



Department of Energy

Washington, DC 20585

QA: L

JUL 28 1997

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 12, Room 1249, M/S 423
Las Vegas, NV 89134

ISSUANCE OF DEFICIENCY REPORT (DR) YM-97-D-070 RESULTING FROM
OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-028 OF
UFA VENTURES, INC.

Enclosed is DR YM-97-D-070 generated as a result of OQA Supplier Audit
OQA-SA-97-028.

Please provide a response to this deficiency that meets the applicable requirements of
Administrative Procedure 16.1Q, Performance/Deficiency Reporting. 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 DR is due 20 working days from the
date of this letter. Any extension to the due date must be requested in writing, with
appropriate justification, prior to the due date.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or
Robert P. Hasson at (702) 794-5023.

R. W. Horton

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1955

Enclosure:
DR YM-97-D-070

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PDR WASTE
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Recip: ums/rec

R. W. Craig

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JUL 28 1997

cc w/encl:

J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
D. J. Sinks, OQA/USGS, Denver, CO
A. M. Whiteside, OQA/USGS, Denver, CO

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
R. P. Hasson, OQA/QATSS, Las Vegas, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 Performance Report
 Deficiency Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Quality Assurance Program For Use At UFA Ventures, Inc., Revision 2, and PNL QA Manual PNL-MA-70
2 Related Report No. OQA-SA-97-028

3 Responsible Organization: USGS/UFA Ventures, Inc.
4 Discussed With: Dr. James L. Conca and Tom H. Chaney

5 Requirement/Measurement Criteria:
A. PNL-MA-70, Section 7-1, states in part: "Supplier evaluations, source verifications, and receiving inspections, when required, shall be performed by qualified personnel in accordance with approved procedures and instructions. Supplier documentation including Nonconformance Reports shall be reviewed and approved or accepted. Determinations shall be made of the acceptability for the use of purchased items. Supplier performance shall be evaluated."
B. Quality Assurance Program For Use at UFA Ventures, Inc., Technical Training section states in part: "All personnel working at UFA Ventures, Inc. must complete QA training within before they can begin work at UFA Ventures."
See Page 3...

6 Description of Condition:
Contrary to the above:
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. 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.
See Page 3...

7 Initiator *Robert P. Hasson* Date 7/15/97
9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)
A. UFA Ventures, Inc., possibly in conjunction with USGS, must qualify a supplier for the balances being used for weighing samples. It is recommended that a review of the Office of Civilian Radioactive Waste Management Qualified Supplier List be performed to determine if an approved supplier exists that can perform the needed calibrations.
See Page 3...

11 QA Review: QAR *Robert P. Hasson* Date 7/15/97
12 Response Due Date: 20 working days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)
Printed Name *Donald G. Herter* Signature *R.W. Clark* Date 7/27/97

22 Corrective Action Verified: QAR Date
23 Closure Approved by: (N/A for PR) DOQA

OFFICE OF CIVILIAN
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

16 Root Cause Determination: (Not required for PR)

Required Yes No

17 Action to Preclude Recurrence: (Not required for PR)

Required Yes No

18 Corrective Action Completion Due Date:

19 Response by:

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

DOQA

Date

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RADIOACTIVE WASTE MANAGEMENT
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PR/DR CONTINUATION PAGE

5 Requirement/Measurement Criteria: (Continued)

- C. PNL-MA-70, Section 12.1, states in part: "Calibration shall include calibrating at prescribed intervals to established standards, documenting evaluation of impact on data/product when Measuring & Test Equipment (M&TE) are found out-of-tolerance, maintaining records, and suitably marking M&TE to indicate calibration status. M&TE control list (Including M&TE description, category, calibration interval, custodian, calibration agency, location, and control number) shall be used to assist in the control of M&TE."
- D. PNL-MA-70, Section 5.1, states in part: "Activities affecting quality shall be prescribed by administrative procedures, operating procedures, technical procedures, test plans, test instructions, or drawings except when supplier procedures are available for standard items, or when there is a high level of certainty that the activity will be done correctly without them. These documents shall adhere to prescribed formats and content. They shall include appropriate acceptance criteria for verifying that the activity has been accomplished satisfactorily."

6 Description of Condition: (Continued)

- C. There is no M&TE status tagging of 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.

10 Recommended Action: (Continued)

- B. Revise the Training Outline to include an initial and date signifying the completion of a required training assignment. Also, have UFA Ventures, Inc. personnel complete the training assignment sheets for any ICNs that have been issued for applicable PNL PAPs, the Quality Assurance Program For Use at UFA Ventures, Inc., PNL's QA Program Manual (PNL-MA-70), and any applicable technical procedures such as UFA-RC-01.
- C. Apply status tags that identify the calibration date, calibration due date, and the initials of the individual that performed the calibration. Also, update the M&TE control listing to include the M&TE used in the facility and to reflect the current information as required.
- D. UFA Ventures, Inc. needs to develop a procedure that addresses the preparation and approval of administrative procedures.