robert B. Constable</i> Date <b>8.7.96</b>
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22 Corrective Action Verified <b>QAR</b> Date	23 Closure Approved by: (N/A for PR) <b>AOQAM</b> Date
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Continuation Page.

15 Extent of Condition: (Not required for PR)

See Continuation Page.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

18 Corrective Action Completion Due Date:

N/A

19 Response by:

Initial  
 Amended

*Chris F. Ell*

Date 9/4/96

SOS  
Phone 822-1544

20 Response Accepted ~~amended~~ N/A 10/10/96

QAR Ronald J. Harris Date 10-9-96

21 Response Accepted (N/A for PR):

AOQAM

N/A

Date

9/5/96 BRADY & Spence

**4.0 PROCEDURE, Continued**

**4.2 Changes**

Responsible Individual(s)	Step	Procedure
Author	1	<p>Upon identifying the need for a procedural change, shall draft the procedure change(s) and revise the procedure. For all procedure revisions provide a description of each change in the Revision History. Review the Revision History each time a revision is proposed, to ensure that commitments are not inadvertently deleted.</p> <p><b>NOTE 1:</b> Editorial corrections may be made to documents without being subject to review requirements. The following items are examples of editorial corrections:</p> <ul style="list-style-type: none"> <li>a) Correcting grammar or spelling,</li> <li>b) Renumbering sections or attachments in a way that does not affect the sequence of work,</li> <li>c) Changing the title or number of the document, and</li> <li>d) Updating organizational titles (not responsibilities).</li> </ul> <p>Editorial changes shall be approved by the PI.</p> <p><b>NOTE 2:</b> If a user of the procedure determines an activity cannot be performed as listed and the change process would cause unreasonable delays, then an <b>EXPEDITED CHANGE</b> may be requested by performing the following steps:</p> <ul style="list-style-type: none"> <li>a) The user contacts the responsible PI.</li> <li>b) The PI reviews the nature of the change required and either authorizes an expedited change or shall stop work until the procedure is revised.</li> </ul>

*Continued on next page*

## 4.0 PROCEDURE, Continued

### 4.2 Changes, continued

Responsible Individual(s)	Step	Procedure
Author	1 cont.	c) If an expedited change is authorized, the procedure is changed at the work location by taking the following steps: <ol style="list-style-type: none"> <li>1) On the controlled copy of the procedure, draw a single line through the text to be changed.</li> <li>2) Insert the corrected text above or adjacent to the text being changed.</li> <li>3) Initial and date the change.</li> <li>4) Notify the PI of the change completion.</li> </ol> d) Shall initiate an expedited change through the normal change process within 15 working days of the approval of the expedited change. The work activity governed by the procedure shall be evaluated if the normal review process results in change that is different from the expedited change. e) In a timely manner, notifies the affected personnel and others, as necessary, of the changes.
	2	Shall obtain reviews and approvals of the TP revision as specified in section 4.1.

## 5.0 RECORDS

The following QA records and record packages, including corrections and changes thereto, generated as a result of implementing this procedure are submitted to the SNL Local Records Receiving Organization by the records source in the applicable procedure:

QA Records

Procedure

The approved procedure or revision.

QAIP 6-1

Non-processed records generated by this procedure may be retained by the PI in a separate record package. The record package includes Document Review and Comment Forms (with mark-ups) for mandatory comments.

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YM-96-D-080 Block 14, "Remedial Action Response"

SNL's Remedial Action Response failed to address if QAIP 20-1, Revision 3, or early versions (revisions) was used to process expedited changes. What was the impact of such expedited changes? Did the proper level of management make the changes? Were the processes through the normal change process within the time limit? Were the changes different from the expedited change? If so, what was the impact?

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14 Remedial Actions:

SEE Amended Response CONTINUATION PAGE.

15 Extent of Condition: (Not required for PR)

SEE AMENDED RESPONSE CONTINUATION PAGE

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

18 Corrective Action Completion Due Date:

SEE A/R Continuation Page

19 Response by:

Initial  
 Amended

SEE AMENDED RESPONSE CONTINUATION PAGE  
Date \_\_\_\_\_ Phone \_\_\_\_\_

20 Response Accepted

QAR al Harris

Date

10/10/96

21 Response Accepted (N/A for PR):

AOQAM James Blaylock

Date

10/18/96

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YM-96-D080, Amended Response

Block 14, Remedial Action:

QAIP 20-1 will be revised to specify the Principal Investigator as the "level of management" authorized to make expedited changes, to specify the time limit for processing such changes through the normal change process, specify an evaluation methodology (if the formal change differs from the expedited change), and specify how the PI is to notify the author and other affected personnel of an expedited change.

Block 15, Extent of Condition:

Investigation shows that the only other procedure that provides for "expedited changes" is QAIP 1-5, governing Work Agreements. QAIP 1-5 does indicate the "level of management" authorized to make expedited changes, but contains wording similar to QAIP 20-1 concerning time limitations and is similarly vague concerning mechanisms for notifying affected parties of an expedited change and how to evaluate differences between expedited and succeeding formal changes. Action: QAIP 1-5 will be revised similarly to QAIP 20-1, described above.

Concerning past expedited changes, investigation shows that expedited changes have only been used for Technical Procedures, four times to date. In each case the appropriate "management level" (the PI) authorized them, and there were no differences between the expedited change and the formal change that followed. It cannot be determined, from available records, whether the time limit specified in QAIP 20-1 for initiating the formal change was adhered to, but all four formal changes were approved within a reasonable time (e.g., 40 working days) after the expedited changes were made.

No root cause determination is considered necessary for this limited situation, and no additional action is needed to preclude recurrence.

Block 18, Corrective Action Completion Due Date:

November 30, 1996

Block 19, Response by:

Amended Robert R. Richards



Date: Oct. 1, 1996 Phone: 505 848 0786

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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: <b>QAIP 4-1, Revision 07, Procurement</b>	2 Related Report No. <b>YM-ARC-96-18</b>
3 Responsible Organization: <b>SNL</b>	4 Discussed With: <b>L. Washurn, R. Richards</b>

5 Requirement/Measurement Criteria:

1) Paragraph 4.2.3, Step 7, the QA Procurement Coordinator, "Shall review the PPC form. Sign the PPC form to indicate that all appropriate QA Requirements are identified. The QA Procurement Coordinator will review the PPC for correctness and the PR Statement-of-Work (SOW) for inclusion of applicable QA standard clauses and assure QA requirements are consistent with applicable work agreement for the stated WBS activity to assure the product or service will meet specified requirements."

6 Description of Condition:

1) Contrary to the above requirements, the PPC attached to PR AS 0296 to Geokon Inc., dated 5/3/95 did not describe QA requirements. The attached PPC indicated that QA requirements were not applicable. Specifically, Section 11, QA Requirements, Items 1) determining if a competitively bid and proposal evaluation plan is required, 2) determining if SNL QA program will control activities and which SNL procedures apply, 3) determine if contractors QA program applies and any exception and hold points, 4) determine what QA standard clauses applies, e.g. subtier suppliers, Rights of Access, Deviations from requirements, Procurement document, Submittal requirements, Record requirements and Hold Points, was marked "N/A". However, Item 5 was marked to indicate services would be accepted by the user. The user did not specify calibration documentation as a basis for acceptance.

Note: The PR SOW and Technical Requirements were for Calibration of Rockbolts Load Cells in a manner which is in accordance with YMP QA requirements. A Certificate of Calibration, which meets YMP QA requirements for Calibration reports must accompany each instrument.

7 Initiator <i>Donald J. Harris</i> Donald J. Harris Date 8/1/96	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Action: (Not required for PR)

1) Verify the Certification of Calibration for each Load Cell contains all the required information in accordance with QAIP 12-1, Revision 05, Measurement and Test Equipment Control.

2) Annotate Procurement Planning Checklist Records Copy with this DR number. Initial and date entry.

11 QA Review: QAR <i>Donald J. Harris</i> Date 8/1/96	12 Response Due Date 20 working days from issuance
13 Affected Organization QA manager Issuance Approval. (QAR for PR) Printed Name <b>R.E. SPENCE</b> Signature <i>Robert Blount</i> Date <b>8.7.96</b>	
22 Corrective Action Verified QAR Date	23 Closure Approved by: (N/A for PR) AOQAM Date

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Continuation Page.

15 Extent of Condition: (Not required for PR)

See Continuation Page.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

18 Corrective Action Completion Due Date:

September 16, 1996

19 Response by: FOR R. RICHTERS OS F Ell

Initial  
 Amended

Date 9/4/96

Phone 846-0641

20 Response Accepted ~~Amended~~

QAR Donald J. Harris

N/A Date 10/10/96

21 Response Accepted (N/A for PR):

AOQAM

N/A

Date

9/5/96 Brady to Spencer

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**BLOCK 14 - REMEDIAL ACTION:**

SNL Department 6853 will verify for the cited procurement that the documentation (calibration certificates for each instrument) required by the procurement document was delivered and that those documents contain all the required information. A revised record copy of the PPC for the cited procurement, which includes reference to this DR, will be submitted to the Local Records Receiving Organization by the QA Department. These remedial actions will be completed by September 16, 1996.

**BLOCK 15 - EXTENT OF CONDITION:**

Even through the Procurement Planning Checklist (PPC) for this purchase was incorrectly marked to indicate that QA requirements (other than an acceptance evaluation of services by the user of the service provided) were not applicable, the Purchase Requisition Form itself included the appropriate QA requirements for the calibration service included in this procurement of geotechnical monitoring hardware. Procurement documents for all other purchases of geotechnical monitoring equipment by SNL Department 6853 are being reviewed to determine if PPCs were completed correctly or not. Of the 18 procurements initially reviewed, the majority appear to be completed correctly. Minor errors on several (e.g. failure to check a box for applicability of QA to the procurement although QA requirements were specified, failure to check the applicability boxes on standard commercial purchases) will be corrected. Because of the minor nature of this deficiency, no root cause analysis is warranted and no additional action to preclude recurrence is needed.

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Block 15, "Extent of Condition"

SNL committed to review procurement documents for all other purchases of geotechnical monitoring equipment procured by SNL Department 6853. When will this review be completed (date), and how will the records be corrected (revised); and will they include this Deficiency Report number on the record?

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14 Remedial Actions:

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15 Extent of Condition: (Not required for PR)

SEE Amended Response CONTINUATION PAGE

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

18 Corrective Action Completion Due Date:

ds 10/10/96  
SEE A/R CONTINUATION PAGE

19 Response by:

Initial  
 Amended

SEE AMENDED RESPONSE CONTINUATION PAGE  
Date \_\_\_\_\_ Phone \_\_\_\_\_

20 Response Accepted

QAR Donald J. Harris Date 10/10/96

21 Response Accepted (N/A for PR):

AQAM James B. [Signature] Date 10/18/96

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YM-96-D083, Amended Response

Block 14, Remedial Action:

SNL department 6853 will verify, for the cited procurement, that the documentation (calibration certificates for each instrument) required by the procurement document was delivered and that those documents contain all the required information. A revised record copy of the Procurement Planning Checklist (PPC) for the cited procurement, which includes reference to this DR, will be submitted to the Local Records Receiving Organization by the QA Department. These remedial actions will be complete by October 10, 1996.

Block 15, Extent of Condition:

Even though the Procurement Planning Checklist for this purchase was incorrectly marked to indicate that QA requirements (other than acceptance evaluation of services) were not applicable, the Purchase Requisition form itself included the appropriate QA requirements for the calibration service provided for this procurement of geotechnical monitoring hardware. Therefore there is no adverse effect for the cited procurement.

Procurement documents for all other purchases of geotechnical monitoring equipment by SNL Department 6853 have been reviewed to determine if PPCs were completed correctly or not. Of the 18 such purchases reviewed, PPCs for the majority are completed correctly. Minor errors occurred on a number of PPCs (e.g., failure to check a box for applicability of QA to the procurement in a case where QA requirements were clearly specified). These documents will be corrected as specified in SNL QAIP 17-1, and this DR will be cited on the documentation for any corrected records that must be submitted to the YMP Records Processing Center for the purpose of replacing records already there.

Because of the minor nature of this deficiency, no root cause analysis is warranted, and no additional action to preclude recurrence is needed.

Block 18, Corrective Action Completion Due Date:

October 31, 1996

Block 19, Response by:

Amended Robert R. Richards



Date: Oct. 2, 1996 Phone: 505 848 0786

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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: <b>QARD, Revision 5</b>	2 Related Report No. <b>Audit YM-ARC-96-18</b>
3 Responsible Organization: <b>SNL</b>	4 Discussed With: <b>Nina Garcia, Eloise James</b>

5 Requirement/Measurement Criteria:

Section 17.2.4, A. states, "Corrections to QA records including documents which will become QA records shall include the initials or signature of the person authorized to make the correction and the date the correction was made."

6 Description of Condition:

SNL procedure for QA records does not meet the requirements of the QARD for the correction of QA records.

QAIP 17-1, Revision 02, Section 4.4 states in part "Records created by Record Sources which do not meet the requirements for corrections shall be processed into the records management system through the completion of an SNL YMP Record/Record Package Deficiency and Justification Form."

Several QA records have been accepted using this method. However, several corrections have been made without showing the signature or initials and date of the person authorized to make them.

Examples are: RMS SL #150478, 150533, 150505 (Record Package)  
 SNL-96-D2 (Deficiency Document)

7 Initiator <b>Mario R. Diaz</b> <i>Mario Diaz</i> Date <b>8/1/96</b>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Action: (Not required for PR)

1. Modify the pertinent SNL procedure in order to comply with this requirement.
2. Review other QA records to evaluate compliance with this requirement and make appropriate corrections of deficient records. Provide objective evidence of review, evaluation, and corrective actions.

11 QA Review: <b>QAR Mario R. Diaz</b> <i>Mario Diaz</i> Date <b>8-1-96</b>	12 Response Due Date <b>20 working days from issuance</b>
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13 Affected Organization QA manager Issuance Approval (QAR for PR) Printed Name <b>R. E. SPENCE</b> Signature <i>Robert B. Spence</i> Date <b>8.7.96</b>
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22 Corrective Action Verified <b>QAR</b> Date	23 Closure Approved by: (N/A for PR) <b>AQAM</b> Date
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**PERFORMANCE/DEFICIENCY REPORT RESPONSE**

14 Remedial Actions:

See Continuation Page.

15 Extent of Condition: (Not required for PR)

Based on the fact that no SNL records have been rejected and sent back to SNL for corrections of the correction of records (e.g. initials, dates, etc.), this deficiency appears to be limited in scope. Completion of the review process identified in Block 14, Remedial Action, will provide further evidence of the scope of the deficient condition but based on the apparent scope and the relatively minor nature of the deficiency, there is no reason to conduct a root cause determination.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

18 Corrective Action Completion Due Date:

October 1, 1996

19 Response by: *For P-LARMA OS F-ELL*

Initial  
 Amended

Date *9/4/96*

Phone *818-0671*

20 Response Accepted

QAR

*N/A*

Date

21 Response Accepted (N/A for PR):

AOQAM

*N/A*

Date

*9/5/96 Brady to Spence*

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**BLOCK 14 - REMEDIAL ACTIONS:**

The RMS SL#s identified above will be reviewed for the extent of the condition within each document or package. Record sources will be contacted to make corrections as necessary. The Participant Data Archive (PDA) staff will make appropriate changes per the designation letter of July 25, 1996 and/or verify that any changes previously made by them are correct and fall within the confines of the letter. If corrections are required for records previously submitted to the Records Processing Center, processing of a superseding record will be required of the record source. Other individual records and record packages that have been processed by the SNL Records staff but have not yet been submitted to the Records Processing Center (RPC) will be carefully re-reviewed and identified corrections will be properly completed prior to submittal.

QAIP 17-1, Revision 02 has been revised to clarify how "Administrative Corrections" may be made and how corrections must be indicated. This change is in the review process now.

The SNL YMP Record/Records Package Deficiency and Justification Form has been modified to remove the capability to use the form to document corrections. The section on "completeness" had the following selection option removed, "\_\_\_ All corrections are reviewed and determined intentional." This change is part of the revision of QAIP 17-1 which is currently in the review process.

The SNL records staff was briefed on July 29, 1996 regarding the fact that use of the form to accomplish "blanket" records corrections is not acceptable. As of July 29, 1996, they no longer will allow the use of or accept submitted forms utilizing the selection option, "\_\_\_ All corrections are reviewed and determined intentional." on the form. Completed.

SNL/CRWM Management signed a memorandum to file on July 25, 1996 designating the Participant Data Archive (PDA) Staff as approved to make administrative changes per verbal direction of the Record Source/Principal Investigator. This is a clarification of the presumed role of Record Source "designee" in the responsibility section of the procedure (copy of memorandum attached). This memo serves as retroactive approval to the effective date of QAIP 17-2, Revision 02, "Participant Data Archive (PDA)". Completed.

Records Management personnel attended an implementation briefing on QAIP 17-1, Revision 02, "record correction" process and on the QAIP 17-3, Revision 02, "record review and acceptance" process.

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Albuquerque, New Mexico 87185-1330

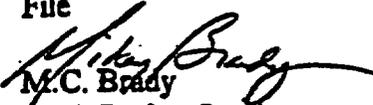
date: July 25, 1996

WBS:1.2.5.3.5.

1.2.11.

to: File

QA

from:   
M.C. Brady  
YMP Project Leadsubject: Delegation of Authority for Participant Data Archive Staff for Procedure Implementation of  
QAIP 17-2, Rev 02 "Participant Data Archive (PDA)" (SCPB:NA)

This memo serves to clarify and provide Delegation of Authority for Sandia Participant Data Archive (PDA) personnel to act as "designee" for YMP Principal Investigators (PI's) for the following procedure activities within QAIP 17-2, Rev. 02.

Section 4.2 PDA Staff Responsibilities clearly states "Assisting the PI with preparation of data release" and "Assisting the Record Source in compilation of data sets as record packages" however, specific procedure activities were not defined. To provide this clarification and to document approval of the completion of these activities I submit this clarification to the record.

Specific procedure activities which may be completed by the PDA staff per verbal direction of the PI are:

- fill out Appendix A - PDA Data Set Opening Index Form's
- fill out Appendix B - PDA Data Set Segment Submittal Form's
- fill out Appendix C - PDA Data Set Segment Inventory Form's
- fill out Appendix D - PDA Data Set Status Tracking Form's
- fill out, sign as "checked by", Appendix F - Technical Data Information Form (TDIF)
- fill out Appendix H - SNL/PDA Computer Magnetic Tape Tape Properties

This memo also serves to provide retroactive Delegation of Authority to the effective date of this procedure as the original intent of the term "designee" as part of the PI Responsibilities was to include the Participant Data Archive staff.

YMP: 1.2.5.3.5 and 1.2.11;PM;QA;Participant Data Archive, Delegation of Authority  
YMP CRF

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Your response cannot be accepted based on the following:

Compliance to procedural requirements is the basis for this adverse condition. However, your answer does not address this topic. Additionally, the designation letter of July 25, 1996, applies only to those records processes in accordance with QAIP 17-2, Revision 2. It does not cover those records related to QAIP 17-1, Revision 2, and/or QAIP 17-3, Revision 3.

No effort is made to review additional QA records packages to verify compliance. One of the requirements from the QARD states that "individuals creating QA records shall ensure that the QA records are accurate, complete, appropriate to the work accomplished and identifiable to the item(s) or activity(ies) to which they apply."

Your statement about records already being accepted by the Records Processing Center (RPC) indicates that the records are in good shape. This is inaccurate and misleading based on the fact that the implementing procedure for the RPC personnel is YAP-17.1Q, Rev. 0, which establishes that they are not responsible to ensure that the QA records packages accepted by them meet and comply with all the requirements of the QARD and associated implementing procedures. This responsibility belongs to the Record Source or Affected Organization. Their acceptance is related to the records being authenticated, transmitted using a Table of Contents and the total amount of pages being accurate.

Based on all of the above, root cause plus corrective action to preclude recurrence are required and should also be part of your response.

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SEE AMENDED RESPONSE CONTINUATION PAGE

15 Extent of Condition: (Not required for PR)

SEE AMENDED RESPONSE CONTINUATION PAGE

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

SEE AMENDED RESPONSE CONTINUATION PAGE

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

SEE AMENDED RESPONSE CONTINUATION PAGE

18 Corrective Action Completion Due Date:

SEE A/R CONTINUATION PAGE

19 Response by:

Initial  
 Amended

SEE A/R CONTINUATION PAGE  
Date \_\_\_\_\_ Phone \_\_\_\_\_

20 Response Accepted

QAR

*Waisi Lau*

Date 10-15-96

21 Response Accepted (N/A for PR):

AOQAM

*James B. ...*

Date 10/18/96

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YM-96-D084 Amended Response

Block 14, Remedial Actions:

The RMS SL#s identified above will be reviewed for the extent of the condition within each document or package. Record sources will be contacted to make corrections as necessary. The Participant Data Archive (PDA) staff will make appropriate changes per the designation letter of July 25, 1996 and/or verify that any changes previously made by them are correct and fall within the confines of the letter. If corrections are required for records previously submitted to the Records Processing Center, processing of a superseding record will be required of the record source. Other individual records and record packages that have been processed by the SNL Records staff but have not yet been submitted to the Records Processing Center (RPC) will be carefully re-reviewed and identified corrections will be properly completed prior to submittal.

Block 15, Extent of Condition:

Twenty records, selected at random, will be reviewed to determine the extent of inappropriate corrections. This selection of records will be in addition to those specifically identified in the audit finding. Documented evidence of this review will indicate problems found and the resolution actions taken.

Block 16, Root Cause Determination:

QAIP 17-1, Revision 02 was not properly implemented by Record Sources and the records management staff in relation to proper record corrections.

Block 17, Action to Preclude Recurrence:

The implementation or completion of the following actions will assure that the noted deficiency will not recur.

(a) QAIP 17-1, Revision 02 has been modified (Revision 03) as follows to include acceptability of "Administrative Corrections" and is in the management approval process:

"Administrative Changes - e.g. enhancing legibility, correcting typographical error, making an editorial change, adding or changing a QA designator, labeling privileged records, and adding or correcting page counts or page numbering may be made without obtaining reapproval from the originating organization."

Action Completion Date: (a) the effective date of the revised procedure, expected on or before October 20, 1996.

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YM-96-D084 Amended Response (continued)

(b) The SNL YMP Record/Records Package Deficiency and Justification Form in QAIP 17-1 has been modified to remove the capability to use the form to document corrections. The section on "completeness" has had the following selection option removed "\_\_\_All corrections are reviewed and determined intentional."

Action Completion Date: (b) the effective date of the revised procedure, expected on or before October 20, 1996

(c) The SNL records staff was briefed on July 29th regarding the appropriate correction process and the appropriate use of the deficiency form. As of July 29th, they no longer will allow the use of or accept submitted forms utilizing the selection option "\_\_\_All corrections are reviewed and determined intentional." from the form.

Action Completion Date: (c) completed July 29, 1996

(d) SNL/CRWM Management signed a memorandum to file on July 25, 1996 designating Participant Data Archive (PDA) Staff as approved to make Administrative Changes per verbal direction of the Record Source/Principle Investigator. This is a clarification of the presumed role of Record Source "designee" in the responsibilities section of the procedure. (copy of memorandum attached) This memo serves as retroactive approval to the effective date of QAIP 17-2, Revision 02 "Participant Data Archive (PDA)".

Action Completion Date: (d) completed July 25, 1996

(e) Records Management personnel attended an implementation briefing of the QAIP 17-1, Revision 02 "record correction" process and on the QAIP 17-3, Revision 02 "record review and acceptance" process.

Action Completion Date: (e) completed July 29, 1996

(f) Required training will be assigned for revisions to QAIP 17-1 and 17-3 when the pending revisions are issued. These two procedures are among those that are management required for all YMP personnel. The record correction process has been clarified in both of the revisions of these procedures.

Action Completion Date: (f) the effective date of the revised procedure, expected on or before October 20, 1996

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YM-96-D084 Amended Response (continued)

(g) Review the record numbers which were identified as being deficient during the audit to establish impacts of the corrections which were noted - correct each as required. If corrections are required for records previously submitted to the Records Processing Center a superseded record will be required of the record source.

Action Completion Date: (g) October 10, 1996

Block 18, Corrective Action Completion Due Date:

November 15, 1996

Block 19, Response by:

✓ Amended P. J. Warner 

Date: October 4, 1996 Phone: 505 848-0130

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WASHINGTON, D.C.**

**THIS IS A REPORT STAMP**  
 Performance Report  
 Deficiency Report  
 NO. YM-96-D085  
 PAGE 1 OF 2  
 QA: L

**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: <b>QAIP 17-1, Revision 02</b>	2 Related Report No. <b>Audit YM-ARC-96-18</b>
3 Responsible Organization: <b>SNL</b>	4 Discussed With: <b>Nina Garcia, Eloise James</b>

5 Requirement/Measurement Criteria:  
**QAIP 17-1, Revision 02, Section 4.2.3. states in part, "The record source shall prepare individual records to include the following information on the first page of the record:**

- SCP number...
- total number of pages...
- "YMP CRF" Code...

Section 4.4 states in part, "The record source shall correct errors on records by scribing a single line through the incorrect information and entering the correct information in close proximity. Date and initial or sign the correction."

6 Description of Condition:  
 QA records have been processed and accepted without being in compliance with procedural requirements. The following SNL QA records were deficient in accordance with one or more of the requirements mentioned in Block 5 above, and some have been corrected by other than the record source:

RMS SL #150498, 150530, 150747 through 150752, 150505, 150531 through 150534, 150750, and 150233.

7 Initiator <b>Mario R. Diaz</b> <i>Mario Diaz</i> Date <b>8/1/96</b>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
--	---

10 Recommended Action: (Not required for PR)

- Correct the records identified as deficient in accordance with procedural requirements.
- Review and evaluate other QA records to verify compliance with these requirements and make appropriate corrections of deficient records. Provide objective evidence of review, evaluation, and corrective actions.

11 QA Review: QAR <b>Mario R. Diaz</b> <i>Mario Diaz</i> Date <b>8-1-96</b>	12 Response Due Date <b>20 working days from issuance</b>
--	--

13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name <b>R.E. SPENCE</b> Signature <i>Robert B Constable</i> Date <b>8.7.96</b>
---

22 Corrective Action Verified QAR _____ Date _____	23 Closure Approved by: (N/A for PR) AOQAM _____ Date _____
---	--

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**PERFORMANCE/DEFICIENCY REPORT RESPONSE**

**14 Remedial Actions:** Based upon a change to YAP-17.1Q and other procedures, it is no longer necessary to include the SCPB Number or the YMP CRF code on records. Therefore, QAIP 17-1 has been revised to remove those items from the requirements for records. This change is in the coordination cycle now. QAIPs 17-1 and 17-3 have been revised to permit the Records Center staff to make administrative corrections to records. Changes to both these procedures are currently in the coordination cycle. Records noted as deficient by the evaluator have been corrected.

**15 Extent of Condition:** (Not required for PR)

The research effort required to locate and correct all such deficiencies would be neither cost effective nor of value to the program as adding two codes that are no longer required would have minimal effect on quality. Because of the limited significance of this deficiency, there is no reason to conduct root cause determination nor to develop additional actions to preclude recurrence.

**16 Root Cause Determination:** (Not required for PR) Required  Yes  No

**17 Action to Preclude Recurrence:** (Not required for PR) Required  Yes  No

**18 Corrective Action Completion Due Date:**  
October 1, 1996

**19 Response by:** *MIR P. VARNER* *OF F 800*  
 Initial  Amended  
Date *9/17/96* Phone *518-0641*

**20 Response Accepted**  
QAR *N/A* Date

**21 Response Accepted (N/A for PR):**  
AOQAM *N/A* Date

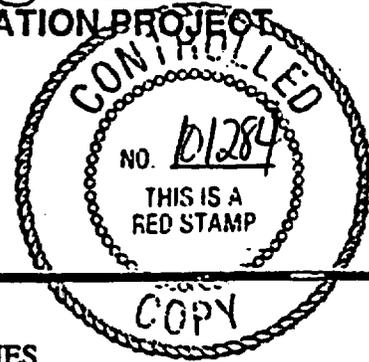
*9/5/96 Brady De Spence*

YMP-175-R1  
06/20/94

# YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT



## PROCEDURE



Title:

**RECORDS MANAGEMENT REQUIREMENTS AND RESPONSIBILITIES**

Procedure No.:  
YAP-17.1Q

Revision: 0

ICN: 4

Page 1 of 30

Approval: *J.J. Adams*

Date: 5/30/95

Approval: N/A

Date:

Approval: N/A

Date:

Concurrence: R.E. Spence

*R.E. Spence*

Date:

6/1/95

### CHANGE HISTORY

<u>Rev. No.</u>	<u>ICN No.</u>	<u>Effective Date</u>	<u>Description of Change</u>
0		05/31/94	Initial Issue - Supersedes AP-1.18Q, <i>Records Management: Las Vegas Record Source Responsibilities</i>
0	1	05/17/95	ICN to delete requirement to include microfilm roll number for corrections and supplements to records, to change Local Records Center to Records Processing Center, and to correct procedure approval responsibility. The above deletion enables Affected Organizations to comply with requirements for supplements and corrections to records. Pages affected are 2, 4, 6, 12, 13, 15, 16, 17, 19, 20, and 21.
0	2	05/17/95	ICN to add definition for Yucca Mountain Site Characterization Office Research and Study Center, to include instructions for cited references in the Process Section, and to delete Instructions for the Preparation of Final Scientific and Technical Reports from Attachment 9.5. Pages affected are 4, 8, 13, 19, and 20. Pages added are 4a and 8a.
0	3	05/17/95	ICN to replace Yucca Mountain Site Characterization Program Baseline (SCPB) Reference Numbers with traceability designators, changing the traceability of the procedure. Pages affected are 4, 7, 15, and 19. Page added is 7a.
0	4	06/14/95	ICN to make editorial corrections. Pages affected are 2, 3, 4, 4a, 8, and 13. Page deleted is 2a.

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QA: L

PR/DR CONTINUATION PAGE

YM-96-D-085

Your response cannot be accepted based on the following:

Your response ignores the fact that your personnel knowingly and willfully have violated procedural requirements contrary to the QARD requirements. These requirements exist to demonstrate that proper controls are in place and are implemented to demonstrate compliance with the QA Program. Violating them is contrary to the QARD requirements.

This adverse condition does require corrective action to preclude recurrence.

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SEE AMENDED RESPONSE CONTINUATION PAGE.

15 Extent of Condition: (Not required for PR)

SEE AMENDED RESPONSE CONTINUATION PAGE

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

SEE AMENDED RESPONSE CONTINUATION PAGE

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

SEE AMENDED RESPONSE CONTINUATION PAGE.

18 Corrective Action Completion Due Date:

SEE A/R CONTINUATION PAGE

19 Response by:

Initial  
 Amended

SEE A/R CONTINUATION PAGE  
Date \_\_\_\_\_ Phone \_\_\_\_\_

20 Response Accepted

QAR *David San*

Date 10-15-96

21 Response Accepted (N/A for PR):

AQQAM *James Blyskal*

Date 10/18/96

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QA: L

**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: <b>QARD, Revision 5</b>	2 Related Report No. <b>Audit YM-ARC-96-18</b>
3 Responsible Organization: <b>SNL</b>	4 Discussed With: <b>R. Richards</b>

5 Requirement/Measurement Criteria:

Section 5.2.2. states "Implementing documents shall include the following information as appropriate to the work to be performed:

H. Identification of the lifetime and nonpermanent quality assurance records generated by the implementing document."

6 Description of Condition:

Technical Procedures are being implemented and generating quality assurance records; however, the technical procedures do not identify records generated as lifetime or nonpermanent as required by the QARD.

Examples are: TP-236, Revision 00; TP-237, Revision 00; TP 244, Revision 00; TP-246, Revision 00; TP-248, Revision 00; TP 250, Revision 00.

7 Initiator <b>Mario R. Diaz</b> Date <b>8/1/96</b>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
--	---

10 Recommended Action: (Not required for PR)

1) Correct Technical Procedures that were identified as deficient.

2) Evaluate other technical procedures to determine compliance with this requirement and make appropriate corrections to deficient procedures. Provide objective evidence of evaluation and corrective actions.

11 QA Review: QAR <b>Mario R. Diaz</b> Date <b>8-1-96</b>	12 Response Due Date <b>20 working days from issuance</b>
13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name <b>R.E. SPENCE</b>	Signature <b>Robert P. Constable</b> Date <b>8.7.96</b>

22 Corrective Action Verified QAR _____ Date _____	23 Closure Approved by: (N/A for PR) AOQAM _____ Date _____
---	--

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Continuation Page.

15 Extent of Condition: (Not required for PR)

See Continuation Page.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

18 Corrective Action Completion Due Date:

N/A

19 Response by: <sup>PR</sup> R. RICHMOND OS F ELL

Initial

Amended

Date 9/4/96

Phone 617-0641

20 Response Accepted

QAR

N/A

Date

21 Response Accepted (N/A for PR):

AOQAM

N/A

Date

3/5/96 Brady to Spencer

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PR/DR CONTINUATION PAGE

**BLOCK 14 - REMEDIAL ACTIONS:**

There is no impact to quality presented by the cited conditions as all technical data are presently submitted forward from Sandia with the records retention designation of "permanent" under the current OCRWM retention schedule. "Permanent" includes the QARD identifier, "LIFETIME". Technical Procedures provide the methods of accomplishing a specific technical activity, but the submittal of generated records is covered by the governing QAIPs (e.g. QAIP 20-1 for scientific notebooks and supporting documentation [LIFETIME], QAIP 20-3 for chain of custody records [LIFETIME], QAIP 2-4 for analysis and review documents [LIFETIME], QAIP 6-2 for SAND reports and review comments [LIFETIME], QAIP 17-2 for technical data information forms [TDIFs] and attached data [LIFETIME], QAIP 19-1 for software documentation and reviews [LIFETIME except for change requests], and QAIP 20-1 for technical procedures and reviews [LIFETIME]). Therefore, no specific actions are required in regards to the LIFETIME/NONPERMANENT status of records produced as a result of performing technical activities. However, to ensure that generated records are properly marked, revised or new technical procedures to be written will indicate whether records created as a result of performing that activity are LIFETIME or NONPERMANENT and the list of LIFETIME/NONPERMANENT records, formally part of QAIP 17-3, has been revised to include, "Note: All records generated as a result of implementing Technical Procedures shall be designated lifetime unless specifically designated nonpermanent in the Technical Procedure." This list has been added to the master list of file codes and will be eliminated from QAIP 17-3 with the next revision.

**BLOCK 15 - EXTENT OF CONDITION:**

Technical Procedures, themselves, did not specifically identify records as LIFETIME or NONPERMANENT. However, further investigation revealed that this designation was being properly applied by the procedure that actually governed the record (rather than the technical activity) and by the Appendix to QAIP 17-3.

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QA: L

PR/DR CONTINUATION PAGE

YM-96-D-088

Your response is not acceptable based on the following:

Your response is inaccurate. Several TP procedures do contain forms originated and required by use of them (i.e., TP 61, 64, 65, 90, etc.). Also, many of the TPs have not been revised to update the identification of the current procedure required to process QA records, which is contrary to QARD requirements. Furthermore, the Appendix to QAIP 17-3 is one element useful to determine the proper identification of the QA Record(s). However, the Record Source using the TP should be made aware in this procedure of how to cross reference this information.

Corrective action is required.

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PR/DR NO. 100-96-1-088  
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QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SEE AMENDED RESPONSE CONTINUATION PAGE.

15 Extent of Condition: (Not required for PR)

SEE AMENDED RESPONSE CONTINUATION PAGE.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

SEE AMENDED RESPONSE CONTINUATION PAGE.

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

SEE AMENDED RESPONSE CONTINUATION PAGE.

18 Corrective Action Completion Due Date:

SEE A/R CONTINUATION PAGE

19 Response by:

Initial  
 Amended

SEE A/R CONTINUATION PAGE  
Date \_\_\_\_\_ Phone \_\_\_\_\_

20 Response Accepted

QAR David Lee

Date 10-15-96

21 Response Accepted (N/A for PR):

AOQAM James B. Taylor Date 10/18/96

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**YM-96-D088 Amended Response**

Block 14, Remedial Actions:

The Technical Procedures cited in block 6 will be revised as necessary to specifically identify records to be submitted and to cite QAIP 17-1 as the governing document for records submittal.

Block 15, Extent of Condition:

Each Technical Procedure which is being utilized on current work will be reviewed to establish whether records to be generated are clearly identified and whether these records are being submitted per upper tier procedures.

Block 16, Root Cause Determination:

The Appendix to QAIP 20-1 "Technical Procedures," did not provide instructions with sufficient detail to direct record sources as to proper identification and submittal of generated records. Additionally, the Lifetime/Nonpermanent Record List (App. A of QAIP 17-3, Rev.2) did not clearly categorize the records generated by TP usage.

Block 17, Action to Preclude Recurrence:

The Appendix to QAIP 20-1, "Technical Procedures," will be revised to require submittal of records per appropriate governing procedures.

The Lifetime/Nonpermanent Record List (Appendix A for QAIP 17-3, Revision 2) will be reviewed and revised as necessary to assure proper categorization of records created through the use of Technical Procedures.

The Records Management and Participant Data Archive staff members will be briefed on the application of the Lifetime/Nonpermanent Records List to technical data and forms which are generated through implementation of Technical Procedures.

Block 18, Corrective Action Completion Date:

December 1, 1996

Block 19, Response by:

Amended *for* P. J. Warner 

Date: October 4, 1996 Phone: 505 848-0130