

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)

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>NOTE 1: 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"> a) Correcting grammar or spelling, b) Renumbering sections or attachments in a way that does not affect the sequence of work, c) Changing the title or number of the document, and d) Updating organizational titles (not responsibilities). <p>Editorial changes shall be approved by the PI.</p> <p>NOTE 2: If a user of the procedure determines an activity cannot be performed as listed and the change process would cause unreasonable delays, then an EXPEDITED CHANGE may be requested by performing the following steps:</p> <ul style="list-style-type: none"> a) The user contacts the responsible PI. 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.

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"> 1) On the controlled copy of the procedure, draw a single line through the text to be changed. 2) Insert the corrected text above or adjacent to the text being changed. 3) Initial and date the change. 4) Notify the PI of the change completion. 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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PERFORMANCE/DEFICIENCY REPORT

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

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
--	---

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

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:

Initial

Amended

for R. Richards OS F Ell

SUR

Date *9/7/96*

Phone *848-0611*

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

9/5/96 Brady to Spence

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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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 QA: L

PERFORMANCE/DEFICIENCY REPORT

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

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 Mario R. Diaz <i>Mario Diaz</i> 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. 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: QAR Mario R. Diaz <i>Mario Diaz</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 D.E. SPENCE	Signature <i>Robert B. Spence for</i>	Date 8.7.96

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)

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:

Initial
 Amended

Date

9/7/96

Phone

585 811-0671

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

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.



Sandia National Laboratories

Operated for the U.S. Department of Energy by
Sandia Corporation

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
M.C. Brady

YMP Project Lead

subject: 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

1 Controlling Document:

QAIP 17-1, Revision 02

2 Related Report No.

Audit YM-ARC-96-18

3 Responsible Organization:

SNL

4 Discussed With:

Nina Garcia, Eloise James

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

Mario R. Diaz *Mario Diaz* Date 8/1/96

9 Is condition an isolated occurrence?

Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

1. Correct the records identified as deficient in accordance with procedural requirements.
2. 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 Mario R. Diaz *Mario Diaz* 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 **R.E. SPENCE**

Signature *Robert B. Constable*

Date 8.7.96

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: *M.R.P. VARGAS* *Os F. Ell*

Initial

Amended

Date *9/7/96*

Phone *848-0641*

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

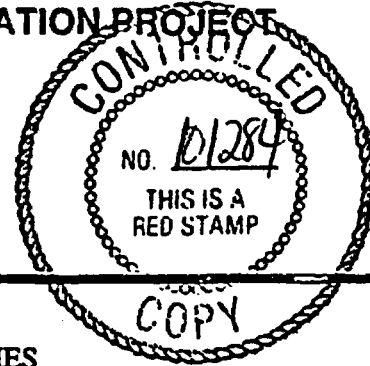
9/5/96 Brady De Spence

YMP-175-R1
06/20/94

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT



PROCEDURE



Title:

RECORDS MANAGEMENT REQUIREMENTS AND RESPONSIBILITIES

Procedure No.: YAP-17.IQ	Revision: 0	ICN: 4	Page 1 of 30
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Approval: <i>J. J. Adams</i> J. J. Adams	Date: 5/30/95	Approval: N/A	Date:
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Approval: N/A	Date:	Concurrence: R.E. Spence <i>R.E. Spence</i>	Date: 6/1/95
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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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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

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

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 Mario R. Diaz <i>Mario Diaz</i> 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
--	---

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 Mario R. Diaz <i>Mario Diaz</i> Date 8-1-96	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name R.E. SPENCE Signature <i>Robert B. Constable</i> Date 8.7.96
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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: ^{EMR} R. Altimiras

Initial

Amended

Date

9/4/96

Phone

605 617-0611

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

9/5/96 Brady to Spence

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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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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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QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Continuation Sheet.

15 Extent of Condition: (Not required for PR)

See Continuation Sheet.

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 Date:

October 31, 1996

19 Response by:

Initial

Amended

Date 8/28/96 Phone 505 648 0786

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

Exhibit AP-16.1Q.2

Rev. 07/15/96

9/5/96 Brady & Spencer

ENCLOSURE 1

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5. Requirement/Measurement Criteria (Continuation):

QAIP 17-1, Revision 02, Section 4.2 states in part "The record source shall review each record package to ensure that it is accurate and complete."

Section 4.4 states, "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 with his initials and date."

6. Description of Condition (Continuation):

Documentation of SNL-96-D4 was found to be part of SNL-96-C-01 without being relevant to that package. Corrections have been made to SNL-96-D2 by other than the record source and initials and dates are missing. Additionally, some memos are dated prior to the deficiency being issued.

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BLOCK 14 - REMEDIAL ACTIONS:

The deficiency report was actually written against the "informal" PR/DR/CAR files maintained by the PR/DR/CAR coordinator for ease in performing that task. Most of the discrepancies noted were of the type that were corrected during the normal records acceptance and closing process, a fact that was borne out by the inspection of the records package to evaluate the remedial actions required to correct this deficiency.

SNL-96-D5 proposed due date for remedial actions is missing: The actual record was inspected and the proposed due date was marked "N/A" since no remedial actions were required. No further action is required.

SNL-96-D2 remedial actions and proposed due dates are missing: The actual record was inspected and the proposed due date was marked "Completed with response" to show that the remedial action had already been completed and there was no proposed due date. Also, the actual record contained a remedial action in block 12. No further action is required.

SNL-96-D5 root cause determination and action to preclude recurrence are missing: The actual record was inspected and both these items were on a continuation sheet in the records package. No further action is required.

SNL-96-D2 was verified and closed; however, the objective evidence reviewed is missing: The remedial action was for the customer to submit a memo to the file to show acceptance of the deliverable. The actual records package was inspected and found to contain an E-mail from the customer which stated, "As the customer for this deliverable, I have agreed that it is not required." This E-mail was also reviewed and verified by the QAR. No further action is required.

SNL-96-D2 and D5 are missing some relevant correspondence:

D2: There was no letter of issuance completed for SNL-96-D2 because the DR was delivered to the responsible individual and responded to and completed in a timely manner. There was no impact on quality because of this omission. Nor is there any appropriate remedial action to correct the deficiency since preparing a letter of issuance after the remedial action has been completed would have no value whatsoever.

D5: The "missing document" was an attachment mentioned by F.J. Schelling in his letter. The actual records package was inspected and Mr. Schelling had crossed out (and initialed and dated the correction) the line mentioning the attachment as the attachment was the DR itself. No further action is required.

SNL-96-C-01 an extension request letter signed by M. Brady and dated 2/27/95 was issued and made part of the QA records package. However, documentation signed by the QA Manager to approve this request does not exist: It is correct; the QA Manager did not document approval of the request for extension although, based on the correspondence in the records package, it is obvious that he was aware of the request and at least did not oppose it. A memo for file will be prepared by the QA Manager stating that he was aware of the extension request and approved it orally.

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Documentation of SNL-96-D4 was found to be part of SNL-96-C01 without being relevant to that package: This deficiency was corrected in the presence of the auditor. No further action is required.

Corrections have been made to SNL-96-D2 by other than the record source and initials and dates are missing: The actual records package was inspected and all corrections were made by the originator of the document or by the PR/DR/CAR Coordinator who is the record source for DR packages. All corrections in the actual records package had initials. One correction did not have the date entered; that deficiency has been corrected. No further action is required.

Some memos are dated prior to the deficiency being issued: In SNL-96-C-01, an extension request letter signed by M. Brady was incorrectly dated 2/27/95 rather than 2/27/96. The record source has corrected this error. No further action is required.

To ensure that the deficiencies noted above are not present in other packages, the SNL QA Staff will inspect all authenticated FY96 deficiency report record packages for errors such as corrections not dated or initialed, blank remedial action due blocks, blank portions of forms, or missing attachments or other correspondence. The conduct of this review will be documented and any deficiencies noted will be documented in accordance with AP-16.1Q and tracked as deficiencies.

BLOCK 15 - EXTENT OF CONDITION:

Authenticated records packages were reviewed to determine the remedial actions necessary to correct this deficiency. Although there are occasional administrative errors in the deficiency records packages, discrepancies of this nature are normally caught and corrected during records processing. The deficient condition is not widespread nor is it sufficiently serious to warrant root cause analysis. Therefore, a root cause determination will not be performed.

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Your response is rejected based on the following:

Your statement about the deficiency report being written against the "informal" PR/DR/CAR files maintained by the PR/DR/CAR coordinator is incorrect. The adverse conditions were documented based on the records found in the SNL Records Processing Center and later discussed with the QA Manager.

Individuals creating QA records shall ensure that the QA records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply. Otherwise, they will become an adverse condition affecting QARD requirements.

These adverse conditions demonstrate that discrepancies of this nature are not usually caught and corrected during records processing. Therefore, corrective action to preclude recurrence is mandatory.

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QAIP 7-3, Revision 01	2 Related Report No. YM-ARC-96-18
3 Responsible Organization: SNL	4 Discussed With: R. R. Richards

5 Requirement/Measurement Criteria:

Paragraph 4.3, Step 3; requires the Delegated Representative to,

“• If the document is accepted:

-Generate SNL's document acceptance letter, coordinating with the QA staff, and send it to the Department Manager for signature.”

Paragraph 4.3, Step 5, requires the Department Manager to, “Sign SNL's document acceptance letter and send it to the contractor via the SNL Delegated Representative.”

6 Description of Condition:

Contrary to the above requirements, SNL evaluated Geokon for approval as a Qualified Supplier; however, there is no evidence that the required SNL acceptance letter of the Supplier's Program was generated.

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

10 Recommended Action: (Not required for PR)

11 QA Review: <i>Donald J. Harris</i> QAR Donald J. Harris 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 R.E.SPENCE Signature <i>Robert B. Spence</i> Date 8.7.96
--

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:

October 30, 1996

19 Response by: *FR R RICHMOND* *OS FELL*

Initial

Amended

Date *7/4/96*

Phone *555-818-0641*

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

9/5/96 Brady to Spence

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BLOCK 14 - REMEDIAL ACTION:

SNL was evaluating Geokon to determine if they could be considered a qualified supplier. The QARD, (Revision 4 and 5) Section 7.2.2C lists three elements that can be used for that evaluation. The method chosen was an evaluation of the supplier's history (7.2.2C1). For corroboration of the supplier's history, selected documents related to their QA program were evaluated. However, no evaluation of Geokon's QA documents was performed for the purpose of accepting those documents. Since QAIP 7-3 defines the process for accepting contractor's QA documents it would not apply in this case and no acceptance letter would be generated. As far as this particular procurement is concerned, no remedial action is required. It appears, however, that we did not clearly document what it was we were doing so that it was obvious that QAIP 7-3 was not applicable. We will review the process we use to evaluate suppliers for inclusion on the qualified suppliers to determine if there are any refinements we can make to the process to more clearly describe our actions.

BLOCK 15 - EXTENT OF CONDITION: N/A

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YM-96-P-030 Block 14, "Remedial Action Response"

The Supplier Evaluation Report (SER) indicated that the evaluation of Geokon, Inc. was based on a Quality Records Review, Supplier History evaluation, and the referenced Quality Assurance (QA) manual dated July 13, 1992. Review was limited to a couple of criteria. The SER was signed by R. R. Richards on October 4, 1995.

The Quality Assurance Requirements and Description (QARD), Revisions 4 and 5, provide the requirements for evaluating and selecting procurement sources based on 1) Supplier history;
2) Current QA records (program); or 3) Supplier facility survey or a combination of one or more of the three.

Sandia National Laboratories' (SNL) Quality Assurance Implementing Procedure (QAIP) 7-3 only addresses evaluating the supplier's current QA records (program). There is no QAIP that addresses evaluating the supplier's history. Therefore, the Block 14, "Remedial Action Response," is not acceptable.

Recommendation: Generate an SNL acceptance letter and submit to Geokon, Inc. and Records, and close the Performance Report based on the letter.