Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

AUG 21 1996

L. Dale Foust
Technical Project Officer
for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
Bank of America Center, Suite P-110
101 Convention Center Drive
Las Vegas, NV 89109

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) YM-96-C-009 RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT OQA-SA-96-021 OF ACTIVATION LABORATORIES, LTD.

Enclosed is CAR YM-96-C-009 generated as a result of OQA-SA-96-021.

Please identify the corrective action to be taken and implemented to correct the deficiency. Send the original of your response to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. Response to the CAR 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 Robert B. Constable at (702) 794-5580 or Daniel A. Klimas at (702) 794-1495.

Robert B. Constable for

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2450

Enclosure:
CAR YM-96-C-009

WM-11
NH33

102.7

YMP-5

ADD: JG SPRAUL

cc w/encl:
D. A. Dreyfus, DOE/HQ (RW-1) FORS
T. A. Wood, DOE/HQ (RW-14) FORS
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. L. Strickler, M&O, Vienna, VA
B. R. Justice, M&O, Las Vegas, NV
R. P. Ruth, M&O, Las Vegas, NV
D. G. Horton, OQA, NV
W. E. Barnes, YMSCO, NV
Records Processing Center

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
W. W. Hudson, YMQAD/QATSS, Las Vegas, NV
D. A. Klimas, YMQAD/QATSS, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

ORIGINAL
THIS IS A RED STAMP

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

CAR NO. YM-96-C-009

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CORRECTIVE ACTION REQUEST

1 Controlling Document:
Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5

2 Related Report No.
OQA-SA-96-021

3 Responsible Organization:
Civilian Radioactive Waste Management System Management and Operating Contractor (M&O)/Activation Laboratories, Ltd.

4 Discussed With:
Eric Hoffman, Activation Laboratories, Ltd./Robert Justice, M&O

5 Requirement:

QARD, Procurement Document Control, Section 4.0, paragraph 4.2.1C.1.: Procurement documents issued by each Affected Organization shall include the following provisions, as applicable to the item or service being procured: C. Quality Assurance (QA) Program Requirements including: 1. A requirement for the supplier to have a documented QA Program that implements applicable QARD requirements prior to the initiation of work.

Implementing Documents, Section 5.0, paragraph 5.2: Work shall be performed in accordance with controlled implementing documents.

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6 Description of Condition:

Contrary to the above requirements of the QARD, Section 4.0

- Training records were incomplete, and in some cases not traceable to specific training that was administered
- The QA Manual needs to be revised or administrative procedures need to be developed to better describe the detailed requirements for procedure development review and approval; document identification, control and distribution; procurement document control; supplier evaluation; calibration control; QA records and audits.

Contrary to the above requirements, although there was a documented QA Program initiated in the form of a QA Manual and technical procedures, the complete QA Program that applies to the Activation Laboratories, Ltd. scope of work was not adequately implemented.

1. The QA Manual and Quality Operating Procedures (QOP) SaNoncon A do not address the issues of procurement document, Section F2.
2. Client name is not included in the worksheets.
3. Mistakes are sometimes obliterated on worksheets and not initialed (dates also need to be added).
4. The QOP SaNoncon forms are in the procedure, but are not being used by the sample receiving personnel.

(Continued on Page 3)

7 Initiator
Dan A. Klimas Date 08/08/96

9 Does a Stop Work condition exist?
Yes ___ No X If Yes, Attach copy of SWO
If Yes, Check One: A☐ B☐ C☐ D☐

10 Recommended Actions:

Prior to any further technical activities, resolve all issues not in compliance with procurement document requirements and QA program requirements. Write appropriate implementing documents or revise QA Manual to reflect the actual process and activities conducted by Activation Laboratories, Ltd.

11 QA Review:
Dan A. Klimas Date 8/08/96

12 Response Due Date:
20 Working Days From Issuance

13 Affected Organization QA Manager Issuance Approval:
Printed Name R.E. SPENCE Signature Robert B Gustable for Date 08·20·96

22 Corrective Action Verified
QAR Date

23 Closure Approved by:
AOQAM Date

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WASHINGTON, D.C.

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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

15 Extent of Condition and Impact:

16 Root Cause Determination prepared in accordance with AP-16Q is attached.

17 Action to Preclude Recurrence:

18 Corrective Action Completion Due	19 Response Due □ Initial □ Amended Date Phone
20 Response Accepted QAR Date	21 Response Accepted AOQAM Date

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☒ Corrective Action Request
☐ Stop Work Order

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CAR/SWO CONTINUATION PAGE

5. Requirement (continued from page 1):

Activation Laboratories, Ltd. QA Manual requirements

1. M&O Procurement Document F2 for Nonconformances.
2. QA Manual, 13.13.1, Chemical laboratory technical worksheets shall include the client name.
3. QA Manual, 13.13.1, Mistakes must be neatly crossed out and corrections initialed.
4. QA Manual, 12.3, QOP SaNoncon forms are to be filled out for nonconforming samples.
5. QA Manual General Requirements.
6. QA Manual, 8.2 The QA Manager maintains responsibility for calibration activities, for monitoring calibrations to a predetermined schedule and related records.
7. QA Manual, 8.4.2 The inventory list of equipment presents the following information: identification of type/model and serial number.
8. QA Manual, 8.6 Calibration sticker must contain indication of the date of last calibration and due date of the next calibration.
9. QA Manual, 8.6 Calibrations are to be recorded in Quality Procedure logbooks kept with each piece of equipment.

6. Description of Conditions (continued from page 1):

5. QA Manual, 13.4 "Test data and calculations are checked against the technician's worksheets."
   QA Manual, 13.6 "National Bureau of Standards traceable standards as well as in house proprietary standards are run with the clientele samples."
   QA Manual, 10.4 "QA Manager is responsible for the safekeeping of test documents and keeps them in the mechanical test lab and the chemical analysis lab."
   These words do not describe what is done in all cases. The QA Manual must be written to address all circumstances for compliance verification.
6. Calibrations are performed by and monitored by the laboratory manager, not QA Manager. This needs to be changed in the manual.
7. The list of equipment does not include model and serial number in several cases.
8. The sticker on the balance weights is past due. Due date is June 1996. Calibration stickers do not indicate due date of next calibration.
9. The sheets do not indicate the instrument being calibrated, i.e., ICPMs Perkin Elmer 6000.