



**Department of Energy**  
Yucca Mountain Site Characterization  
Project Office  
P. O. Box 98608  
Las Vegas, NV 89193-8608

WBS 1.2.11  
QA: N/A

**FEB 05 1993**

Les E. Shephard  
Technical Project Officer  
for Yucca Mountain  
Site Characterization Project  
Sandia National Laboratories  
P.O. Box 5800  
Organization 6302  
Albuquerque, NM 87185

**EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-93-023 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-93-03 OF SANDIA NATIONAL LABORATORIES (SNL)**

The YMQAD staff has evaluated the response to CAR YM-93-023. The response has been determined to be unsatisfactory based on the following:

1. YMQAD is in disagreement with the note contained in the SNL response. The note infers that no requirements were violated. New England Research (NER) is a contractor currently working to and under the SNL quality assurance (QA) program. Consequently, NER is responsible to perform in accordance with the contract, similar to augmented staff under the direct management of SNL. Therefore, SNL is responsible to assure that their QA program is being implemented effectively through internal and external audits or annual performance evaluations of SNL's suppliers.
2. Response 1a, Remedial Action is not clearly stated.
3. The Quality Assurance Requirements Document DOE/RW-0214, Element 16, basic requirement requires conditions adverse to quality to be corrected as soon as practical. It appears that eight months for the limited corrective action is not timely, especially when it does not include the performance of an audit of those suppliers place on the audit schedule as a result of this CAR.
4. The Office of Civilian Radioactive Waste Management Quality Assurance Administrative Procedure 16.1, Corrective Action, Attachment III, requires the name of the assigned individual and the anticipated completion date for each phase, e.g., remedial, investigative and action to preclude recurrence to be entered on the CAR response.

120019

9302170122 930205  
PDR WASTE  
WM-11 PDR

YMP-5

ADD: Ken Hooks *Ur. Encl.*

102.7  
WM-11  
N403

FEB 05 1993

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Donald J. Harris at (702) 794-7356.



Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2270

Enclosure:  
CAR YM-93-023

cc w/encl:

~~R. R. Hooks, NRC, Washington, DC~~  
S. W. Zimmerman, NWPO, Carson City, NV  
R. R. Richards, SNL, 6319, Albuquerque, NM  
R. L. Maudlin, MACTEC, Las Vegas, NV  
F. J. Schelling, SNL, Las Vegas, NV

cc w/o encl:

J. H. Hines, OGD, AL  
J. W. Gilray, NRC, Las Vegas, NV  
N. J. Brogan, SAIC, Las Vegas, NV

ORIGINAL

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

**THIS IS A RED STAMP**  
8 CAR NO.: YM-93-023  
DATE: 12/8/92  
SHEET: 1 OF 2  
QA

**CORRECTIVE ACTION REQUEST**

1 Controlling Document QAIP 18-1, Revision 00		2 Related Report No. YM-93-03	
3 Responsible Organization SNL		4 Discussed With R. Richards	
5 Requirement: SNL QAIP 18-1, Revision 00, Quality Assurance Audits, Paragraph 4.1, Scheduling, states in part: <div style="margin-left: 20px;">           Step 1 PI for audits shall evaluate quality assurance programs of SNL contractors who are performing quality-affecting activities at least annually. This evaluation, identifying contractor's Quality Assurance Programs requiring audit, shall be documented.             Step 2 PI for audits shall, on an annual basis, develop an audit schedule for internal and external audits and periodically review and revise the audit schedule.             Appendix A, Audit Scheduling             Step 3 Contractor audits shall be scheduled and performed on a triennial basis, when         </div>			
6 Adverse Condition: Contrary to the sited requirements 1 and 2 And 3 <span style="float: right;">JYA 12-15-92</span> <div style="margin-left: 20px;">           1. The SNL annual evaluation of SNL contractors, documented in a letter with attachments, to R. R. Richards from D. R. Hawkinson, subject: Proposed SNL audit schedule, dated October 17, 1992, did not include an evaluation of New England Research (working under SNL QA Program) suppliers of calibration services, e.g., MTS Systems Corporation, ESSCO Laboratory and Omega.             Contrary to the sited requirements 2 and 4             2. SNL audit schedule for fiscal years 1993 and 1992 failed to include the suppliers of calibration services: MTS System Corporation, ESSCO Laboratory and Omega, who provide calibration services for New England Research, who is currently performing quality-affecting activities of WBS 1232713A         </div>			
9 Does a significant condition adverse to quality exist? Yes <u>    </u> No <u>X</u> If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes <u>    </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	
11 Response Due Date: 20 Working Days from Issuance			
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination			
13 Recommended Actions: SNL should evaluate the methodology of evaluating suppliers qualified by contractors working under SNL's QA Program and the subsequent auditing and annual evaluation of those suppliers.			
7 Initiator Donald J. Harris <i>K.T. McFall</i> Date <u>12/8/92</u>		14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>12/15/92</u>	
15 Response Accepted QAR Date		16 Response Accepted QADD Date	
17 Amended Response Accepted QAR Date		18 Amended Response Accepted QADD Date	
19 Corrective Actions Verified QAR Date		20 Closure Approved by: QADD Date	

ENCLOSURE

REV. 08/91

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

8 CAR NO.: YM-93-023  
DATE: 12/8/92  
SHEET: 2 OF 2  
QA

**CORRECTIVE ACTION REQUEST (Continuation Page)**

**5 Requirements (continued)**

supplemented by annual evaluations.

**Step 4** At least annually (triennial for contractors) or at least once during the life of the activity affecting quality, whichever is shorter, an audit of the adequacy and effectiveness of the QA program shall be performed.

## **Response to CAR YM-93-023**

---

**Note:** Careful reading of the Requirements in comparison with the cited Adverse Condition reveals that no violations of the Requirements occurred (e.g., Step 1 refers to "SNL contractors"; the cited contractors are not SNL contractors). Nevertheless, the QARD seems to indicate that participants are responsible for evaluating the implementation of QA at subtier contractors where the upper-tier contractor works to the participant's QA Program. Therefore, the following response is provided.

---

### **1. Corrective Action Response for CAR# YM-93-023.**

#### **1A. Remedial Action**

An evaluation of the nature of the work being conducted by the SNL QA Audit Schedule for FY93 may be revised to include audits of NER calibration services subcontractors:

- MTS Systems Corporation
- ESSCO Laboratory
- Omega Corporation

#### **1B. Investigative Action**

The extent of this CAR deficiency will be determined by identification of subtier contractors who:

- are subcontractors to a SNL contractor who works under the SNL QA Program, and
- are performing or will perform work subject to the QA Program.

The nature of the work of those subtier contractors will be evaluated. If appropriate, they will be added to the SNL QA Audit Schedule.

#### **1C. Root Cause Determination** N/A this CAR.

**1D. Corrective Action to Preclude Recurrence**

SNL Procedure 4-1, "Procurement" and Appendix A Procurement Planning Checklist, Section 3 standard clause (F) will be clarified to require all contractors provided with procurement responsibility to inform SNL of the names of subtier contractors used and methodology of qualification.

SNL Procedure 18-1, "Quality Assurance Audits," will be revised to call for evaluation of subcontractors of SNL contractors who work under the SNL QA Program for determination of whether they must be audited.

**2. 1A,B,C and D R. R. Richards**

Estimated completion date for 1A, 1B, and 1D — October 1, 1993

**3. Response Approved:**

*R. R. Richards*  
for Manager, YMP Management Dept.

19 Jan 93  
Date