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

SUPPLIER AUDIT REPORT

OF

PAROSCIENTIFIC, INC. REDMOND, WASHINGTON

REPORT NUMBER OQA-SA-96-025 SEPTEMBER 10-11, 1996

Prepared by: Likely and

Date: 09-17-96

Richard L. Maudlin Audit Team Leader Yucca Mountain Quality Assurance Division

Approved by:

Date:

Donald G. Horton

Director

Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Paroscientific, Inc. revealed that implementation in the areas evaluated was satisfactory. Two conditions adverse to quality were found and corrected prior to the close of the audit. The corrected conditions are detailed in Section 5.0 of this report. Personnel performing the calibrations demonstrated a good knowledge and understanding of the calibration process. The facility capability and environment were determined to be adequate for the calibration services being provided. The calibration process for pressure transducer sensors is an automated system which gathers data from instruments and logs information for later printout in hard copy form. Paroscientific, Inc. is also in the process of automating its recall system.

The results of the audit do not warrant any recommendation for limitations or other conditions that should be invoked relative to the items or services being provided by Paroscientific, Inc.; however, responsibility for final determination of acceptability rests with the U.S. Geological Survey (USGS).

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of Paroscientific, Inc.'s quality program. This was accomplished by determining if the Paroscientific, Inc.'s program satisfies the quality assurance (QA) requirements specified in Purchase Order No. 1434-CR-95-SA-01227, implementation of the Paroscientific, Inc.'s Quality Assurance Manual, Q8501, Revision D, as accepted by the USGS, and the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD) for the scope of work. 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; Control of Measuring and Test Equipment; Corrective Action; QA Records; and Audits.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance, Yucca Mountain Quality Assurance Division

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

- S. Winters, QA Manager, Paroscientific, Inc.
- W. Schuchman, Quality Engineer, Paroscientific, Inc.
- R. Romerdahl, Director of Engineering and QA, Paroscientific, Inc.
- T. Schaad, Head of Metrology, Paroscientific, Inc.
- L. Kezner, Service Technician, Paroscientific, Inc.
- T. Chau, Calibration Technician, Paroscientific, Inc.
- P. Settles, Buyer-Purchasing, Paroscientific, Inc.

5.0 SUMMARY OF AUDIT RESULTS

Paroscientific, Inc.'s Quality Assurance Manual, Q8501, Revision D, addresses the applicable elements of USGS Purchase Order No. 1434-CR-95-SA-01227 and the applicable elements of the OCRWM QARD for the intended scope of work. Implementation of the Paroscientific, Inc.'s Quality Assurance Manual, Q8501, Revision D, was considered effective in producing the desired results. Two conditions adverse to quality were found and corrected during the audit. The first condition related to a lack of reference, in Paroscientific Purchase Order No. 7498, for the supplier to implement a QA program which complies with ISO 9001 International Quality Standard. The intent of this requirement was not to require a full ISO 9001 QA program but to assure traceability to National Institute of Standards and Technology (NIST). The corrective action taken was to revise Paroscientific, Inc.'s procedure Q8521 to clarify the intent as to what QA requirements apply to a supplier. The supplier in question had been surveyed and was on the Paroscientific Approved Vendors List. There was no impact on quality. The second condition related to the lack of calibration stickers on the piston and mass weight sets for the Dead Weight Tester. This condition was resolved by revision to Paroscientific, Inc.'s procedure Q8521 which addressed cases where it was impractical to place the cal sticker on the item; it was acceptable as long as there was traceability between the instrument calibrated and the calibration records. This change brought the condition found into compliance. In all instances reviewed, the calibration documentation was traceable to the item calibrated. There was no impact on quality as a result of this condition.

The area of procurement document control will be evaluated during future audits to assure that the appropriate references to QA requirements are being included in procurement documents for USGS activities.

6.0 **DEFICIENCIES/RECOMMENDATIONS**

None