



Department of Energy

Washington, DC 20585

QA: L

JUN 30 1997

L. D. Foust, Technical Project Officer
for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
1180 Town Center Drive, M/S 423
Las Vegas, NV 89134

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-042 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SURVEILLANCE M&O-SR-97-025 OF THE UNIVERSITY OF NEVADA AT RENO

The OQA staff has evaluated the response to DR YM-97-D-042. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to that date. Please send a copy of extension requests to Deborah G. Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Daniel A. Klimas at (702) 734-0853.

R.W. Clark
For Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1781

Enclosure:
DR YM-97-D-042

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8 ☐ Performance Report
☒ Deficiency Report

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Rev. 5		2 Related Report No. M&O-SR-97-025	
3 Responsible Organization: Management and Operating Contractor (M&O), University of Nevada, Reno (UNR)		4 Discussed With: David Von Seggern, J. N. Brune, Ken Smith, Glenn Biasi, Darrell Porter	
5 Requirement/Measurement Criteria: QAP-2-1, Rev. 05, Indoctrination and Training, requires a completed Activity Evaluation to be reviewed. (Section 5.2.1A), Reading/Self study records or attendance of classroom training for each individual working on the project (Section 5.2.1C) QAP-2-2, Rev. 2, PO3, Verification of Personnel Qualifications, requires a Resume or Summary of work experience (Section 5.1.4), and verification of education and experience for each individual (Sections 5.2.1 and 5.3). QAP-7-0, Rev. 0, Procurement Control Process, requires Section 5 steps to be followed to acquire "services that are subject to Quality Assurance Requirements and Description (QARD) requirements." QAP-SIII-3, Rev. 1, Scientific Notebooks, requires an initial entry to include, among other things, a Table of Contents, list of personnel making entries, etc. (Continued on Page 2)			
6 Description of Condition: Contrary to the above requirements: <ul style="list-style-type: none"> Training records did not contain the Activity Evaluation for any of the UNR staff, reading/self study records were not found for Rasool Anooshehpour and Walter Nicks. Resumes were not found for Glenn Biasi, Brant Wilhelm, and Nancy Stennes. verification of education and experience was not complete for Gordon Shields, Ken Smith, Walter Nicks, Arthur Aburto, Brant Wilhelm, and John Torrisi. No training records were available for Diane DePolo. Scientific Notebooks do not comply with the requirements of the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) procedure QAP-SIII-3, "Scientific Notebooks." Services for the calibration of a voltmeter were not obtained using the M&O procedure QAP-7-0, "Procurement Control Process." Records of tapes for seismic activity are not being retained in a 1-hour fire rated area, dual storage, or submitted within 90 days of completion to the Records Processing Center. Nevada Work Instructions did not contain the requirements for Control of Electronic Management of Data from Supplement V of the QARD that apply to the University work. 			
7 Initiator Daniel Klimas Date <u>5/13/97</u>		9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR	
10 Recommended Actions: (Not required for PR) Complete the training records to meet the M&O procedures, clean up Scientific Notebooks to meet QAP-SIII-3 and close out notebooks that will not be used beyond the transition date of work from the U.S. Geological Survey to the M&O/UNR, resolve the procurement issue with the M&O to preclude procurement of services outside the procedure requirements, find a storage location in another building to house the data tapes or submit records to the Records Processing Center within 90 days of completion, and include in the appropriate NWIs the implementation steps for compliance with the appropriate requirements of Supplement V of the QARD.			
11 QA Review QAR <u>Daniel Klimas</u> Date <u>5/13/97</u>		12 Response Due Date 20 days after date of issue.	
13 Affected Organization QA Manager Issuance Approval: (QAR for PR) Printed Name <u>Donald G. Horton</u> Signature <u>[Signature]</u> Date <u>5/19/97</u>			
22 Corrective Actions Verified QAR _____ Date _____		23 Closure Approved by: (N/A for PR) AOQAM _____ Date _____	

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Block 5 (Continued)

AP-17.1Q, Rev. 0 ICN0, requires storage of records in a 1-hour fire rated container or facility, dual storage, or submittal of records to the Records Processing Center within 90 days of completion.

The QARD, Supplement V, Control of the Electronic Management of Data, requires the security of the data is maintained including integrity of the data and when data is retrieved using a query language, the query is checked to ensure it satisfies the Affected Organization's requirements for its intended use. (Section V.2.1C. and D.)

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

Deficiency - Bullet 1: There was no evidence presented that an Activity evaluation had been completed for any of the UNR (Selsinic Lab) staff, and that Reading/Self Study records were not available for several active technical participants. Also, resumes were not found for Biasi, Wilhelm, Steines, and verification of education /experience were not completed for all personnel. No training records were available for DePolo.

Response - An Activity Evaluation showing the subject task to be a Q activity existed whereby the participants examined are required to perform Q activities as reflected by their PDs. The reading/self study and missing resume deficiencies are being corrected. The personnel had been verified, although the process used was not in compliance with QAP-2.2; therefore, the process has been repeated and the credentials, as stated in the Position Descriptions of all participants, have been (See Continuation Sheet)

15 Extent of Condition: (Not required for PR)

The first four of the five conditions cited are administrative or operational in nature, and are nearing correction. Additional attention to stricter compliance will prevent recurrence of these deficiencies. The last deficient condition (compliance with QARD Supplement V) will be remedied procedurally. The conditions cited do not impact the quality of the data being produced; therefore it is believed there is no root cause determination required for the issues of this deficiency report.

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:

09/15/97

19 Response by:

David von Seggern &
Darrell Porter

David von Seggern
Darrell Porter
Date 06/13/97

Phone 295-5784

20 Response Accepted

QAR

David von Seggern
Kuman

Date

6/19/97

21 Response Accepted (N/A for PR)

DOQA

R.W. [Signature]

Date

6/30/97

Exhibit AP-16.1Q.2

Rev. 06/02/87

6/16/97

LV.SPO.PPDDP 06/97-057

P. 3064

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14 Remedial Actions (Continued)

verified. Because Diane DePolo was a new participant, her records were not complete or available for review by the surveillance team. Ms. DePolo has been appropriately trained and the records will be in the system.

Deficiency - Bullet 2: Scientific Notebooks do not comply with QAP-SIII-3.

Response - All currently active Scientific notebooks are being thoroughly reviewed, and corrected as appropriate, for compliance with the current revision of the subject procedure. Those notebooks in use before the advent of the M&O procedure for controlling the use of Scientific Notebooks will be closed out, reviewed, and submitted as records. New notebooks are being initiated as the specific activities warrant; internal compliance overview of all notebook users will be stressed by the responsible project scientist.

Deficiency - Bullet 3: "Services for the calibration of a voltmeter were not obtained using the M&O procedure QAP-7-0....".

Response - The voltmeter was calibrated by a qualified vendor who the University historically had been using as standard practice. It is recognized that the subject procedure requires the supplier be selected as an appropriately qualified YMP vendor as denoted by the status of a listing on the YMP Qualified Supplier's List. Prior to this surveillance the determination had been made that future calibrations would be provided by, and one subsequent voltmeter calibration has been made by the QSL-listed Bechtel Calibration Laboratory. All voltmeter calibrations in the foreseeable future will continue to be made by this Bechtel Calibration Laboratory.

Deficiency - Bullet 4: "Records of tapes for seismic activity are not being retained in a 1-hour fire rated area, dual storage, or submitted within 90 days of completion".

Response - The location of tape storage was believed to be appropriately within the requirements. The facility is secure and in an adjacent building, believed to meet the separation requirements, which was a source of discussion at the surveillance. Apparently the surveillance team's final discretion was that the latter assumption was not appropriate. Accordingly, this facility will be abandoned and a commitment is made to meet the 90 day rule for these records. In the event of need for storage under extenuating circumstances, a planned fallback position is to make an arrangement with a University colleague to store a copy of these records in a separate, totally free standing building until such time that the records can be submitted.

Deficiency - Bullet 5: "Nevada Work Instructions did not contain the requirements for Control of Electronic Management of Data from Supplement V of the QARD..."

Response - At the present time the M&O procedures are silent on the requirements of Supplement V. The UNRSL will approach resolution of this issue by modifying their NWI-UNR Work Instructions that generate data bases where the issues of Supplement V for electronic data exist, to incorporate the appropriate controls.