

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

SUPPLIER AUDIT REPORT

-OF

DESERT RESEARCH INSTITUTE
LAS VEGAS, NEVADA

REPORT NUMBER OQA-SA-96-027
AUGUST 22-23, 1996

Prepared by:

Stephen D. Harris

Date: sept. 3, 1996

Stephen D. Harris
Audit Team Leader
Yucca Mountain Quality
Assurance Division

Approved by:

Donald G. Horton

Date: 9/4/96

Donald G. Horton
Director
Office of Quality Assurance

Enclosure

9609110334 960905
PDR WASTE
WM-11 PDR

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Desert Research Institute (DRI) revealed unsatisfactory implementation of the Quality Assurance (QA) requirements for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Many of the processes described in the DRI QA manual were performed in a manner other than that described. Some of the QA processes had not been implemented. The technical work performed appeared to be done in a satisfactory manner; however, due to the extent of nonimplementation, the QA program was determined to be ineffective. DRI performs chemical laboratory analyses for the U.S. Geological Survey (USGS).

The unsatisfactory conditions identified during the audit were discussed with the Director of Yucca Mountain activities at DRI and the QA manager of the USGS. Corrective actions associated with Deficiency Report (DR) number YM-96-D-093 will be evaluated by the Office of Quality Assurance (OQA) and closed as appropriate. The unsatisfactory conditions are detailed in Section 5.0

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of the DRI quality program. This was accomplished by determining if the DRI's program meets the quality and technical requirements specified in the USGS procurement document, number 1434-CR-95-SA-00498, the DRI QA Manual, Revision 0, dated November 16, 1994, with associated technical procedures, and the OCRWM Quality Assurance Requirements and Description (QARD) for the specific scope of work. The QA program elements determined to be applicable are: Organization; Quality Assurance Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Control of Measuring and Test Equipment; Nonconformances; Corrective Action; Quality Assurance Records; Audits; Software; and Sample Control.

3.0 AUDIT TEAM AND OBSERVERS

Stephen D. Harris, Audit Team Leader, OQA, Yucca Mountain Quality Assurance Division

4.0 PERSONNEL CONTACTED DURING THE AUDIT

Dr. Herbert Haas, Director
Todd Enerson, Laboratory Technician

5.0 SUMMARY OF AUDIT RESULTS

The DRI QA Manual, Revision 0, dated November 16, 1994, did address the applicable elements of the OCRWM QARD for the intended scope of work; however, many of the processes were not performed in the manner described. Some processes of the QA program were not implemented. Technical procedures were in place and appeared to satisfactorily describe the processes performed.

The details of the audit, along with the objective evidence reviewed and items corrected during the audit, are contained within the audit checklist which is available from the OQA's quality records files.

6.0 DEFICIENCIES/RECOMMENDATIONS

The deficiencies have been documented on DR number YM-96-D-093 and will be submitted to the USGS for resolution with DRI.

DEFICIENCIES

1. No objective evidence was available of QA Program training for Todd Enerson on form Attachment 2.2. The forms, Attachments 2.1 and 2.2, were not used to indicate the QA Program Indoctrination and Training and Personnel Qualification for Dr. Haas. (QA Manual, 2.2.2)
2. Reports of data and tests run, submitted to USGS, did not include dates of analysis. (Purchase Order, Section III, Analytical Services)
3. There are no documented hand calculations for data manipulation by the spreadsheets used with signature and date traceable to the software. (QA Manual, 3.2.1, Paragraph 2; Data Processing, 2.0, Step 11)
4. There is no procurement agreement for calibration services for the balance used on Yucca Mountain Site Characterization Project (YMP) activities. (The balance is currently in calibration; however, not by an organization on the Quality Suppliers List. A determination needs to be made based on the need for the precision and accuracy of the data, whether or not a procurement for calibration service is needed.) (QA Manual, 4.2.1, Paragraph 3)
5. There is no documentation of receipt of Oxalic Acid from the National Institute of Standards and Technology (NIST) on Attachment 4.1. (QA Manual, 4.2.2)

6. There is no identification of QA records in the procedures. (The records are implied but not specified.) (QA Manual, 5.2.1)
7. There is no evidence of review by independent personnel of the technical procedures. (QA Manual, 6.2)
8. There is no evidence of a formal review of the QA Manual and procedures using the Document Review Form, Attachment 6.1. (QA Manual, 6.2)
9. Attachment 7.1 is not used to track samples. (This issue has been identified by USGS on a Performance Report - USGS-96-P-020.) (QA Manual, 7.2.2)
10. There is no calibration system in place for the balance used on YMP activities. (QA Manual, 8.2.1)
11. The calibration sticker, attached to the balance, does not indicate the procedure used to calibrate it. No calibration stickers are on the counters used. (QA Manual, 8.2.7)
12. Records were not available for:
 - Personnel indoctrination and training of the QA program
 - Personnel qualification forms for Dr. Haas
 - Receipt inspection forms, purchase order forms
 - Review sheets (Document Review Records)
 - Sample tracking forms (Attachment 7.1)(QA Manual, 10.2.2)

RECOMMENDATIONS

1. Data Processing procedure, Section 4.0, states: "Current hard copy of data is held outside of room 229." This section should be rewritten in the procedure to indicate where all data is retained or removed from the procedure.
2. Reference to procedure locations needs to be clarified in RLD-02, "Preparation of Benzene from Samples":
 - Section 2.1.6. The references made here should be 2.1.4 and 2.1.5.
 - Page 5, Step 7. References should be 2.1.5 through 2.1.11.
 - Page 6, Step 6. This reference should be 2.1.10.

In addition, pages 23-25 are numbered incorrectly. The numbers should be changed to be sequential in the procedure.

3. RLD-04, "Scintillation Counting in Benzene Samples," Section 2.2, Paragraph 3, references Section 7 of the procedure. The reference should be 2.6.
4. The USGS should assure all sections of the QARD that apply to the scope of work of DRI are included in the purchase order and related documentation sent to DRI and OQA.
5. Based on discussions with DRI personnel during the course of the audit, it is recommended that USGS explain to DRI how the deficiency reporting system is used within their scope of work.