



Department of Energy

Washington, DC 20585

QA: L

JUL 10 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

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) YM-97-C-004
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT
OQA-SA-97-026 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT
SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (CRWMS M&O)
AND SANDIA NATIONAL LABORATORIES' (SNL) VENDOR, GEOKON

Enclosed is CAR YM-97-C-004 generated as a result of OQA Supplier Audit
OQA-SA-97-026.

Please provide a response to this deficiency that meets the applicable requirements of
Administrative Procedure 16.2Q, Corrective Action and Stop Work. Send the original of
your response to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455,
North Las Vegas, Nevada 89036-0307. Response to the CAR is due 20 working days
from the date of this letter. Any extension to due date must be requested in writing, with
appropriate justification, prior to the due date.

Block 10, Recommended Actions, requires actions on the part of CRWMS M&O as well
as SNL. Each are requested to respond to items A, C, D, E and F, as appropriate.

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

NH33

OQA:JB- 1870

Enclosure:
CAR YM-97-C-004

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WM-11 PDR

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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
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3 Responsible Organization: CRWMS M&O/SNL/Geokon	4 Discussed With: Marty Gibson, Barrie Sellers, Thomas Reynolds, John McGoldrick
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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

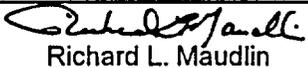
6 Description of Condition:

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.

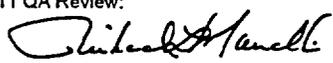
See pages 3-4

7 Initiator  Richard L. Maudlin Date <u>07/01/97</u>	9 Does a Stop Work condition exist? Yes _____ No <u>X</u> ; If Yes, Attach copy of SWO If Yes, Check One: A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
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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 <u>07/01/97</u>	12 Response Due Date: 20 Working Days From Issuance
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13 Affected Organization QA Manager Issuance Approval:

Printed Name Donald G. Horton Signature  Date 7/14/97

22 Corrective Action Verified QAR Date _____	23 Closure Approved by: AOQAM Date _____
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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

15 Extent of Condition and Impact:

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

17 Action to Preclude Recurrence:

18 Corrective Action Completion Due Due

19 Response Due

Initial

Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted

AOQAM

Date

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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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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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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 CRMWS M&O Contract A02249JM7CX and SNL PO AU-5504.