

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

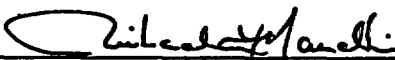
SUPPLIER AUDIT REPORT OQA-SA-97-028

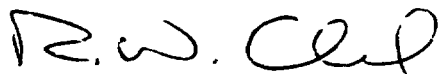
OF

UFA VENTURES, INC.

RICHLAND, WASHINGTON

JULY 10-11, 1997

Prepared by:  Date: 07-21-97
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Office of Quality Assurance

Approved by:  Date: 7/27/97
for Donald G. Horton
Director
Office of Quality Assurance

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ENCLOSURE

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of UFA Ventures, Inc. revealed effective implementation of the UFA Ventures, Inc. Quality Assurance (QA) Program except for those unsatisfactory conditions which resulted in the issuance of Deficiency Report (DR) YM-97-D-070. The DR relates to: (1) No objective evidence that UFA Ventures, Inc. has qualified the supplier being used for the calibration of scales used in weighing samples; (2) Training assignment sheets have not been completed for various documents and there is no documented evidence that Training Outline assignments have been completed for all UFA Ventures, Inc. personnel; (3) No Measuring & Test Equipment (M&TE) status tagging for the AVI Micro 210A Infusion Pumps. Also, the M&TE control list is not current; and (4) UFA Ventures, Inc. does not have a procedure in place for the preparation and approval of administrative procedures. The DR has been issued to the US Geological Survey (USGS) for action which relates to the QA program for the Office of Civilian Radioactive Waste Management activities. In addition, two deficiencies were corrected during the audit, and four recommendations were identified.

The results of the audit warrant a recommendation that use of UFA Ventures, Inc. be placed on hold until a calibration supplier has been selected, evaluated, and the scales have been calibrated by the qualified supplier. Immediate action needs to be taken to place a restriction on the Qualified Supplier List to restrict use of UFA Ventures, Inc. until the calibration of the scales have been completed and documented by a qualified supplier.

The unsatisfactory conditions identified during the audit were discussed with the President of UFA Ventures, Inc. who agreed to work with USGS in resolving the unsatisfactory conditions.

2.0 SCOPE

The supplier audit was conducted to evaluate the implementation and effectiveness of UFA Ventures, Inc.'s QA program. This was accomplished by verifying the implementation of UFA Ventures, Inc.'s QA program as specified in UFA Ventures, Inc.'s QA Program Manual 001, Revision 002, as accepted by USGS, and USGS Purchase Order (PO) 1434-CR-97-SA-00717. 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; Nonconformance Control; Corrective Action; QA Records; and Sample Control.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Office of Quality Assurance (OQA), Audit Team Leader
Robert P. Hasson, OQA, Audit Team Member

Thomas H. Chaney, USGS, Observer
David Hudson, USGS, Observer

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

J. Conca, President, Research Director, UFA Ventures, Inc.
A. Wright, Administrator, UFA Ventures, Inc.
T. Mochler, Operations Director, UFA Ventures, Inc.
P. Heller, Soil Scientist, UFA Ventures, Inc.
P. Didzerekis, Information Systems Management, UFA Ventures, Inc.

5.0 SUMMARY OF AUDIT RESULTS

Implementation of UFA Ventures, Inc.'s QA Program Manual 001, Revision 002, was considered satisfactory and effective in producing the desired results, except for those areas referenced in Section 6.0, "Deficiencies," of this report.

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/DEFICIENCIES CORRECTED DURING THE AUDIT/ RECOMMENDATIONS

The unsatisfactory conditions have been documented on the respective corrective action document and submitted to USGS for resolution.

DEFICIENCY

DR YM-97-D-070

The PNL QA Program PNL-MA-70, Section 7.1, requires that supplier evaluations, source verifications, and receiving inspections, when required, shall be performed by qualified personnel in accordance with approved procedures and instructions. Section 12.1 requires that M&TE be suitably marked to indicate calibration status and that an M&TE control listing (including M&TE description, category, calibration interval, custodian, calibration agency, location, and control number) be used to assist in the control of M&TE. Section 5.1 requires that activities affecting quality shall be prescribed by administrative procedures, operating procedures, technical procedures, and that these documents adhere to prescribed formats and content. They shall include appropriate acceptance criteria for verifying that the activity has been accomplished satisfactorily.

The UFA Ventures QA Program, Technical Training section, requires all personnel working at UFA Ventures, Inc. must complete QA training within before they can begin work at UFA Ventures.”

Contrary to the above requirements, the following conditions were identified:

- A. There is no objective evidence that UFA Ventures, Inc. has qualified the supplier being used for the calibration of scales used in weighing samples.
- B. There is no documented evidence for the completion of assignments identified in the UFA Ventures, Inc. Training Outline for all UFA Ventures, Inc. personnel. Additionally, training assignment sheets have not been completed for the following:
 - ICN revisions to applicable PNL PAP procedures;
 - Quality Assurance Program For Use At UFA Ventures, Inc.;
 - PNL’s Quality Assurance Program Manual PNL-MA-70; and
 - Technical Procedures such as UFA-RC-01.
- C. There is no M&TE status tagging on the AVI Micro 210A Infusion Pumps. Also, the M&TE control listing did not include all current M&TE. The latest list available was 1994.
- D. The Quality Assurance Program For Use At UFA Ventures, Inc. makes reference to PNL PAP-70-501 for the preparation and approval of administrative procedures. However, this procedure has been canceled by PNL. As a result, UFA Ventures, Inc. does not have a replacement which addresses the requirements for preparation and approval of administrative procedures.

DEFICIENCIES CORRECTED DURING THE AUDIT

1. There are no procedures and/or instructions for the receipt, identification and control of samples. UFA Ventures, Inc. prepared procedure UFA-0005, Revision 0, “Procedure For Logging In Samples.” With the generation of this procedure, the condition adverse to quality has been satisfactorily resolved.
2. There was no procedure and/or instruction for performing the calibration of the AVI Micro 210A Infusion Pumps. UFA Ventures, Inc. developed procedure UFA-0004, Revision 0, “AVI Infusion Pump Calibration Verification.” This condition adverse to quality was satisfactorily resolved with the issuance of this procedure.

RECOMMENDATIONS:

1. The PNL MA-70 QA Manual and PAPs were written for a large organizational QA program. As a result, implementation of the PNL's QA program PNL-MA-70 and associated PAPs is extremely difficult for UFA Ventures, Inc. due to the limited application for their scope of services. It is recommended that UFA Ventures, Inc. re-write the QA program for their scope of services and only address the functions and requirements of PNL-MA-70 and associated PAPs which apply. Some examples of areas that need to be addressed by UFA Ventures, Inc. include: Qualification, Indoctrination, and Training of Personnel; Procurement Control; Preparation and Approval of Administrative Procedures; Control of M&TE; Control of Nonconforming Items; Corrective Action; and QA Records.
2. USGS Technical Contact should review all technical procedures used by UFA Ventures, Inc. for the USGS procurement to determine adequacy for the intended work to be performed by the supplier.
3. USGS needs to review the status of the UFA Ventures, Inc. PO in light of the fact that UFA Ventures, Inc. is not using PNL to perform calibrations of the balances. Also, USGS makes reference to a technical procedure to be used by UFA Ventures, Inc. which has been superseded (UFA-CA-010).
4. The USGS PO, Attachment of YMP QA Requirements, implies that UFA Ventures, Inc. does not have a documented QA program. This is not the case. UFA Ventures, Inc. endorses PNL's QA program PNL-MA-70 which is based on the requirements of NQA-1. USGS should revise the attachment to the PO to reference implementation of general requirements that are to be addressed by the suppliers QA program.