

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION

QUALITY ASSURANCE SURVEILLANCE REPORT OF

EG&G ENERGY MEASUREMENTS, INC.

SURVEILLANCE NO. YMP-SR-93-001

CONDUCTED OCTOBER 15 THROUGH 16, 1992

PROGRAM ELEMENTS SURVEILLED:

- 1.0 Organization
- 2.0 Quality Program
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, or Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items, Samples, and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

Prepared by: Frank J. Kratzinger Date: 10/23/92
Frank J. Kratzinger
Surveillance Team Leader
Yucca Mountain Quality Assurance Division

Approved by: Donald G. Horton For Date: 10/29/92
Donald G. Horton
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

This surveillance was conducted at the EG&G Energy Measurements, Inc. (EG&G/EM), facilities in Las Vegas, Nevada, on October 15 through 16, 1992, by members of the Yucca Mountain Quality Assurance Division (YMQAD) of the Office of Quality Assurance in accordance with Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Administrative Procedure QAAP 18.3, Revision 3.

The intent of this surveillance was to verify that EG&G/EM has developed the procedures required to implement the requirements of the OCRWM Quality Assurance Requirements Document (QARD) for which EG&G/EM has responsibility and has been described in the EG&G/EM Quality Program Description (QPD).

In addition, another part of the surveillance was to verify the implementation of those procedures for which quality-affecting activities have occurred.

Six Corrective Action Requests (CARs) were issued as a result of this surveillance. Two of the CARs were for requirements contained in the EG&G/EM QPD document and not addressed in the implementing procedures. Four of the CARs were for failure to follow existing implementing procedures. There were no conditions adverse to quality corrected during the surveillance.

With the completed corrective actions to the CARs initiated from this surveillance, EG&G/EM would have an acceptable QA program to implement quality-affecting activities.

2.0 PURPOSE AND SCOPE

The purpose of this surveillance was to verify that EG&G/EM has developed the procedures required to implement the requirements of the OCRWM QARD for which EG&G/EM has responsibility and has been described in the EG&G/EM QPD.

In addition, another part of the surveillance was to verify the implementation of those procedures for which quality-affecting activities have occurred.

3.0 SURVEILLANCE TEAM

Frank J. Kratzinger, Surveillance Team Leader, YMQAD, Las Vegas, Nevada
Charles C. Warren, Surveillance Team, YMQAD, Las Vegas, Nevada

4.0 PERSONNEL CONTACTED DURING THE SURVEILLANCE

Enos H. Baker, QA Specialist III, EG&G/EM
James W. Beckett, Senior Scientist, EG&G/EM
James P. DeMarre, QA Specialist III, EG&G/EM
Carol E. Ezra, Office Manager, EG&G/EM
Vickie Kelly, Administrative Assistant, EG&G/EM
Kent Ostler, Department Manager, EG&G/EM
Joanna L. Wiggins, QA Specialist, EG&G/EM

5.0 SURVEILLANCE RESULTS

5.1 The adequacy of EG&G/EM Quality Procedures (Y100 Series) intended to implement selected requirements of the EG&G/EM QPD were evaluated for the following Quality Program Elements:

- 1.0 Organization
- 2.0 Quality Program
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, or Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items, Samples, and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

The results of this evaluation indicated that for resolution of disputes (Quality Program Element 1.0), identification and control of data (Quality Program Element 8.0), and designation of a Measuring and Test Equipment custodian (Quality Program Element 12.0), EG&G/EM has not developed quality program procedures to describe implementation of these activities as required by the EG&G/EM QPD. These conditions adverse to quality are documented in OCRWM CAR YM-93-005.

The EG&G/EM QPD for Quality Program Element 4.0, requires that changes to procurement documents be evaluated in the same manner as the original. A review of EG&G/EM Quality Program Procedure Y100-072.A excludes the Quality

Assurance Office (QAO) from evaluation and review of changes to subcontracts although QAO was required to review the original purchase acquisition/requisition. This condition adverse to quality is documented in CAR YM-93-006.

In addition to the above evaluation, implementation of the following EG&G/EM Quality Program Procedures was assessed:

- Y100-011.A YMP Interface Control
- Y100-021.A Indoctrination
- Y100-051.A Document Development, Revision, Review, and Approval
- Y100-061.A Document Control
- Y100-161.A Reporting of Conditions Adverse to Quality
- Y100-181.A Independent Assessment

Implementation of procedure Y100-051.A found that the use of Document Review Requests (DRR) and Document Review Sheets (DRS) required by the procedure was not performed during the review of the Y300-051 series quality-affecting procedures. This condition adverse to quality was documented on CAR YM-93-007.

Implementation of procedure Y100-061.A found that document control activities required to be performed by the QAO were being performed by the Responsible Office Manager rather than by the QAO for Y300 series procedures. This condition adverse to quality was documented on CAR YM-93-008.

A review of the implementation of procedure Y100-161.A found that Concern CO-92-010 was issued as a concern when it should have issued as a condition adverse to quality since the reported condition violated a requirement of procedure 28-280.A, Paragraph E.1.A. This condition adverse to quality was documented on CAR YM-93-009.

A review of the implementation of procedure Y100-181.A found that there was no assessment plan as required by the procedure for the assessment Q92-U2-09 of the Yucca Mountain Project conducted 10/7-8/92. This condition adverse to quality was documented on CAR YM-93-010.

Implementation of the following EG&G/EM Quality Program Procedures, could not be evaluated since they have not been implemented for the Yucca Mountain Project activities:

- Y100-027.A Stop Work Authority
- Y100-028.A Management Assessments
- Y100-041.A Procurement Process

Y100-042.A Purchase Requisitions
Y100-071.A Supplier Qualification
Y100-074.A Inspection-Incoming
Y100-122.A Calibration Data Sheet/History Record
Y100-123.A Calibration Intervals
Y100-124.A Equipment Calibration Status Requirements
Y100-125.A Calibration Recall System
Y100-126.A Out-of-Tolerance Notification
Y100-131.A Handling, Storage, and Shipping
Y100-132.A Film Use
Y100-151.A Control of Nonconforming Items
Y100-163.A Tracking and Trending
Y100-171.A Quality Assurance Records
Y100-183.A Supplier Qualifications Assessment Process

Since the EG&G/EM Software Plan has not been approved by the Yucca Mountain Site Characterization Project Office, there was no attempt to evaluate software procedures.

5.2 Synopsis of Corrective Action Requests

The following CARs, which are included for information as Enclosure 1 to this report, were issued:

- YM-93-005 - EG&G/EM implementing procedures do not contain all the requirements imposed by the QPD.
- YM-93-006 - EG&G/EM implementing procedure does not allow for the same organization to review and approve changes to procurement documents.
- YM-93-007 - No DRR or DRS forms were utilized to request and document comments during the review of Y300-051 series Technical Procedures.
- YM-93-008 - QAO did not perform document control functions for the Y300 series procedures.
- YM-93-009 - Concern CO-92-010, issued as a Concern, should have been issued as a Condition Adverse to Quality.

YM-93-010 - There was no assessment plan for the assessment Q92-U2-09 of the Yucca Mountain Site Characterization Project (YMP) conducted 10/7-8/92.

5.3 Deficiencies Corrected During the Surveillance

None.

6.0 RECOMMENDATIONS

6.1 Of the four Concerns which were written as a result of EG&G/EM assessment Q92-U2-09, three were worded such that they appeared to be Conditions Adverse to Quality (CO-92-008, CO-92-009, and CO-92-011).

A further review of the circumstances surrounding the Concerns, indicated that they were recommendations and not Conditions Adverse to Quality.

It is recommended that EG&G/EM's use of making recommendations to eliminate possible future problems through the proceduralized concern format be eliminated and recommendations be included in the text of the assessment report.

6.2 The QAO should involve itself in the review of procurement packages prior to their close-out to further reduce the possibility of errors in the content of the packages. Currently, EG&G/EM procedures do not address this involvement.

ENCLOSURE 1

CORRECTIVE ACTION REQUESTS

ORIGINAL
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO. <u>YM-93-005</u> DATE: <u>10/16/92</u> SHEET: <u>1</u> OF <u>1</u> GA
CORRECTIVE ACTION REQUEST		
1 Controlling Document EG&G/EM QPD, Revision 0		2 Related Report No. YMP-SR-93-001
3 Responsible Organization EG&G/EM		4 Discussed With E. Baker
5 Requirement: <ol style="list-style-type: none"> 1. The EG&G/EM QPD, Section 1.8.1, requires that EG&G/EM identify in procedures the methodology for evaluating disputes regarding differences of opinion involving quality issues ... 2. The EG&G/EM QPD, Section 8.2.1, requires that EG&G/EM procedures establish measures to ensure that data are properly identified and traceable to the source for which the data were generated. 3. The EG&G/EM QPD, Section 12.1, requires that the EG&G/EM procedure shall specify and establish a NIST custodian. 		
6 Adverse Condition: <ol style="list-style-type: none"> 1. Contrary to requirement 1, EG&G/EM has no procedure that addresses the methodology for evaluating disputes. 2. Contrary to requirement 2, EG&G/EM has no Y-100 procedures that address identification and traceability measures for data. 3. Contrary to requirement 3, EG&G/EM has no calibration procedures which specify a NIST custodian. 		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes ___ No <u>X</u> : # Yes - Attach copy of SWO If Yes, Circle One: A B C D
11 Response Due Date: 20 days after issue		
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: Identify the remedial action to correct the deficiencies identified in Block 6 and the planned corrective action to prevent recurrence.		
7 Initiator <u>C.C. Warren</u> <u>C.C. Warren</u> Date <u>10-19-92</u>		14 Issuance Approved by QADD <u>[Signature]</u> <u>for</u> Date <u>10-21-92</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 1

CORRECTIVE ACTION REQUESTS
 (Continuation)

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>IN-93-006</u> DATE: <u>10/16/92</u> SHEET: <u>1</u> OF <u>1</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document EG&G/EM QPD, Revision 0		2 Related Report No. YMP-SR-93-001
3 Responsible Organization EG&G/EM		4 Discussed With C. Ezra, J. DeMarre
5 Requirement: The EG&G/EM QPD, Section 7.6, requires that changes to procurement documents be controlled, evaluated, and processed in the same manner as the original.		
6 Adverse Condition: Contrary to this requirement, EG&G/EM procedure Y100-072.A, section F.11 allows subcontracts to be changed by the buyer and when necessary, approval from the technical representative and quality control. This excludes the evaluation and review by the Quality Assurance Office (QAO) although QAO is required to review original purchase acquisitions and requisitions in accordance with Y100-042.A.		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 days after issue
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: Identify the remedial action to correct the deficiency identified in Block 6 and the planned corrective action to prevent recurrence.		
7 Initiator C.C. Warren <u>CCW</u> Date <u>10-15-92</u>	14 Issuance Approved by: QADD <u>[Signature]</u> Date <u>10-21-92</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 1

CORRECTIVE ACTION REQUESTS
 (Continuation)

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		CAR NO.: <u>YI-93-007</u> DATE: <u>10/16/92</u> SHEET: <u>1</u> OF <u>1</u> GA
CORRECTIVE ACTION REQUEST		
1 Controlling Document EG&G/EH Procedure Y100-051.A		2 Related Report No. YMP-SR-93-001
3 Responsible Organization EG&G/EH		4 Discussed With C. Ezra, E. Baker
5 Requirement: EG&G/EH procedure Y100-051.A, section F.3, requires the use of a Document Review Request (DRR) and a Document Review Sheet (DRS) to request and document comments for document reviews. This procedure also requires that DRR and DRS forms be signed by the reviewer and are considered Quality Assurance Records.		
6 Adverse Condition: Contrary to these requirements, no DRR or DRS forms were utilized to request and document comments during the review of Y300-051 series Technical Procedures. These procedures describe EG&G/EH quality affecting activities.		
8 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 days after issue
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: Identify the remedial action to be taken to correct the deficiency noted in Block 6. Identify the extent of the condition and the planned corrective action to prevent recurrence.		
7 Initiator C.C. Warren <u>C.C. Warren</u> Date <u>10-16-92</u>	14 Issuance Approved by: <u>[Signature]</u> OADD <u>[Signature]</u> Date <u>10-21-92</u>	
15 Response Accepted OAR _____ Date _____	16 Response Accepted OADD _____ Date _____	
17 Amended Response Accepted OAR _____ Date _____	18 Amended Response Accepted OADD _____ Date _____	
19 Corrective Actions Verified OAR _____ Date _____	20 Closure Approved by: OADD _____ Date _____	

ENCLOSURE 1

CORRECTIVE ACTION REQUESTS
 (Continuation)

ORIGINAL
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		6 CAR NO.: <u>YH-93-008</u> DATE: <u>10/16/92</u> SHEET: <u>1</u> OF <u>1</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document EG&G/EM Procedure Y100-061.A		2 Related Report No. YMP-SR-93-001
3 Responsible Organization EG&G/EM	4 Discussed With E. Baker	
5 Requirement: EG&G/EM procedure Y100-061.A, section F.3, 4 and 5 requires QAO to: prepare and distribute procedures and Transmittal/Acknowledgement (T/A) Records, maintain a receipt-tracking checklists to reflect controlled distribution and ensure that all T/A records have been returned, and to ensure that responsible personnel are issued correct and current documents.		
6 Adverse Condition: Contrary to these requirements, QAO has not performed these activities for the Y300 series procedures. These activities were performed by the responsible manager for the Y300 series procedures.		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 days after issue
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: Identify the remedial action to be taken to correct the deficiency noted in Block 6. Identify the extent of the condition and the planned corrective action to prevent recurrence.		
7 Initiator <u>C.C. Warren</u> C.C. Warren Date <u>10-19-92</u>	14 Issuance Approved by: <u>[Signature]</u> QADD Date <u>10-21-92</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 1

CORRECTIVE ACTION REQUESTS
 (Continuation)

ORIGINAL
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YM-93-009</u> DATE: <u>10/16/92</u> SHEET: <u>1</u> OF <u>1</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document EG&G/EM Procedure Y100-161.A		2 Related Report No. YMP-SR-93-001
3 Responsible Organization EG&G/EM	4 Discussed With E. Baker	
5 Requirement: EG&G/EM procedure Y100-161.A, section F.1, states that "Upon discovering a deficiency, EG&G/EM personnel shall inform their immediate supervisor or QA personnel and assist in completion of the Deficiency Level Matrix to determine whether the deficiency should be a Concern, CAQ, or '9QAC."		
6 Adverse Condition: Concern CO-92-010 was issued as a concern, when it should have been issued as a Condition Adverse to Quality (CAQ) since the condition violated a requirement of procedure 28-28C.A, paragraph E.1.A.		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 days after issue
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: Identify the remedial action to correct the deficiency noted in Block 6 and the planned corrective action to prevent recurrence.		
7 Initiator F.J. Kratzinger <i>F.J. Kratzinger</i> Date <u>10/15/92</u>	14 Issuance Approved by: <i>[Signature]</i> Date <u>10-21-92</u>	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
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ENCLOSURE 1

CORRECTIVE ACTION REQUESTS
 (Continuation)

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YM-93-010</u> DATE: <u>10/16/92</u> SHEET: <u>2</u> OF <u>1</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document EG&G/EM Procedure Y100-181.A		2 Related Report No. YMP-SR-93-001
3 Responsible Organization EG&G/EM	4 Discussed With E. Baker, J. Higgins	
5 Requirement: EG&G/EM procedure Y100-181.A, section F.4 states that "The ATL shall prepare an assessment plan and notification letter using the the assessment plan form..."		
6 Adverse Condition: Contrary to the requirement, there was no assessment plan for the assessment 092-02-09 of the YMP conducted 10/7-8/92.		
8 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 days after issue
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: Identify the remedial action to correct the deficiency noted in Block 6 and the planned corrective action to prevent recurrence.		
7 Initiator F.J. Krattinger <i>[Signature]</i> Date <u>10/19/92</u>	14 Issuance Approved By: QADD <i>[Signature]</i> - Date <u>10-21-92</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 _____	