

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

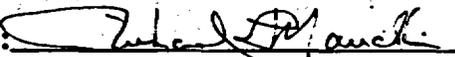
**SUPPLIER AUDIT REPORT**

**OF**

**JOHN FLUKE MANUFACTURING CO., INC.**

**EVERETT, WASHINGTON**

**REPORT NUMBER OQA-SA-96-010  
JANUARY 23-25, 1996**

Prepared by:  Date: 2-5-96

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Approved by:  Date: 2/6/96

**Donald G. Horton  
Director  
Office of Quality Assurance**

## 1.0 EXECUTIVE SUMMARY

The results of the supplier audit of John Fluke Manufacturing Co, Inc., revealed unsatisfactory conditions resulting in the issuance of one Performance Report to the United States Geological Survey for action which relates to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. The Performance Report relates to a lack of adequate records storage facilities to protect records from hazards such as fire damage. Also, two internal John Fluke Corrective Actions Requests were generated to document deficiencies related to training records. The majority of calibrations performed by John Fluke Manufacturing Co, Inc. are accomplished using manufacturer or fluke developed standards. The QA Program is implemented through the requirements established in the CSS Quality Assurance Manual, CSS PD400, dated May 1995. This QA Program document is considered to be effective in producing the desired results except in the areas found unsatisfactory. John Fluke Manufacturing Co, Inc. has instituted a computerized "Re-Call System" which tracks all of the equipment used in calibrating customer equipment. In addition, the Corrective Action System has been computerized for tracking all open items to closure.

The unsatisfactory conditions identified during the audit were discussed with the QA Coordinator of John Fluke Manufacturing Co, Inc. who agreed to resolve the unsatisfactory conditions identified on the Fluke internal corrective action documents. At the close of the audit, the Fluke QA Coordinator indicated that they were meeting their internal requirements for the storage of QA records. The issue of temporary records storage needs to be resolved between USGS and John Fluke Manufacturing Co., Inc. None of the conditions found appear to have an adverse impact on the activities associated with John Fluke Manufacturing Co, Inc.'s scope of work.

## 2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of John Fluke Manufacturing Co, Inc.'s quality program. This was accomplished by determining if the John Fluke Manufacturing Co, Inc.'s program satisfies the QA requirements specified in the U.S. Geological Survey (USGS) procurement document 1434-CR-96-SA-00133, implementation of the John Fluke Manufacturing Co, Inc.'s CSS Quality Assurance Manual, CSS PD400, dated May 1995 as accepted by the USGS, and the OCRWM Quality Assurance and Requirements 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; Measuring & Test Equipment; Nonconformance Control; Corrective Action; QA Records; Audits; and Control of Software.

In addition to the above, identification and calibration of standards in John Fluke Manufacturing Co., Inc.'s Primary Standards Laboratory was reviewed based on a certificate of calibration from the PSL for calibration of USGS equipment. The John Fluke Primary Standards Laboratory works to Fluke's QSD Corporate QA Manual, 111.0,

Revision June 1995 and QSD 111.44, Revision June 1995. The results of the evaluation found the Primary Standards Laboratory complying with requirements. The standards used by John Fluke Manufacturing Co., Inc's CSS are calibrated by the Primary Standards Laboratory.

### 3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD)

### 4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

G. Blanchard, Sr. QA Coordinator, John Fluke Manufacturing Co., Inc.  
E. Ferguson, CSS QA Manager, John Fluke Manufacturing Co., Inc.  
M. Kidd, Metrology Technician, John Fluke Manufacturing Co., Inc.  
K. Knypstra, Associate Buyer, John Fluke Manufacturing Co., Inc.  
A. Meyrick, PSL Operations Supervisor, John Fluke Manufacturing Co., Inc.  
E. Nester, CSS Service Manager, John Fluke Manufacturing Co., Inc.  
J. Pickard, Sr. QA Auditor, John Fluke Manufacturing Co., Inc.  
C. Weaver, Purchasing Specialist, John Fluke Manufacturing Co., Inc.

CSS - Customer Support Services  
PSL - Primary Standards Laboratory

### 5.0 SUMMARY OF AUDIT RESULTS

John Fluke Manufacturing Co, Inc.'s CSS Quality Assurance Manual, CSS PD400, dated May 1995, addresses the applicable elements of the USGS procurement document No. 1434-CR-96-SA-00133 and the applicable elements of the OCRWM QARD for the intended scope of work. Fluke calibration procedures and instructions/standards were in place and implementation was considered to effectively produce the desired results, except for those areas deemed unsatisfactory and noted in Section 6.0 of this report and as documented on Fluke Corrective Action Requests IA-96112 and IA-96113. Specifics of the unsatisfactory conditions are described in Section 6.0 of this report "Deficiencies/Recommendations."

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/RECOMMENDATIONS

The unsatisfactory condition has been documented on the respective corrective action documents and submitted to USGS for resolution. There were no recommendations.

### DEFICIENCIES

1. PR No. YMQAD-96-P022 - OCRWM's QARD, Section 17.0, Subsection 17.2.11 (A) requires that QA records be temporarily stored in a container or facility with a fire rating of 1 hour or dual storage. Fluke's QSD 111.0, Section 16.0 requires that all quality records be stored and retained to provide a suitable environment to prevent damage and deterioration and to prevent loss. Contrary to these requirements, QA records such as audit reports, corrective action documents, and training records are not being stored to prevent damage by fire.
2. Fluke CAR IA-96112 - No training records available for Ivan Albrecht as per CSS PD400-para. 4.18 Training.
3. Fluke CAR IA-96113 - CSS PD400 4.18 states hire date and education are part of training records requirements. PD403 8.4 states education and experience are part of employees personnel records. These two statements are in conflict of requirements. Also, training records pulled for review were inconsistent - some had education, some did not, and none of the records had hire dates.

### RECOMMENDATIONS

None