

Department of Energy

Washington, DC 20585

QA: L

OCT 17 1997

L. D. Foust, Technical Project Officer  
for Yucca Mountain Site  
Characterization Project  
TRW Environmental Safety Systems, Inc.  
1180 Town Center Drive; M/S 423  
Las Vegas, NV 89134

EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR)  
YM-97-C-004 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA)  
SUPPLIER AUDIT OQA-SA-97-026 OF GEOKON, INC.

The OQA staff has evaluated the response to CAR YM-97-C-004. The response has been determined to be unsatisfactory because of reasons stated in the enclosed CAR.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, OQA/QATSS; P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Richard L. Maudlin at (702) 794-1302.

Donald G. Horton, Director  
Office of Quality Assurance

OQA:JB-0078

Enclosure:  
CAR YM-97-C-004

cc w/encl:

- T. A. Wood, DOE/HQ (RW-55) FORS
- J. O. Thoma, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- B. R. Justice, M&O, Las Vegas, NV
- R. A. Morgan, M&O, Las Vegas, NV
- J. F. Graff, OQA/SNL, Albuquerque, NM, M/S 1395
- F. J. Schelling, M&O/SNL, Albuquerque, NM, M/S 1325
- S. A. Orell, M&O/SNL, Las Vegas, NV

cc w/o encl:

- W. L. Belke, NRC, Las Vegas, NV
- R. L. Maudlin, OQA/QATSS, Las Vegas, NV
- D. G. Sult, OQA/QATSS, Las Vegas, NV
- R. W. Clark, DOE/OQA, Las Vegas, NV

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PDR



recip: NRCSS/Pahl

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8  
CAR NO. YM-97-C-004  
PAGE 1 OF 5 QA: L

CORRECTIVE ACTION REQUEST

1 Controlling Document:  
Geokon Quality Assurance (QA) Manual, May 2, 1997/Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) Contract A02249JM7C/Sandia National Laboratories (SNL) Purchase Order (PO) AU-5504

2 Related Report No.  
OQA-97-SA-026

3 Responsible Organization:  
CRWMS M&O/SNL/Geokon

4 Discussed With:  
Marty Gibson, Barrie Sellers, Thomas Reynolds, John McGoldrick

5 Requirement:

Geokon QA Manual, Section 1.1, states in part, "Training sessions are held on any revision made to the Quality Manual that has an impact on product or daily operations."

Geokon QA Manual, Section 2.2, states in part, "Three types of Quality Documents are used to fully detail the operation of the Quality Assurance Program. The quality documents comprise: Quality Assurance Manual, Operating Procedures Manual, and Calibration/Test Procedures."

Geokon QA Manual, Section 6.2, states in part, "It is the Company's documented policy to choose sub-contractors on their ability to meet all aspects of the contractual agreement which include, but are not limited to, the applicable elements of the quality assurance program...Through an auditing process, the Company assures that a selected supplier/sub-contractors quality program is adequate and adhered to."

See Page 3


6 Description of Condition:

There is a breakdown in implementation of the Geokon quality program and implementation of contractual requirements based on the following:

A. There is no documented evidence to demonstrate that personnel performing calibrations have received the training as identified by the calibration training matrix established by the department manager.

B. Geokon has issued three POs (5050 dated 03/18/97, 5299 dated 4/24/97 and 5548 dated 06/03/97) to suppliers for quality affecting activities with no evidence of an evaluation of the supplier which reflects the existence of an acceptable QA program.

See pages 3-4

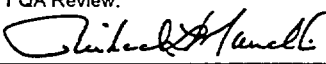
7 Initiator   
Richard L. Maudlin Date 07/01/97

9 Does a Stop Work condition exist?  
Yes \_\_\_\_\_ No X ; If Yes, Attach copy of SWO  
If Yes, Check One: A  B  C  D

10 Recommended Actions:

A. Take immediate action to determine the impact on the calibrations performed by the use of an unqualified supplier to fulfill the CRWMS M&O and SNL open contracts.

See Pages 4-5

11 QA Review:  Date 07/01/97

12 Response Due Date:  
20 Working Days From Issuance

13 Affecting Organization QA Manager Issuance Approval:  
Printed Name Donald G. Horton Signature  Date 7/19/97

22 Corrective Action Verified  
QAR Date

23 Closure Approved by:  
AOQAM Date

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

CAR NO. YM-97-C-004  
PAGE                      OF  
                                    QA: L

**CORRECTIVE ACTION REQUEST RESPONSE**

14 Remedial Actions:  
See attached.

15 Extent of Condition and Impact:

1. The SNL PI will identify other QA Geokon contracts and identify and mitigate adverse impacts resulting from conditions similar to those identified in this CAR. Investigative action to date indicates that SNL are the only YMP user of Geokon services. Due 9/8/97.

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached.

17 Action to Preclude Recurrence:

1. The M&O Procurement Representative and Geokon QA Manager will document training/retraining to procurement procedures by 9/10/97.
2. The President of Geokon will demonstrate the company's continuing commitment to quality by:
  - a. Having the Geokon QA Manager ensure internal audits/surveillances are conducted to evaluate the overall effectiveness of the Geokon QA program. Problem areas will be documented and tracked until effective implementation achieved.
  - b. Documenting that audit results are discussed at meetings between the President and QA Manager, by audit number.
  - c. Continuing progress towards ISO 9000 certification.
  - d. Participating in future YMP audits of Geokon.

18 Corrective Action Completion Due Date:

12/31/97

19 Response by:

Marty Gibson

*Marty Gibson* 8/28/97

Date 08/28/97

Phon (603) 448-1562

20 Response Accepted

21 Response Accepted

QAR

Date

DOQA

Date

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8

CAR NO. YM-97-C-004

PAGE 3 OF 5

QA: L

**CAR/SWO CONTINUATION PAGE**

**5 Requirement: (Continued)**

Geokon QA Manual, Section 6.3 states in part: "All purchase orders are reviewed for completeness and accuracy before being released to suppliers/sub-contractors."

CRWMS M&O Contract A02249JM7C, Attachment C, Section II, Subsection D states: "Your firm shall not be allowed to subcontract without CRWMS M&O approval. Justification requirements for any plans by your firm to use sub-tier suppliers shall be provided to the CRWMS M&O Task Manager identifying what is intended to be subcontracted, the identity of the proposed subcontractor(s), and the quality program requirements elements to be followed by the proposed subcontractor. Should subcontracting be approved by the CRWMS M&O Task Manager, your firm shall be responsible for assuring that all sub-tier suppliers implement a QA Program commensurate with the item supplied or services rendered. When a sub-tier supplier is used to satisfy the specific actions defined in the subcontract, all technical and quality requirements imposed in the CRWMS M&O subcontract and its supplements shall be transmitted to the sub-tier supplier, whether the sub-tier is specifically identified in the subcontract or not. Your firm shall either maintain documentation of the evaluation and acceptance of sub-tier suppliers' QA programs, or use OCRWM qualified suppliers only."

Geokon QA Manual, Section 10.0 states in part: "The company operates a program that controls, calibrates, and maintains measuring and test equipment which can affect product quality, in compliance with the United States of America, Department of Defense, MIL-STD-45662A. All calibrations are traceable to National Institute of Standards and Testing (NIST)."

MIL-STD-45662A, Section 5.5 states in part: "Procedures shall be available and utilized for the calibration of all M&TE and measurement standards."

MIL-STD-45662A, Section 5.6 states in part: "If any M&TE or measurement standard is found to be significantly out of tolerance during the calibration process, the contractor's calibration system shall provide for notification....so that appropriate action can be taken."

Geokon QA Manual, Section 14.0 states in part: "Audit results are documented and reviewed by management having responsibility for the area or process being audited...."

**Block 6 Description of Condition: (Continued)**

There is a breakdown in implementation of the Geokon quality program and implementation of contractual requirements based on the following:

- C. There is no objective evidence in the form of audit reports for audits of RDP Electrosense and ASL to determine if the suppliers have an adequate quality program and that it is being adhered to. (Geokon POs 5050, 5299 and 5548)
- D. There is no objective evidence of the review of Geokon purchase orders 5050, 5299 and 5548 by the Geokon QA Manager for completeness and accuracy.
- E. There was no evidence provided by Geokon which shows compliance with CRWMS M&O Contract A02249JM7CX, Attachment C, Section II, Subsection D, for example:

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

8

CAR NO. YM-97-C-004

PAGE 4 OF 5

QA: L

**CAR/SWO CONTINUATION PAGE**

**6 Description of Condition: (Continued)**

- There was no evidence provided by Geokon which reflects CRWMS M&O approval of the use of RDP Electrosense in Pottstown, PA and/or RDP Electronics, Ltd in Wolverhampton, West Midlands, UK.
  - There was no objective evidence of written justification submitted to the CRWMS M&O Task Manager identifying what is intended to be subcontracted, the identity of the proposed subcontractor(s) and the quality program requirements elements to be followed by the proposed subcontractor.
  - There was not documented evidence of CRWMS M&O Task Manager approval.
  - There was no documented evidence provided by Geokon for assuring that all sub-tier supplier were implementing a QA Program commensurate with the item supplied or services rendered.
  - There was no evidence provided that Geokon transmitted to RDP Electrosense and RDP Electronic, LTD a copy of the CRWMS M&O technical and quality requirements as imposed by the CRWMS M&O contract and supplements.
  - There was no evidence of a documented evaluation of RDP Electrosense or RDP Electronics LTD's QA program.
- F. Geokon P.O.s 5050, 5299, and 5548 were issued in part or all for the performance of calibration. None of the P.O.s identified the pass down of the requirements of MIL-STD-45662A or any other quality requirements. In addition, Geokon's QA Manual does not clearly address the flow down of QA requirements to sub-tier suppliers.
- G. There is no evidence that an implementing operating procedure (Level II) has been issued for the control of Geokon M&TE. The initial issue of Geokon Operating procedure QAOP 1100 is in draft form only.
- H. There is no calibration instruction (Level III) which details the 3 point calibration of Geokon calibration standard GK-401 which is one of the standards used in the calibration of strain gages similar to that used for previous SNL calibrations (SNL contract AS-0311).
- I. A piece of M&TE (Control #105) was sent out for re-calibration. Upon receipt by the supplier, the equipment was found to be non-operational. As a result the equipment needed to be repaired before it could be re-calibrated. There was no evidence which supported the documentation of the non-operational condition, the evaluation for impact on previous calibrations back to the date of the last calibration and the results of the evaluation.
- J. There was no documented evidence that the audit results (audit reports for internal audits I2970528 and I297418) had been transmitted or provided to management for review.

Note: Geokon responsible for responding to conditions identified in Block 6, Items A thru D, and F thru J.  
CRWMS M&O responsible for responding to conditions identified in Block 6, Item E.

**10 Recommended Actions:**

- B. Take immediate action to evaluate the quality program of RDP Electrosense to determine if that supplier has a quality program that meets the OCRWM QARD and any contractual requirements for calibration services. Establish a plan for verification of implementation of RDP Electrosense's QA Program once the QA Program document has been found acceptable.
- C. Take immediate action to bring Geokon into compliance with the CRWMS M&O contract. Implement CRWMS M&O procurement actions when a contract violation is identified.

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

8

CAR NO. YM-97-C-004

PAGE 5 OF 5

QA: L

CAR/SWO CONTINUATION PAGE

**10 Recommended Actions: (Continued)**

- D. Take immediate action to place a restriction on the use of Geokon until all of the above conditions have been satisfactorily resolved and a follow-up verification has been performed on Geokon to determine satisfactory compliance with its accepted QA Program.
- E. CRWMS M&O and SNL identify all previous contracts related to quality affecting work with Geokon and perform an evaluation to determine what impact the above deficiencies had on that work.
- F. SNL and CRWMS M&O, in conjunction with Geokon quality assurance, provide a detailed root cause analysis as to why the conditions adverse to quality occurred. Include in this root cause why the CRWMS M&O contract was not complied with and where the breakdown in compliance occurred. Then, based on the results of this analysis, identify the actions to be taken to prevent recurrence.
- G. Geokon revise POs 5050 and 5299, issued to RDP Electrosense, to specifically use RDP Electronics, Ltd., in use for calibration of items specified in CRWMS M&O Contract A02249JM7CX and SNL PO AU-5504.

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RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

8  Corrective Action  
 Request

NO. YM-97-C-004  
PAGE OF  
QA: L

CAR/SWO CONTINUATION PAGE

Block 14 Continued.

1. The SNL PI will identify adverse impacts resulting from conditions identified in this CAR by 9/30/97.
2. The Geokon QA Manager will evaluate the QA program of RDP for inclusion as a Geokon qualified supplier by 9/30/97.
3. The Geokon QA Manager and Site Evaluation Program Operations (SPO) procurement representative will produce and/or develop documentation demonstrating compliance with the procurement contract. Specifically: 1) M&O approval of the use of RDP, 2) qualification of RDP QA program by Geokon, and 3) evidence that RDP's tasks complied with QA requirements that should have been transmitted. Due 9/30/97.
4. SNL Management will advise their PIs on restrictions that should be applied to the use of Geokon equipment until adverse impacts are identified and mitigated. Due 9/10/97.
5. The Geokon QA Manager will revise POs 5050, 5299, and 5548 to include QA requirements by 9/30/97.
6. The Geokon QA Manager will ensure that Geokon personnel who conducted work related to Purchase Order A02249JM7C and AU-5504 document their training by 9/10/97.
7. The Geokon QA Manager will issue QAOP 1100, or equivalent, that will address control of M&TE to include documentation and evaluation of out of compliance M&TE. Due 11/30/97.
8. The Geokon QA Manager will issue a level III procedure for calibration of standard GK-401 used in the calibration of strain gages by 10/20/97.
9. The Geokon QA Manager will revise or issue a procedure to address flow down of QA requirements to sub-tier suppliers by 12/31/97.

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Page 1 of 4

Refer to Subsection 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. Identify the adverse condition.
  - A. There is a breakdown in implementation of the Geokon quality program.
  - B. Requirements for procurement of calibration services were not formally transmitted to the sub-tier supplier.
  
2. Indicate *Where* the condition was found.
  - A+B. The condition was initially found during OQA Supplier Audit OQA-SA-97-026, in which adequate documentation of implementation of the Geokon quality program and implementation of quality requirements was unavailable.
  
3. Note *When* the condition was first found.
  - A+B. The condition was found as a result of OQA Supplier Audit OQA-SA-97-026, and was documented in CAR YM-97-C-004 on 7/10/97.
  
4. Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)
  - A+B. Repository (Scientific Investigations) is affected by this condition.
  
5. Denote the specific area(s) or discipline(s) of the major program element the condition occurred. (e.g., engineering, design, ES&H)
  - A+B. This condition is specific to equipment calibrated by Geokon.
  
6. Determine if the condition is isolated or recurring.
  - A+B. The condition is recurring, as indicated by the existence of a previous M&O QA deficiency (YM-97-D-025) documenting a similar condition.
  
7. Determine if the condition is hardware (item) or programmatic (procedures, personnel) related or both.
  - A+B. The condition is programmatic in nature.
  
8. Denote what organizations are affected by this condition (M&O, USGS, Weston, OCRWM, etc.).
  - A+B. This condition is specific to Sandia National Labs (SNL) who are the sole users of Geokon calibrated equipment on the Yucca Mountain Project.



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ROOT CAUSE DETERMINATION QUESTIONNAIRE

- 9 Document the changes that have taken place that could have caused the condition.  
A. Geokon has recently begun the ISO 9000 certification process. This task has included changes to existing procedures, issuance of new procedures, and modifications to methods of conducting business.  
B. No recent changes seem relevant to the cause of failure to formally transmit requirements to the sub-tier supplier.

10. Determine the need for sketches or photographs.  
A+B. No sketches or photographs apply to this condition.

11. Determine the need for laboratory tests.  
A+B. No laboratory tests apply to this condition.

12. Identify the physical evidence examined.  
A+B. No physical evidence relates to this condition.

13. Note the relevant documents reviewed.  
A + B. See attached.

14. Document any other information that may be pertinent to supporting the selection of the correct root cause.  
A+B. N/A

15. Interviews conducted:  Yes  No  
If Yes, refer to page 3 of this attachment.

RI or designee: (Print)  
Tom Reynolds

Signature:

*Thomas B Reynolds*

Date:

*8/28/97*

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ROOT CAUSE DETERMINATION QUESTIONNAIRE

TELEPHONE OR PERSONAL INTERVIEW RECORD

Person Interviewed: (Print)

Title:

Organization/Location:

Telephone No.:

Date/Time:

CAR No./DR No.:

Interview Details:

N/A

\_\_\_\_\_  
Interviewer

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ROOT CAUSE DETERMINATION QUESTIONNAIRE**

Root Cause Code:  
A) 3.A.d B) 2.A.b

CAR No./DR No.:  
CAR YM-97-C-004

**Root Cause:**

- A. Management systems - Standards, policies, administrative controls (SPAC) recently changed.
- B. Personnel - Lack of attention to task - oversight.

**Justification or Rationale for Selected Root Cause:**

A. Geokon is in the process of obtaining ISO 9000 certification. As part of implementing this improvement Geokon has made significant changes to existing procedures and issued new procedures. Lessons learned from the initial implementation of new procedures results in improvements being made and effectiveness increasing. This is the case with many new procedures and may take some time. In addition, the correlation may be ambiguous between some YMP QA requirements and those from ISO 9000. Geokon has shown a sincere desire to modify their program where required to meet the OCRWM QA program.

B. The documents cited in section 13 of this root cause determination indicate that the initial decision to use RDP as a sub-tier supplier for calibration was communicated to all the relevant parties within the M&O. Approval was given to Geokon for the use of RDP, subject to certain conditions (placement of RDP on the Geokon QSL, and flowdown of contractual requirements). Geokon has not been able to formally document implementation of the requirements of the M&O contract and Geokon quality program with respect to sub-tier suppliers. Formal documentation that those requirements were met was never transmitted from Geokon to M&O/Procurement. This transmission of formal documentation was not pursued by M&O/Procurement due to lack of attention to task caused by lack of oversight within Procurement, and also lack of oversight by M&O/SPO and M&O/QA.

Designee: (Print)  
Tom Reynolds

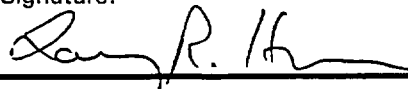
Signature:



Date:  
08/28/97

RI: (Print)  
Larry R. Hayes

Signature:



Date:  
08/28/97

Block 13 Continued

- 1) Facsimile Transmission, Geokon (Brian Brown) to John McGoldrick (M&O/Procurement), dated January 23, 1997
- 2) Letter, J.P. McGoldrick (M&O/Procurement) to Geokon (Brian Brown), dated January 23, 1997: LV.SC.JPM.1/97-076
- 3) Letter, J.P. McGoldrick (M&O/Procurement) to Geokon (Brian Brown), dated January 24, 1997: LV.SC.JPM.1/97-079
- 4) E-mail, J.P. McGoldrick to Gail Abend (M&O/QA), Larry hayes (M&O Task Manager), et. Al., dated 01/24/97, 02:14:34 PM
- 5) E-mail, Gail Abend (M&O/QA) to J.P. McGoldrick (M&O/Procurement), Larry Hayes (M&O Task Manager) et. Al., dated 01/24/97 12:26:51
- 6) Facsimile Transmission, Geokon (Brian Brown) to RDP Electrosense (Cindy Sosie), dated January 23, 1997: contains portions of technical requirements and calibration documentation requirements from subject purchase.
- 7) Letter, Marty Gibson (Geokon QA Manager) to Andrew Burningham (M&O), dated August 05, 1997.

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

8  Corrective Action Request  
 Stop Work Order

NO. YM-97-C-004  
PAGE OF  
QA: L

CAR/SWO CONTINUATION PAGE

EVALUATION OF RESPONSE TO CAR YM-97-C-004

The response has been evaluated and found, in part, unacceptable in resolving the conditions adverse to quality as follows:

Root Cause Determination Questionnaire

A. Item 3 response indicated that the condition was initially found during OQA Supplier Audit OQA-SA-97-026.... However, your response to Item 6 states that this is a recurring condition as indicated by the existence of a previous deficiency YM-97-D-025.

Item 6 implies that a similar condition was found prior to the supplier audit referenced in Item 3. Subsequently, this condition was really identified before the supplier audit. Please identify, for Item 3, when or how the condition was first identified which resulted in the issuance of DR YM-97-D-025.

B. Item 5 response indicates that the conditions identified in CAR YM-97-C-004 are specific to equipment calibrated by Geokon. The response does not include the calibrations which may have been the responsibility of Geokon but were actually performed by subtier suppliers (Example RDP Electronics, LTD).

Please include a list of subtier suppliers who Geokon may have used to perform calibrations which impact M&O/SNL work.

C. Item 8 response indicates that the only organization affected by CAR YM-97-C-004 is SNL. CAR YM-97-C-004 also impacts the work performed by Geokon for the CRWMS M&O under contract A02249JM7C.

Please reevaluate your response to Item 8 to include all organizations including the CRWMS M&O as being affected by the conditions cited in this CAR.

D. Item 9, Part A of your response indicates that due to the recent move by Geokon towards ISO 9000 certification, this may have contributed to the cause of the problems noted in CAR YM-97-C-004. The QA Program in place during the QA supplier audit is the same program that has been in place for several years. Based on the evaluation looking at historical activities, the question becomes, what do recent activities in Geokon's QA program have on work that was performed prior to Geokon's recent move towards ISO 9000 certification.

Please re-evaluate your response to Item 9, Part A and identify the bases for the lack of QA program implementation related to past work.

E. Item 15 response indicates that Geokon was not contacted. It is difficult to understand how conclusions regarding implementation of Geokon's QA program could have been reached without contacting Geokon and discussing the issues.

Please re-evaluate your response to Item 15. It is recommended that Geokon personnel be contacted, if not already done so, and those discussions documented in the "Interview Details" section of the root cause evaluation.

F. The response provided for the justification or rationale for the selected root cause, Item A, does not accurately reflect the issue. The major issue in CAR YM-97-C-004 is that Geokon was not implementing an effective QA Program. Discussion on ISO 9000 and recent significant changes does not appear to address the issue of program implementation.

Please re-evaluate your response to address the failure to implement the approved QA program. There apparently was a breakdown in implementation which has existed for some time, even prior to this recent move towards ISO 9000. In order to identify what actions are required for the long term, the true cause must be derived. The recent activities do not justify the lack of compliance for previous work back to when Geokon started performing work to the OCRWM QA program.

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

8  Corrective Action Request  
 Stop Work Order

NO. YM-97-C-004  
PAGE OF  
QA: L

CAR/SWO CONTINUATION PAGE

Corrective Action Request Response Section:

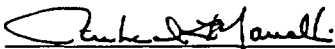
Block 14:

The response to Item 2 reflects that Geokon will evaluate the QA Program of RDP for inclusion as a Geokon qualified supplier. What about other suppliers such as for Geokon PO 5548 issued to ASL, Inc. and Geokon PO 5684 issued to Tekserv? Re-respond to include a commitment by Geokon to evaluate the QA programs for all suppliers performing quality affecting work to support YMP activities.

Block 17:

The response (Item 1) indicates in part that only the QA Manager is going to be trained /retrained to procurement procedures. There are other Geokon personnel involved in the procurement process, such as those responsible for the preparation and review of Geokon POs. Please re-evaluate your response to assure that all Geokon personnel involved in the procurement process receive training/retraining.

The response (Item 2) does not address actions related the evaluation and control of Geokon subtier suppliers. Also, there is no discussion on what actions are going to take place to assure that subtier suppliers are evaluated and audited prior to the issuance of Geokon POs. Please address these issues in your response.

  
Richard L. Maudlin, QAR

10-06-97  
Date