

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

SUPPLIER AUDIT REPORT

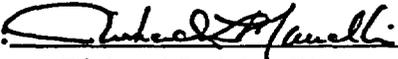
OF

GEEKON, INC.

LEBANON, NEW HAMPSHIRE

REPORT NUMBER OQA-SA-97-026

JUNE 26-27, 1997

Prepared by: 
Richard L. Maudlin
Audit Team Leader
Office of Quality Assurance

Date: 07/09/97

Approved by: 
Donald G. Horton
Director
Office of Quality Assurance

Date: 7/24/97

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ENCLOSURE

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Geokon, Inc. revealed ineffective implementation of Geokon, Inc.'s Quality Assurance (QA) Program, resulting in the issuance of one Corrective Action Request (CAR) to the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) and Sandia National Laboratories (SNL) for action which relates to the QA Program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. The CAR relates to: A general breakdown in the implementation of Geokon, Inc.'s quality program, especially in the area of procurement and calibration. The specific conditions adverse to quality relate to: (1) No evidence that personnel performing calibrations have been trained; (2) No evidence of qualification of suppliers performing quality affecting work; (3) No objective evidence of audits of suppliers; (4) No evidence of QA review of purchase orders; (5) No evidence provided by Geokon, Inc. to reflect compliance with the CRWMS M&O contract as it relates to the use of sub-tier suppliers; (6) Purchase orders issued to procure quality affecting services did not address quality requirements to be imposed on the supplier; (7) There are no operation procedures which address and control measuring and test equipment; (8) Calibration instructions are not in place for the calibration of all Geokon, Inc.'s standards; (9) No documentation for M&TE found to be non-operational as to an impact evaluation on previous calibrations; and (10) No documented evidence of management reviews of audit results.

The unsatisfactory conditions identified during the audit were discussed with the President, QA Manager, and other principle parties of Geokon, Inc. who agreed to work with the CRWMS M&O and SNL in resolving the unsatisfactory conditions. Based on the above, impact on the calibrations previously performed by Geokon, Inc. needs to be evaluated.

The results of the audit warrant a recommendation that future use of Geokon, Inc. be suspended until a full evaluation of the impact of the deficiencies on calibrations performed by Geokon, Inc. have been performed and a determination that Geokon, Inc. is in full compliance with its quality program. Immediate action needs to be taken to place a restriction on the Qualified Supplier List to restrict the use of this supplier until all actions regarding the CAR have been responded to, evaluated as acceptable, and verification of implementation of corrective action has occurred.

2.0 SCOPE

The supplier audit was conducted to evaluate the implementation and effectiveness of Geokon, Inc.'s quality program. This was accomplished by verifying the implementation of Geokon, Inc.'s quality program as specified in Geokon, Inc.'s QA Manual, Revision dated May 2, 1997 as accepted by the SNL, the SNL procurement document AU 5504, and the CRWMS M&O contract A02249JM7C. The QA Program elements determined

to be applicable are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Measuring and Test Equipment; Corrective Action; QA Records; and Audits.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Office of Quality Assurance (OQA), Audit Team Leader

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

B. Sellers, President, Geokon, Inc.
J. McRae, Vice President, Geokon, Inc.
M. Gibson, QA Manager, Geokon, Inc.
J. Taylor, Operations Manager, Geokon, Inc.
T. Simmonds, Director of Marketing and Sales, Geokon, Inc.
G. Hagen, Personnel Manager, Geokon, Inc.
B. Brown, Sales, Geokon, Inc.
C. Sobel, Sales Manager, RDP Electrosense, Pottstown, PA.
T. Hopkins, Engineering Manager, RDP Electronics Ltd., West Midlands, UK
R. Garbid, Managing Director, RDP Electronics Ltd., West Midlands, UK
J. Fryer, Quality Manager, RDP Electronics Ltd., West Midlands, UK

5.0 SUMMARY OF AUDIT RESULTS

Implementation of Geokon, Inc.'s QA Manual, Revision May 2, 1997, was considered ineffective in producing the desired results and, as a result, impact on the work performed is indeterminate. Also, implementation of the requirements of the CRWMS M&O contract A02249JM7C, as it relates to the use of sub-contractors by Geokon, Inc., was ineffective. Failure of Geokon, Inc. to implement the requirements of the CRWMS M&O contract could have an adverse impact on the work performed for the CRWMS M&O. Specifics of the unsatisfactory conditions are described in Section 6.0 of this report, "Deficiencies." No deficiencies were noted with the implementation of the SNL procurement document AU 5504.

The details of the audit, along with the objective evidence reviewed, are contained within the audit checklist which is available from the OQA's supplier evaluation files.

6.0 DEFICIENCIES

The unsatisfactory conditions have been documented on a CAR submitted to the CRWMS M&O and CRWMS M&O/SNL for resolution.

CAR YM-97-C004 - Geokon, Inc.'s QA Manual, Section 1.1, reflects that training sessions will be held on any revision made to the Quality Manual that have an impact on product or daily operations. Section 2.2 identifies that three types of Quality Documents

are used to fully detail the operation of the QA Program. The quality documents comprise: Quality Assurance Manual; Operating Procedures Manual; and Calibration/Test Procedures. Section 6.2 indicates that 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 QA Program. Through the auditing process, the Company assures that a selected supplier/sub-contractor's quality program is adequate and adhered to. Section 6.3 requires all purchase orders to be reviewed for completeness and accuracy before being released to suppliers/sub-contractors. Section 10.0 reflects that 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). Section 14.0 requires that audit results be documented and reviewed by management having responsibility for the area or process being audited.

CRWMS M&O Contract A02249JM7C, Attachment C, Section II, Subsection D, requires the following: Your firm (Geokon, Inc.) 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.

MIL-STD-45662A, Section 5.5, requires that procedures be available and utilized for the calibration of all M&TE and measurement standards. Section 5.6 requires that, 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.

There is a breakdown in implementation of Geokon, Inc.'s quality program and implementation of contractual requirements based on the following:

1. 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 supervisor.
2. Geokon, Inc. has issued three Purchase Orders (PO) (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.

3. There is no objective evidence in the form of audit reports which reflect the 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)
4. There is no objective evidence of the review of Geokon, Inc. POs 5050, 5299, and 5548 by the QA Manager for completeness and accuracy.
5. There was no evidence provided by Geokon, Inc. which reflect compliance with CRWMS M&O Contract A02249JM7C, Attachment C, Section II, Sub-section D, as follows:
 - There was no evidence provided by Geokon, Inc. which reflects CRWMS M&O approval of the use of RDP Electrosense in Pottstown, PA and 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, Inc. for assuring that all sub-tier suppliers were implementing a QA Program commensurate with the items supplied or services rendered.
 - There was no evidence provided that Geokon, Inc. transmitted to RDP Electrosense and RDP Electronic, LTD a copy of the CRWMS M&O subcontract and its supplements.
 - There was no evidence of a documented evaluation of RDP Electrosense or RDP Electronics LTD's QA Program.
6. Geokon, Inc. POs 5050, 5299, and 5548 were issued in part or all for the performance of calibration. None of the POs identified the pass down of the requirements of MIL-STD-45662A or any other quality requirements. In addition, Geokon, Inc.'s QA Manual does not clearly address the flow down of QA requirements to sub-tier suppliers.
7. There is no evidence that an implementing operating procedure (Level II) has been issued for the control of M&TE. The initial issue of Geokon, Inc.'s Operating Procedure QAOP 1100 is in draft form only.

8. There is no calibration instruction (Level III) which details the three point calibration of Geokon, Inc.'s calibration standard GK-401 which is one of the standards used in the calibration of strain gauges similar to that used for previous SNL calibrations (SNL contract AS-0311).
9. 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.
10. 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.