Department of Energy
Washington, DC 20585

QA: L

MAR 0 3 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

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

The OQA staff has verified the corrective actions to CAR YM-96-C-009 and determined the results to be satisfactory with the exception of the procurement process of controlling quality-affecting work. This concern will be resolved through activities performed to close CAR YM-97-C-001 written to require clarification of this concern within the Civilian Radioactive Waste Management System Management and Operating Contractor. As a result, the CAR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Stephen D. Harris at (702) 794-5522.

R.W. Clark

for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1051

Enclosure:
CAR YM-96-C-009

cc w/encl:
L. H. Barrett, DOE/HQ (RW-1) FORS
T. A. Wood, DOE/HQ (RW-55) FORS
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV
Records Processing Center

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
D. A. Klimas, OQA/QATSS, Las Vegas, NV
S. D. Harris, OQA/QATSS, Las Vegas, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV
W. E. Barnes, DOE/YMSCO, Las Vegas, NV

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NMSS/DWM

Recip:

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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

PAGE 1 OF 12

QA: L

DS 10/9/96

CORRECTIVE ACTION REQUEST

1 Controlling Document:	2 Related Report No.
Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5	OQA-SA-96-021
3 Responsible Organization:	**4 Discussed With:**
Civilian Radioactive Waste Management System Management and Operating Contractor (M&O)/Activation Laboratories, Ltd.	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.

(Continued on Page 3)

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	9 Does a Stop Work condition exist?
Dan A. Klimas Date 08/08/96	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:	12 Response Due Date:
Dan A. Klimas Date 8/08/96	20 Working Days From Issuance

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

22 Corrective Action Verified	23 Closure Approved by:
QAR S. D. Harris Date 2/13/97	AOQAM R.W. Cox Date 3/3/97

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8

☒ Corrective Action Request
☐ Stop Work Order

NO. YM-96-C-009

PAGE 22 OF 25

QA: L

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.

2 of 23

CAR NO. YM-96-C-009
PAGE 1 OF 5
QA: L

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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:
M&O SPO will work with ACTLABS to prepare the laboratory for assured compliance with their revised QA program that reflects actual practice. This update may include revised procedures as necessary to correct deficient conditions as noted in Supplier Audit report OQA-SA-96-021. Additionally, it will specify that before further sample processing is resumed for YMP, the 17 deficient items listed in the audit report and CAR are corrected and resolved through implementation of revised procedures and manual and verification performed by OCRWM OQA.

see continuation page:

15 Extent of Condition and Impact:
The audit report states "technical work performed was determined to be satisfactory; however, without full implementation of the QA program, the results of the data are considered to be indeterminate". Specific deficiencies documented above that resulted from inadequate application of the QA procedures that had been required in the QA Manual will be evaluated to determine what can be done to remove the indeterminate status of the data. During the time prior to this audit, 800 samples were processed, including blanks, blind and control samples. These analytical results will be evaluated for qualification in accordance with the requirements of acceptance criteria in the procurement document. Because the deficiencies were primarily related to documentation of training, certificates of (see continuation page:)

18 Root Cause Determination prepared in accordance with AP-16.4Q is attached.

17 Action to Preclude Recurrence:
ACTLABS will be held to compliance with the remedial actions listed above before additional YMP samples are submitted for analysis. Appointment of a QA Manager and revision of the QA manual, plus issuance of relevant procedures are expected to prevent recurrence.

16 Corrective Action Completion Due Date:	19 Response by: DR. E-HOFFMAN
10/03/96	☑ Initial ☐ Amended Date Oct 3/96 Phon 905-648-9611
20 Response Accepted QAR N/A Date	21 Response Accepted AQQAM N/A Date

Exhibit AP-16.20.1-2 Rev. 07/15/96

10/3/96 LV.SPO.LRH.10/96-71

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U.S. DEPARTMENT OF ENERGY
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8 ☑ Corrective Action
☐ Request

NO. YM-96-C-0009
PAGE 2 OF 5
QA: L

CAR/SWO CONTINUATION PAGE

14. Remedial Actions: (continued from page 1)
Deficiencies

1. Some training records were incomplete and did not show evidence of what specific training was administered.

ACTLABS will demonstrate that Position Descriptions exist, that training assignments were made, and that training assignments have been accomplished, all of which will be on file in duplicate storage.

2. Procurement documents for calibration services were unavailable as the services were procured verbally and payment was made by invoice.

The QA Manual or procurement procedure will be further revised to include the methodology for subvendor selection and a memo concerning the selection of VACS LTD as the calibration supplier has been placed in the QA file. ACTLABS performed a desktop evaluation of the calibration vendor (VACS LTD) in accordance with approved procedure QOP-PROCURE, Rev. 0, and established that they are ISO and SCC certified. With these credentials, they were accepted as a qualified vendor without needing further credentials or programs. For future work, a purchase order will be placed with the selected calibration supplier in accordance with approved procedures.

3. Procedures and the QA Manual did not receive independent review and approval as required by the QA Manual.

The QA manual and all procedures now have been reviewed and are currently effective. Documentation of the reviews will be on file at ACTLABS prior to performing continued work for the Yucca Mountain Project. The QA Manual or relevant procedures will be further revised to clarify aspects of this review process; a procedure, QOP-QOP, Rev. 0, has been developed describing this process.

4. Distribution of procedures and the QA Manual are not controlled in accordance with the QA Manual requirements.

Control of distribution of procedures and the QA Manual will be further revised so that there is a record of what procedures are required to complete their contractual requirements, a record of who has access to designated procedures, and a record of evidence that the most recent procedure is in use. Appropriate training will be provided to these procedures.

5. No supplier evaluation information was available for calibration services performed by VACS LTD.

An evaluation was made, but the evaluation was not documented. This problem has been remedied by creating a memo to the QA file stating the facts of the qualification. The process and criteria for qualification are described in the procedure QOP-BALAN, Rev. 1.

6. The calibration of balance weight set, serial number AL01, is past due.

Balance weights will be required to be calibrated for five year intervals; this is now the established requirement of procedure QOP-BALAN, Rev. 1. In the case of balance weight set with serial number AL01, the sticker appeared to show that a recalibration was due after one year, although this was a suggestion by the calibration service, not a requirement of the calibration service (their requirement is five years). In accordance with calibration requirements of the relevant procedure, the weights were not out of calibration when the work was done. When the work was performed on the Yucca Mountain samples (November, 1995-March, 1996), the balance weight set was within one year of the last calibration, which the procedure required at that time. Having an appropriate certification on file will be addressed. If an issue develops, ACTLABS will resolve it through a nonconformance report.

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 ☑ Corrective Action
☐ Request

NO. YM-96-C-0009
PAGE 3 OF 5
QA: L

CAR/SWO CONTINUATION PAGE

14. Remedial Actions: (continued from page 2)

7. QA records are not maintained as required by the QA Manual.

The QA manual will be further revised to indicate ACTLABS' records management practices specific to the various types of records generated. Some of these practices are now in place (QA Manual, Section 16, Paragraphs 16.3 and 16.6). Training appropriate to records requirements will be provided.

8. Internal audits are not being conducted as required by the QA Manual.

The internal audit will be performed within 30 days of implementing Revision 2 of the QA manual.

9. The QA Manual and Quality Operating Procedures (QOP) SaNoncon A do not address the issues of the CRWMS M&O procurement document, Section F2.

The procurement document, Section F2, states "ACTLABS shall submit, to the PI for approval, reports of nonconformances to technical and/or quality assurance requirements in this procurement document whenever the following exist: technical requirements in the description of services are violated, a requirement in this procurement document is violated, or the nonconformance cannot be corrected by reanalyzing the sample." This is now addressed in revised procedure QOP-NONCONFO, Rev.1 (Section 5, Paragraph 5.3) under client's complaints.

10. Client name is not included in the chemical laboratory technical worksheets, as required.

Actual practice at the time the Yucca Mountain Project samples were analyzed included the work order number or report number on worksheets rather than the client name. However, there was no impact to quality because the workorder number was on the worksheets and there is no value in correcting the worksheets to include the client name. The QA manual has been revised to reflect the actual practice.

11. Mistakes are sometimes obliterated on worksheets and not initialed (dates also need to be added).

The relevant QOP's have been amended to require single line striking out of data with initialing and dating (Section 13, Paragraph 13.3.3 and 13.3.4). All workers have been apprised of this necessity, and additional training will be given to reinforce this practice that is now in effect. The technical manager will review the corrections with respect to impact on quality and will write a memo to the QA file documenting the results and resolution of any deficiencies.

12. The QOP SaNoncon forms are in the procedure, but are not being used by the sample receiving personnel.

This subject was revised in the QA manual and is now more user friendly, which will contribute to more accurate and reliable compliance. Additional training has been given to the workers concerning the nonconformance procedure. No new nonconformances have occurred; when one does occur, it will be appropriately documented on the appropriate forms as designated.

13. The following sections of the QA Manual contain statements that are not performed in all cases:
13.4, "Test data and calculations are checked against the technician's worksheets."
13.6, "National Bureau of Standards traceable standards as well as in house proprietary standards are run with the clientele samples."
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."

CAR/SWO CONTINUATION PAGE

14. Remedial Actions: (continued from page 3)
13 (continued):

ACTLABS will evaluate the impact of not complying with these sections and will write a memo to the QA file documenting the results of the evaluation. If conditions adverse to quality are found, appropriate corrective actions will be taken according to ACTLABS' QA manual. The QA Manual has been revised to address circumstances for compliance verification. The above sections have been revised to reflect actual practice.

14. Calibrations are performed and monitored by the Laboratory Manager, not QA Manager. The QA Manual should be changed to reflect who actually performs these activities.

It is not believed that there is any quality impact from this deficiency. The QA Manual has been changed to reflect the actual practice that calibrations are performed by approved personnel and monitored by the technical manager.

15. The list of equipment does not include model and serial number in several cases.

The list of equipment has been revised to include model and serial numbers for all equipment where the numbers are available and the QA Manual has been amended.

16. The sticker on the balance weights is past due. Calibration stickers do not indicate due date of next calibration.

Evidence of current calibration certification will be on file and due dates for the next calibration will be added to the sticker placed on the balance weights.

17. The calibration equipment sheets do not indicate the instrument being calibrated by model number (i.e., ICPMs Perkin Elmer 6000).

The calibration equipment sheets have been modified now to indicate the instrument being calibrated by model number.

Recommendations:

1. The nonconformance documentation and reporting system is at an indeterminate stage of implementation due to the changes recently made and incorrect forms used in the past. The criteria used and described in the QA Manual need to be carefully evaluated as to what is considered a nonconformance. Once established, training of personnel to the process and forms to be used needs to be performed.

A new QOP has been written to address this issue (QOP-NONCONFO,Rev.1). Personnel have been trained to the process and forms used and this training has been documented.

2. ACTLABS needs to review the actual processes of the laboratory against the described processes in the QA Manual and procedures to make certain they address actual practices. Determine that the data trail from receipt of sample through data obtained from the analysis identifies and captures all required documentation to support the results of the analysis.

The QA Manual has been revised to reflect actual practices and documentation of the data trail and capture of the required documentation to support the results of the analysis. ACTLABS will consider further evaluation and will make appropriate changes to the QA manual related to this issue as appropriate.

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WASHINGTON, D.C.

8 ☑ Corrective Action
☐ Request

NO. YM-96-C-0009
PAGE 5 OF 5
QA: L

CAR/SWO CONTINUATION PAGE

14. Remedial Actions: (continued from page 4).

3. Make sure Certificate of Conformances are signed and dated by a designated and technically qualified individual,

The Certificate of Conformance will be signed by a qualified individual within ACTLABS when the results of the analyses are finalized.

4. Purge the documents located throughout the laboratory to ensure the latest document is the one that is identified as the latest approved version being used and obsolete documents are removed from the system.

The QA Manual has been revised to include this provision.

5. Consideration should be given to filling the position of QA Manager to comply with the requirements in the QA Manual for the responsibilities and duties described for the QA Manager as far as implementation of the QA program.

The position of QA Manager has been filled to comply with the requirements in the QA Manual.

15. Extent of Condition and Impact: (continued from page 1).

calibration, and administrative implementation deficiencies, documenting the actual practice will clear most of the indeterminate status. Resolution and verification of the concerns documented in the Corrective Action Request (CAR)YM-96-C-009 will permit future samples to be analyzed under an approved QA program with emphasis on compliant implementation. Our evaluation indicates that there were no detrimental impacts on the quality of data already produced, because the calibration- and training-related deficiencies concern inadequate documentation and not deficient actual practices that directly impact validity of the data.

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ROOT CAUSE DETERMINATION QUESTIONNAIRE

Refer to Subsection 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. Identify the adverse condition.
   Deficiencies are documented in Audit report OQA-SA-96-021 and CAR-YM-96-C-0009.

2. Indicate *Where* the condition was found.
   Activation Laboratories (ACTLABS), Ancaster, Ontario, Canada.

3. Note *When* the condition was first found.
   DOE OQA audit of ACTLABS on July 29-30, 1996.

4. Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)
   Potential for human interference into waste isolation.

5. Denote the specific area(s) or discipline(s) of the major program element the condition occurred.
   (e.g., engineering, design, ES&H)
   Acceptance of results of procurement of ventor pertinent to scientific investigations: ACTLABS had deficiencies in document control, training records, calibration records of measuring & test equipment.

6. Determine if the condition is isolated or recurring.
   isolated

7. Determine if the condition is hardware (item) or programmatic (procedures, personnel) related or both.
   programmatic (implementation of procedures)

8. Denote what organizations are affected by this condition (M&O, USGS, Weston, OCRWM, etc.).
   OCRWM, Managment and Operating Contractor - University of Nevada, Reno- Nevada Bureau of Mines and Geology

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ROOT CAUSE DETERMINATION QUESTIONNAIRE

9 Document the changes that have taken place that could have caused the condition.
Changes in supervision and personnel (QA manager quit in fall of 1995); deficiencies in implementing QA manual.

10. Determine the need for sketches or photographs.
N/A

11. Determine the need for laboratory tests.
N/A

12. Identify the physical evidence examined.
See audit report No. OQA-SA-96-021, July 29-30, 1996

13. Note the relevant documents reviewed.
See audit report No. OQA-SA-96-021, July 29-30, 1996

14. Document any other information that may be pertinent to supporting the selection of the correct root cause.
N/A

15. Interviews conducted: ☐ Yes ☑ No
If Yes, refer to page 3 of this attachment.

RI or designee: (Print)	Signature:	Date:
Jan C. Rasmussen	Jan C. Rasmussen	10/3/96

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

TELEPHONE OR PERSONAL INTERVIEW RECORD

Person Interviewed: (Print)		Title:	
Organization/Location:	Telephone No.:	Date/Time:	CAR No./DR No.:

Interview Details:
N/A

Interviewer

CAR-YM-96-C-009

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Root Cause Code:	CAR No./DR No.:
1Ca, 2Ad, 3Ab, 3Bc, 4Ac, 5Ba	YM-96-C-0009

Root Cause:

Error in Following Implementing documents - format confusing; Personnel - lack of attention to a task, procedures not used or used improperly; Management system - inadequate communication of standards and controls and not independent; Immediate supervision, preparation, inadequate instructions to subordinates; Inadequate Training Methods, incomplete.

Justification or Rationale for Selected Root Cause:

The isolated deficiencies found during a DOE audit of ACTLABS, Ancaster, Ontario, Canada, on July 29-30, 1996, were documented in Audit report OQA-SA-96-021 and CAR-YM-96-C0009; they appeared to result from the loss of the ACTLABS former QA Manager in the fall of 1995 and from delayed appointment of an independent QA Manager focused on implementation of the QA program. A contributing factor to the deficiences was having a QA Manual that contained extraneous overcommitments; this led to confusion in the implementation of the QA-related aspects of the program. As a result, ACTLABS did not document their actual practices in accordance with appropriate quality assurance discipline.

Designee: (Print)	Signature:	Date:
RI: (Print) Jan C. Rasmussen	Signature: Jan C. Rasmussen	Date: 10/3/96

CAR NO. CAR.YM-96-C-0003.
PAGE 1 OF 4
QA: L

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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:
M&O SPO will modify and update the purchase order with ACTLABS to create their status as augmented staff to the M&O during period of ACTLABS' performance to complete the analytical services on the planned remaining sample analyses. This approach will include ACTLABS implementing M&O procedures throughout the part of the program dealing with Yucca Mountain samples. In implementing this approach on future work, the deficient conditions noted in Supplier Audit report OQA-SA-96-021 are expected to be fully resolved. A Responsible Individual in the SPO will coordinate with ACTLABS and oversee their appropriate implementation of the M&O procedures during additional services. The process of qualifying the existing data will be coordinated with the Quality Assurance Representative. Through the course of these actions, additional data will become available for use in technical assessment, peer review, or reanalysis on a sample basis to enable a full evaluation of the determinacy of existing data that is the subject of this CAR. (see continuation page:)

15 Extent of Condition and Impact:
The audit report states "technical work performed was determined to be satisfactory; however, without full implementation of the QA program, the results of the data are considered to be indeterminate". Specific deficiencies documented above that resulted from inadequate application of the QA procedures that had been required in the QA Manual will be evaluated to determine what can be done to remove the indeterminate status of the data. During the time prior to this audit, 800 samples were processed, including blanks, blind samples, and control samples. These analytical results will be evaluated for qualification in accordance with the projects procedures for qualifying data not produced by a qualified QA program. Because the deficiencies were primarily related to training, calibration, and administrative implementation deficiencies, augmented staff working to the M&O procedures will clear the issues. (see continuation page:)

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached.

17 Action to Preclude Recurrence:

ACTLABS will be held to compliance with the remedial actions listed above before additional YMP samples are submitted for analysis. Appointment of a QA Manager and working to relevant M&O procedures, are expected to prevent recurrence.

18 Corrective Action Completion Due Date:	19 Response by:		
02/03/97	☐ Initial ☑ Amended	Oct 18/96 (Date)	505-648-9611 (Phone)

20 Response Accepted		21 Response Accepted	
QAR	Date	AOQAM	Date

10/18/96 LV.SPO.LRH.10/96-77

CAR NO. CAR YM-96-C-0009
PAGE 1 OF 4
QA: L

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

CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:
M&O SPO will modify and update the purchase order with ACTLABS to create their status as augmented staff to the M&O during period of ACTLABS' performance to complete the analytical services on the planned remaining sample analyses. This approach will include ACTLABS implementing M&O procedures throughout the part of the program dealing with Yucca Mountain samples. In implementing this approach on future work, the deficient conditions noted in Supplier Audit report OQA-SA-96-021 are expected to be fully resolved. A Responsible Individual in the SPO will coordinate with ACTLABS and oversee their appropriate implementation of the M&O procedures during additional services. The process of qualifying the existing data will be coordinated with the Quality Assurance Representative. Through the course of these actions, additional data will become available for use in technical assessment, peer review, or reanalysis on a sample basis to enable a full evaluation of the determinacy of existing data that is the subject of this CAR. (see continuation page:)

15 Extent of Condition and Impact:
The audit report states "technical work performed was determined to be satisfactory; however, without full implementation of the QA program, the results of the data are considered to be indeterminate". Specific deficiencies documented above that resulted from inadequate application of the QA procedures that had been required in the QA Manual will be evaluated to determine what can be done to remove the indeterminate status of the data. During the time prior to this audit, 800 samples were processed, including blanks, blind samples, and control samples. These analytical results will be evaluated for qualification in accordance with the projects procedures for qualifying data not produced by a qualified QA program. Because the deficiencies were primarily related to training, calibration, and administrative implementation deficiencies, augmented staff working to the M&O procedures will clear the issues. (see continuation page:)

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached.

17 Action to Preclude Recurrence:

ACTLABS will be held to compliance with the remedial actions listed above before additional YMP samples are submitted for analysis. Appointment of a QA Manager and working to relevant M&O procedures, are expected to prevent recurrence.

18 Corrective Action Completion Due Date:	19 Response by: ☐ Initial ☑ Amended	See faxed copy Date	Phone
02/03/97			

20 Response Accepted QAR	Date 10/24/96	21 Response Accepted AOQAM	Date 10/31/96

CAR/SWO CONTINUATION PAGE

14. Remedial Actions (continued from page 1):
The item by item discussion on the continuation pages of specific deficiencies indicates how each deficiency will be addressed.

as applied to box 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.

Response: ACTLABS will work with the M&O to fully implement procedures QAP-2-1 and 2-2. Analysis of the resulting indoctrination, training, and qualifications information is expected to verify the adequacy for resolving this condition.

- 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.

Response: Through the process of creating the "augmented staff" status of personnel working on Yucca Mountain samples at ACTLABS, all the requirements of this deficiency will be addressed through implementation of the approved M&O QA procedures. Through the M&O coordination of future work, the deficient items as listed will be resolved by implementation of specific M&O procedures. All pertinent procedures are now in place, except for specific work instructions which will be produced and reviewed in accordance with NLP-5.1, Preparation of Nevada Work Instructions', before remaining work is begun. Document identification, control, and distribution will be performed in accordance with QAP-6-1. The procurement of calibration services will be from suppliers identified on the YMP Qualified Suppliers List, or in accordance with the appropriate M&O procurement procedures. Calibration control will be done accordance with QAP-12-1. QA records produced will be submitted in accordance with QAP-17-1. By being augmented staff, the audit issue will become subject to M&O surveillance procedure QAP-2-5. Information produced through implementation of these procedures will be analyzed by the M&O in qualifying existing data per YAP-SIII.1Q.

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 SaNoncon A do not address the issues of procurement document, Section F2.

Response: The procurement document, Section F2, states "ACTLABS shall submit, to the PI for approval, reports of nonconformances to technical and/or quality assurance requirements in this procurement document whenever the following exist: technical requirements in the description of services are violated, a requirement in this procurement document is violated, or the nonconformance cannot be corrected by reanalyzing the sample." When ACTLABS works to procedures such as AP-16.1Q, AP-16.2Q, and YAP-15.1Q for Yucca Mountain samples, this condition will be corrected.

2. Client name is not included in the worksheets.

Response: Actual practice at the time the Yucca Mountain Project samples were analyzed included the work order number or report number on worksheets rather than the client name, which was cross-indexed to the work order number on file. However, there was no impact to quality because the work order number was on the worksheets and there is no value in correcting the worksheets to include the client name. Through implementing the M&O QA procedures, traceability will be maintained. Furthermore, through M&O SPO overview, emphasis will be given to ACTLABS to ensure performance of work as prescribed in the implementing documents.

CAR/SWO CONTINUATION PAGE

3. Mistakes are sometimes obliterated on worksheets and not initialed (dates also need to be added).

Response: Implementation of the M&O QAP-17-1 will fully prescribe the appropriate records requirements. The importance of properly correcting documentation and additional training will be stressed to reinforce proper implementation of this requirement. Any further deficiencies in the continuing course of ACTLABS' performance will be resolved through QAP-17-1.

4. The QOP SaNoncon forms are in the procedure, but are not being used by the sample receiving personnel.

Response: Appropriate personnel at ACTLABS will be trained on the use of YAP-15.1. If continued deficient implementation of this procedure is found, ACTLABS or the M&O will document the deficiency per YAP-15.1. The use of this procedure and its forms apply to the various elements of ACTLABS contracted scope of performance.

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.

Response: Appropriate training to the M&O QA procedures will impress upon ACTLABS personnel working on Yucca Mountain samples the importance of performing their work in accordance with specifics in the approved procedures. The impacts of past deficiencies will be evaluated during the qualification of the indeterminate data.

6. Calibrations are performed by and monitored by the laboratory manager, not QA Manager. This needs to be changed in the manual.

Response: It is not believed that there is any quality impact from this condition. The issue is a product of the employee changes at the time of the subject work, and that has been corrected. Through implementation of QAP-12-1, this issue will disappear.

7. The list of equipment does not include model and serial number in several cases.

Response: The list of equipment has been revised to include model and serial numbers for all equipment where the numbers are available. Maintenance of the appropriate equipment list now in place will be in conformance with the requirements of QAP-12-1

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.

Response: When ACTLABS comes into compliance with M&O procedures, particularly QAP-12-1 for Yucca Mountain samples, this condition will be corrected. If analysis shows that data quality has been impacted by this condition, the issue will be documented on a nonconformance report and resolved in accordance with YAP-15.1.

CAR/SWO CONTINUATION PAGE

9. The sheets do not indicate the instrument being calibrated, i.e., ICPMs Perkin Elmer 6000.

Response: The calibration equipment sheets have been corrected to indicate the instrument being calibrated by model number.

Recommendations:

Audit Recommendation 1. The nonconformance documentation and reporting system is at an indeterminate stage of implementation due to the changes recently made and incorrect forms used in the past. The criteria used and described in the QA Manual need to be carefully evaluated as to what is considered a nonconformance. Once established, training of personnel to the process and forms to be used needs to be performed.

Response: When ACTLABS works to M&O procedures (such as YAP-15.1Q and QAP-2-1) for Yucca Mountain samples, this condition will be corrected. Personnel will be trained to the process and forms used and this training will be documented.

Audit Recommendation 2. ACTLABS needs to review the actual processes of the laboratory against the described processes in the QA Manual and procedures to make certain they address actual practices. Determine that the data trail from receipt of sample through data obtained from the analysis identifies and captures all required documentation to support the results of the analysis.

Response: ACTLABS will evaluate their sample management process and make appropriate changes to their practices to be within compliance with a NWI prepared for this activity. When ACTLABS works to the M&O procedure (to be prepared) for Yucca Mountain samples, this condition will be corrected.

Audit Recommendation 3. Make sure Certificate of Conformances are signed and dated by a designated and technically qualified individual.

Response: Any Certificate of Conformance will be signed by a qualified individual within ACTLABS when the results of the analyses are finalized.

Audit Recommendation 4. Purge the documents located throughout the laboratory to ensure the latest document is the one that is identified as the latest approved version being used and obsolete documents are removed from the system.

Response: ACTLABS will remove obsolete documents. QAP-6-1 will be implemented for the scope of Yucca Mountain sample analyses in response to this recommendation.

Audit Recommendation 5. Consideration should be given to filling the position of QA Manager to comply with the requirements in the QA Manual for the responsibilities and duties described for the QA Manager as far as implementation of the QA program.

Response: The position of QA Manager has been filled to comply with the requirements in the QA Manual.

15. Extent of Condition and Impact: (continued from page 1).

Resolution and verification of the concerns documented in the Corrective Action Request (CAR)YM-96-C-009 will permit future samples to be analyzed under an approved QA program with emphasis on compliant implementation. Our evaluation indicates that there were no detrimental impacts on the quality of data already produced, because the calibration- and training-related deficiencies concern inadequate documentation and not deficient actual practices that directly impact validity of the data.

Refer to Subsection 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. Identify the adverse condition.
   Deficiencies are documented in Audit report OQA-SA-96-021 and CAR-YM-96-C-0009.

2. Indicate *Where* the condition was found.
   Activation Laboratories (ACTLABS), Ancaster, Ontario, Canada.

3. Note *When* the condition was first found.
   DOE OQA audit of ACTLABS on July 29-30, 1996.

4. Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)
   Potential for human interference into waste isolation.

5. Denote the specific area(s) or discipline(s) of the major program element the condition occurred.
   (e.g., engineering, design, ES&H)
   Acceptance of results of procurement of ventor pertinent to scientific investigations: ACTLABS had deficiencies in document control, training records, calibration records of measuring & test equipment.

6. Determine if the condition is isolated or recurring.
   isolated

7. Determine if the condition is hardware (item) or programmatic (procedures, personnel) related or both.
   programmatic (implementation of procedures)

8. Denote what organizations are affected by this condition (M&O, USGS, Weston, OCRWM, etc.).
   OCRWM, Managment and Operating Contractor - University of Nevada, Reno- Nevada Bureau of Mines and Geology

17 of 23

9 Document the changes that have taken place that could have caused the condition.
Changes in supervision and personnel (QA manager quit in fall of 1995); deficiencies in implementing QA manual.

10. Determine the need for sketches or photographs.
N/A

11. Determine the need for laboratory tests.
N/A

12. Identify the physical evidence examined.
See audit report No. OQA-SA-96-021, July 29-30, 1996

13. Note the relevant documents reviewed.
See audit report No. OQA-SA-96-021, July 29-30, 1996

14. Document any other information that may be pertinent to supporting the selection of the correct root cause.
N/A

15. Interviews conducted: ☐ Yes ☑ No
If Yes, refer to page 3 of this attachment.

RI or designee: (Print)	Signature:	Date:
Jan C. Rasmussen	Jan C. Rasmussen	10/3/96

TELEPHONE OR PERSONAL INTERVIEW RECORD

Person Interviewed: (Print)		Title:	
Organization/Location:	Telephone No.:	Date/Time:	CAR No./DR No.:

Interview Details:
N/A

Interviewer

Root Cause Code:	CAR No./DR No.:
1Ca, 2Ad, 3Ab, 3Bc, 4Ac, 5Ba	YM-96-C-0009

Root Cause:
Error in Following Implementing documents - format confusing; Personnel - lack of attention to a task, procedures not used or used improperly; Management system - inadequate communication of standards and controls and not independent; Immediate supervision, preparation, inadequate instructions to subordinates; Inadequate Training Methods, incomplete.

Justification or Rationale for Selected Root Cause:
DP 10/25/96
The isolated deficiencies found during a DOE audit of ACTLABS, Ancaster, Ontario, Canada, on July 29-30, 1996, were documented in Audit report OQA-SA-96-021 and CAR-YM-96-C0009; they appeared to result from the loss of the ACTLABS former QA Manager in the fall of 1995 and from delayed appointment of an independent QA Manager focused on implementation of the QA program. A contributing factor to the deficiences was having a QA Manual that contained extraneous overcommitments; this led to confusion in the implementation of the QA-related aspects of the program. As a result, ACTLABS did not document their actual practices in accordance with appropriate quality assurance discipline.

Designee: (Print)	Signature:	Date:
RI: (Print) Jan C. Rasmussen	Signature: Jan C. Rasmussen	Date: 10/3/96

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	8 ☑ Corrective Action Request ☐ Stop Work Order NO. YM-96-C-009 PAGE OF QA: L

CAR/SWO CONTINUATION PAGE

Verification actions for YM-96-C-009:

A verification visit was made to ACTLABs on January 9-14, 1997. The following information was obtained either during this visit or subsequently based on commitments made by the M&O as Remedial Action and Extent of Condition and Impact.

1. Training records were found to be incomplete (QAP-2-2) for Verification of Education and Work Experience for John Rajari, Robert Eismont, Xia Li, Dan Sleeth, Maureen Foster, Judy Young, and Donna Cole on 2-5-97. The incomplete paperwork was changed to be acceptable on 2-12-97.

2. The Purchase Order #A02246YS7A, from the M&O to Activation Labs, passed along information for indoctrination and training for initial work to close out this CAR, however, there was no modification to P.O. BA0000000-017-0500-00001-rev00, sent to ACTLABs, dated October 27, 1995, with update to create their status as "augmented staff" as was committed to in the CAR response. A memo was submitted, dated Feb. 13, 1997, explaining the reason for not modifying the P.O. This procurement process is considered unacceptable for compliance to the QARD. The issue will be resolved through CAR YM-97-C-001.

3. Appointment of a QA Manager was verified as Donna Cole on 1-10-97.

4. Procedures were in place, both the NWI-ACT-001, rev. 0, EICN 1, and other procedures as required by the M&O in the reading assignment lists prepared and signed by each person at ACTLABs and McMaster University doing work to the M&O procedures. Verified 1-13-97 and NWI-ACT-001, rev. 0, EICN 1, approved on 1-23-97.

5. The process for qualifying existing data, prepared by ACTLABs prior to verification of an adequate QA program under the QARD, had not been initiated as of 2-5-97. However, this was initiated and verified on 2-11-97.

6. Calibration of equipment used at ACTLABs was observed for the balance used under the procedural process of NWI-ACT-001, and commitment was made to follow the M&O procedure QAP-12-1 for any other calibration work. Reading assignment lists for those persons impacted contained this procedure. Verified 1-13-97.

7. Traceability of client name in worksheets was verified to be included in the Work Order system traceable to the Invoice Number included with the Work Order Traveller and entered in a database system at ACTLABs. Verified 1-13-97.

8. The list of equipment to contain model and serial number is controlled under implementation of QAP-12-1. Verified 1-13-97.

9. Calibration equipment sheet is to indicate the instrument being calibrated by model number. As part of the M&O staff for this part of their scope of work, ACTLABs uses the M&O procedures NWI-ACT-001 to implement calibration of the balance and QAP-12-1 for other calibrations. Since this was a finding of the ACTLABs QA program , and they are now working under the M&O procedural process, this finding is superseded by implementation of these procedures. Verified 1-13-97.

NWI-ACT-001, rev. 0 was changed to EICN 1 DRAFT during the verification visit to ACTLABs 1-10 through 1-14-97. The procedure needed to include more step-by-step process. The process steps that were added were already being performed by ACTLABs personnel, the words just had not been added to the procedure. The reading assignment lists were updated with signature and date by required staff after reading this draft. No substantive changes were made during the approval process performed between the DRAFT 1-14-97 and approval 1-23-97. The QA program was considered to be adequately in place prior to implementation of procedures for irradiation of samples and analytical work .

Stephen D. Harris — Stephen D. Harris

2/13/97 — Date

Information for YM-96-C-009
see item #2 on V ation actions.
S. D. Harris

TRW

TRW Environmental
Safety Systems Inc.

1180 Town Center Drive
Las Vegas, NV 89134
702.295.5400

WBS: 1.2.3.2.8.3.6
QA: N/A

Contract #: DE-AC01-91RW00134
LV.SPO.ATRST.NEB.2/97-005

February 13, 1997

Robert W. Clark, Director
Yucca Mountain Quality Assurance Department (YMQAD)
U.S. Department of Energy
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

Subject: Activation Laboratories, Inc., (ACTLABS) Procurement re Corrective Action Request (CAR) YM-96-C-009

To support the project's Natural Resources site characterization effort, we have been obtaining geochemical analytical services from Activation Laboratories, Inc., Ancaster, Ontario Canada. This service was interrupted as a result of deficiencies identified in Supplier Audit OQA-SA-96-021 which resulted in the issuance of CAR No. YM-96-C-009. We find that the resolution of this CAR, and resumption of the analytical work, has resulted in the need to clarify an issue with the procurement process.

In the course of resolving the CAR response commitments, it became necessary to place a Purchase Order to allow ACTLABS to perform actions necessary to achieve the requirements for closing the CAR within a time dictated by the Project's planned schedule for the study. Under this non-Q Purchase Order, ACTLABS was able to meet the requirements; and upon achieving satisfactory verification onsite by Quality Assurance (QA) personnel from both Management and Operating Contractor and Department of Energy, they were given verbal permission to continue their sample analyses that had been interrupted. The data production began immediately and was barely completed in time to meet the project schedule. Because it was assumed that the processes and controls put in place during the CAR resolution process would continue as applicable to the actual work of obtaining the sample analyses, a modified

Purchase Order was not issued to cover this continued sample geochemical analysis. We have every confidence that ACTLABS performed their analyses in accordance with all the appropriate QA requirements and controls necessary to produce qualified data.

Please direct further coordination of these efforts to Darrell Porter at (702) 295-9167.

Sincerely,

Norma E. Biggar

Norma E. Biggar, Technical Lead for Geology
Site Evaluation Program Operations
Management and Operating Contractor

NEB/DDP/kb

cc:
F. C. Arth, M&O, Las Vegas, Nevada, M/S 423/715
O. J. Gilstrap, M&O, Las Vegas, Nevada, M/S 423/715
S. D. Harris, QATSS, Las Vegas, Nevada, M/S 455/HL-455
L. R. Hayes, M&O, Las Vegas, Nevada, M/S 423/1265
E. Hoffman, ACTLABS, Ancaster, Ontario, Canada
D. D. Porter, M&O, Las Vegas, Nevada, M/S 423/822
J. C. Rasmussen, M&O, Las Vegas, Nevada, M/S 423/822
RPC=2