



Department of Energy

Washington, DC 20585

QA: L

SEP 12 1997

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
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Las Vegas, NV 89134

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

The OQA staff has evaluated the response to DR YM-97-D-070. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed upon receipt of objective evidence by the Quality Assurance Representative. Upon satisfactory verification of corrective actions performed by UFA Ventures, Inc., the DR may be closed.

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

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2320

Enclosure:
DR YM-97-D-070

cc w/encl:

J. O. Thoma, NRC, Washington, DC
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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 ☐ Performance Report
☒ Deficiency Report
NO. YM-97-D-070
PAGE 1 OF 3
QA: L

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*
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. Hester Signature *R.W. Clark* Date 7/27/97

22 Corrective Action Verified
QAR Date

23 Closure Approved by: (N/A for PR)
DOQA

ORIGINAL

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

• PR/DR NO. DR-YM-97-DO70

PAGE 2 OF 3

QA:L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

¹⁴Remedial Actions:

A. UFA Ventures agrees to use QSL vendors to provide their calibration services until they establish their own vendor qualification program. The UFA Venture scales have been calibrated by QC Services of Portland, OR, which is on the QSL.

B. UFA Ventures has revised its QA Manual to appropriately reflect procedures that it will work to and has updated the training assignment sheets accordingly. The training assignment sheets have been issued to reflect the UFA Ventures QA Manual and procedures.

C. Tags have been placed on the AVI Micro 210A Infusion pumps and the M&TE control listing has been updated to reflect all current M&TE.

D. The revised UFA Ventures QA Manual now specifies the process by which UFA Venture procedures will be prepared and controlled.

¹⁵Extent of Condition (not required for PR):

The extent of the conditions is limited to the conditions identified in the DR.

¹⁶Root Cause Determination (not required for PR):

Required

☐ Yes

☒ No

Not required.

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

Required

☐ Yes

☐ No

UFA Ventures QA Manual has been revised to reflect the appropriate requirements for their scope of work. All staff have been trained to the revised program.

¹⁸Corrective Action Completion Due Date:

CORRECTIVE ACTIONS
COMPLETED. RPH 9/2/97

¹⁹Response by:

☒ Initial

☐ Amended

Date

Phone

Tom Koney

*8/22/97
*(PER CRAIG TO
HORTON LTR) RPH
9/2/97

²⁰Response Accepted:

QAR *Robert P. Harrison* Date *9/2/97*

²¹Response Accepted (N/A for PR):

AOQAM

Date *9/11/97*

8/22/97 Craig Horton

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.**

⁸ ☐ Performance Report
☒ Deficiency Report

NO. YM-97-D-070

PAGE 3 OF 3
QA: L

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.