U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT OF

WESTINGHOUSE

GOVERNMENT AND ENVIRONMENTAL SERVICES COMPANY (GESCO)

OAK RIDGE, TENNESSEE

AUDIT NO. HQ-SA-95-001

AUGUST 21 THROUGH AUGUST 25, 1995

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Date: 9/14/95

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Date: 9/21/95

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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Supplier Audit HQ-SA-95-001, the audit team determined that Westinghouse Government and Environmental Services Company (referred to as GESCO) is not satisfactorily implementing its QA program. Although it is an acceptable program as written, the implementation of that program is ineffective. Due to this condition, the audit team can not recommend GESCO for placement on the OCRWM Qualified Suppliers List (QSL) as a qualified supplier. As soon as corrective action has been completed relevant to the described deficiencies, then a re-audit of GESCO will take place to verify corrective actions and to ensure satisfactory implementaton.

In summary, of the ten QA Program Elements audited for adequacy and implementation of procedures, five were determined to be unsatisfactory, two marginal, and three satisfactory.

The audit team identified twenty eight (28) deficiencies, of which thirteen (13) were corrected during the audit (CDA). The CDAs are described in Section 5.5.2 of this report. The remaining identified deficiencies resulted in the issuance of two (2) Corrective Action Requests (CARs), seven (7) Deficiency Reports (DRs), and two (2) Performance Reports (PRs) which are described in Section 5.5.1 of this report. Also, there were four recommendations presented for consideration by GESCO management which are described in Section 6 of this report.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy and the effectiveness of GESCO's implementation of their QA Program. The QA Program Elements and requirements evaluated during the audit, in accordance with the approved audit plan, are as follows:

1.0	Organization
2.0	Quality Assurance Program
4.0	Procurement Document Control
5.0	Instructions, Procedures, Plans, and Drawings
6.0	Document Control
7.0	Control of Purchased Items and Services
15.0	Control of Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
18.0	Audits

The following QA Program Elements were not reviewed during the audit because they have been deemed outside GESCO's scope of responsibility:

3.0 Design Control
8.0 Identification and Control of Items
9.0 Control of Special Processes
10.0 Inspection
11.0 Test Control
12.0 Control of Measuring and Test Equipment
13.0 Handling, Storage, and Shipping
14.0 Inspection, Test, and Operating Status

Requirements were drawn from the GESCO QA Plan, the SEG Quality Management System Manual (and related implementing procedures), the contract Design Procurement Specifications, and the Contract Statement of Work.

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, their assigned areas of responsibility, and observers:

NAME	TITLE/ORGANIZATION	QA PROGRAM ELEMENT
Richard Peck	Audit Team Leader/QATSS	All Elements
Dennis Threatt	Auditor/QATSS	Elements 1,2,5,18
Jack Walsh	Auditor/QATSS	Elements 4,6,17,18
Charles Betts	Auditor/QATSS	Elements 7,15,16,18
Dick Boyt	Observer/TESS	
Doug Franks	Observer/TESS	
Bob Clark	Observer/DOE	
Dennis Reid	Observer/NRC	
Prasanna Kumar	Observer/DOE	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A preaudit meeting was held at the GESCO offices in Oak Ridge, Tennessee on August 21, 1995. A daily debriefing status meeting was held with GESCO management and staff to discuss issues and potential deficiencies. The audit concluded with a post audit meeting held at GESCO'S offices on August 25, 1995. Personnel contacted during the audit are listed in Attachment 1. The list also identifies those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that the GESCO is not adequately and effectively implementing its QA Program. Individually, QA Program Elements 1.0, 5.0, and 6.0 were the only areas found satisfactorily implemented. Implementation of QA Program Elements 2.0, 4.0, 7.0, 16.0, and 18.0 was found to be unsatisfactory; while Elements 15.0 and 17.0 were marginal. Elements 4.0 and 7.0 were found to be unsatisfactory based upon the audit team's review of the procurement process and existing documented deficiencies previously generated by the CRWMS M&O and GESCO. This position was previously established through the Office of Quality Assurance (OQA) observation of M&O Surveillance 95-VIS-36 and the results of that surveillance.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders. However, there were immediate corrective action measures requested of GESCO by OQA concerning the imminent verification activities (audits, surveillances, etc.) that GESCO was preparing to perform in the subsequent weeks. In response to OQA's concern, GESCO issued letter MPC1-L-GES-95-067, dated August 24, 1995. This letter documented actions planned and/or taken to resolve the identified deficiencies in lead auditor/auditor qualifications, nonconformance reporting, corrective action, and training. OQA deemed the actions taken to be constructive and appropriate towards the resolution of significant conditions identified during the audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The details of the audit evaluation, along with the objective evidence reviewed, are contained within the audit checklists. The checklists are kept and maintained as QA Records.

5.4 Technical Activities

Because the audit was conducted to evaluate programmatic adequacy and implementation by GESCO of its QA Program, the audit team did not evaluate any technical activities.

5.5 Summary of Deficiencies

The audit team identified twenty-eight (28) deficiencies; of which thirteen (13) were corrected during the audit.

5.5.1 Corrective Action

As a result of the audit, the following deficiency documents were issued:

Corrective Action Requests (CARs)

CAR HQ-95-C-014

10CFR Part 71, Subpart H, Para. 71.133, requires: "The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management."

GESCO procedure SEG/QA-16.1, titled *Corrective Action*, paragraph 5.1.2 states, "If a deficiency is significant, the Project Manager or the Vice President, QA initiates a CAR."

Contrary to the requirements, the corrective action program as implemented by GESCO is not assuring that the cause of deficient condition(s) and corrective action(s) taken to prevent recurrence are being determined.

CAR HQ-95-C-015

The GESCO QA Plan, section 4.18, states, "Quality Systems shall be audited by qualified and independent personnel in accordance with Part B, Section 15.0, of the Quality Management System Manual and procedures SEG/QA-18.1 and SEG/QA-18.2." Procedure SEG/QA-18.2, para. 5.1.4, states, "The Cognizant Manager approves the qualification of auditors-in-training based on documented training, previous experience, as well as Lead Auditor evaluation."

Procedure SEG/QA-18.2, para. 5.2.3 states, "The Cognizant Manager completes the Lead Auditor Certification Form for each Lead Auditor candidate and attaches documentary evidence to the form."

Contrary to the requirements, there was no objective evidence of Cognizant Manager approval for the qualification of two auditors, qualification records did not contain objective evidence of previous experience or Lead Auditor evaluation, the Lead Auditor Certification Forms for five individuals did not have documentary evidence attached to provide evidence of the required education and/or experience and there was no objective evidence available to verify audit participation for three individuals.

Deficiency Reports (DRs)

DR HQ-95-D-002

GESCO procedure SEG/QA-15.1, *Nonconformance Reporting*, paragraph 5.9, states, in part, that "The manager or supervisor assigned responsibility for corrective action by QA conducts an investigation to determine the root cause of the deficiency and the appropriate corrective action to prevent recurrence. The results of the investigation is documented on the NCR form in Section 3."

GESCO procedure SEG/QA-16.1, *Corrective Action*, paragraph 5.4.1, states, that "The Department/Project Manager coordinates the investigation of a deficiency to determine the root cause and assist in the development of measures to prevent recurrence with the responsible organization and Vice President, QA."

Contrary to the requirements, root cause evaluations are not being conducted and documented on GESCO's NCR/CAR forms as required, nor is the criteria used in determining the root cause of deficiencies defined in either of the above GESCO procedures. In addition, SEG's audit program does not identify the criteria used in determining the cause of deficiencies documented on the Audit Finding Form.

DR HQ-95-D-003

GESCO procedure SEG/QA-17-2, titled, *Preparation and Storage of Records*, paragraph 5.4 states, in part "...the records are entered into storage and maintained in the records retrieval database." Paragraph 5.8.1 states, in part "...the Records Index (RI) contains all the information to be entered into the records retrieval database..."

Contrary to the requirements, there was no objective evidence that records are being maintained in the records retrieval database.

DR HQ-95-D-004

GESCO procedure SEG/QA-17.2, titled, *Preparation and Storage of Records*, paragraph 5.5.1 states, "The Record Index (RI) is completed by the Department/Project Personnel."

Contrary to the requirement, a review of a sample Completed Record Index Forms from the Document Control Department, Engineering Department, and Health Physics Department revealed that the Record Index Form was not being completed and was missing required information. Examples of missing information include Department Name, Title Number, Quality Record, Expiration Date, and Storage Type.

DR HQ-95-D-005

GESCO procedure SEG/QA-16.1, titled *Corrective Action*, paragraph 4.1 states that "Adverse conditions affecting items governed under the NRC are evaluated in accordance with SEG/QA-15.2 to determine if reporting requirements in accordance with 10CFR Part 21 are applicable."

Contrary to the requirements, Audit Findings Reports are not required to be reviewed for 10CFR Part 21 reportability. In addition, objective evidence of the evaluation to determine the 10CFR Part 21 reportability requirements of CAR Nos. 95-002 and 95-003 did not exist.

DR HQ-95-D-006

The GESCO QA Plan, section 2 states, "GESCO Phase 1 activities and responsibilities shall be controlled consistent with the Scientific Ecology Group (SEG) Quality Management System Manual, Revision 4, and the Implementing Line Procedures referenced in Appendix 2 of this QAP."

Procedure SEG/QA-2.1, paragraph 4.1 states, "The Department Manager is responsible for:

- Designating a Department Training Coordinator and Department Instructor(s).
- Developing and maintaining a Department Task List and Department Training Plans.
- Ensuring that personnel are trained per Department Training Plans, training is approved using approved lesson plans, and Department Instructor(s) is qualified to perform training."

Contrary to the above requirements, training for the Westinghouse/GESCO MPC Project was conducted without approved lesson plans and there was no objective evidence to indicate that Instructors were designated or qualified.

DR HQ-95-D-007

The GESCO QA Plan, section 4.5, states, "GESCO plans, procedures, and instructions issued in support of this project shall be controlled and approved in accordance with Part B, section 2.0, of the Quality Management System Manual and procedure SEG/QA-5.1."

Procedure SEG/QA-5.1, para. 5.2.2, states, "The Procedure Coordinator ensures the document is reviewed and comments are returned to the Originator in a timely fashion. Reviewers are not to be an Originator nor have prepared the sections to be reviewed."

Contrary to the requirements, plans and procedures issued in support of the

MPC Project were signed indicating completion of reviews by persons who were also the Originators. The following procedures were specifically identified with this discrepancy:

MPC-CD-02-001, Rev. 1, Quality Assurance Plan

MPC-CD-02-004, Rev. 0, Project Management Plan

MPC-CD-02-010, Rev. 0, GESCO/SEG Quality Assurance Interface Document

MPC-CD-02-011, Rev. 0, Stop Work Authorization

MPC-CD-02-012, Rev. 0, GESCO Document Review

DR HQ-95-D-008

The SEG Quality Management Systems Manual, Part B, section 15.0, states, "Audits are performed by personnel qualified in accordance with SEG approved procedures."

SEG procedure SEG/QA-18.2, section 6, states, "Training records, qualification documentation, results of examinations, documentation of prior experience and education, performance evaluation reports, executed copies of the Lead Auditor Certification Form, and letters of certification/memos of re-certification are maintained for each Auditor/Lead Auditor in accordance with the applicable records storage procedure."

Contrary to the requirements, an individual performed activities as a Lead Auditor prior to completion of the Lead Auditor Certification Form and Lead Auditor Certification Forms were not completed according to record keeping requirements in that corrections were made using "white-out."

Performance Reports (PRs)

PR HQ-95-P-002

GESCO procedure SEG/QA-15.1, titled *Nonconformance Reporting*, paragraph 5.14 states that "Corrective Action is typically to be completed within 30 days. When corrective action becomes delinquent, the Vice President, QA contacts the responsible Vice President or other appropriate top-level manager for action or to determine a reasonable time period for completion."

Contrary to the requirement, delinquent corrective actions are not being presented to GESCO's responsible Vice President or other appropriate manager for action to determine a responsible time period for completion.

PR HQ-95-P-003

The statement of work for the MPC contract identifies Phase 1 of the contract to be for Safety Analysis Report Design.

Contrary to the contract, the GESCO Quality Assurance Plan for Phase 1 indicates in Section 4.3 that Design Control is not applicable to the GESCO scope of work.

5.5.2 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and only require remedial action may be corrected during the audit. The following deficiencies were corrected during the audit:

1. MPC-CD-02-010 - During review of the GESCO/SEG Quality Assurance Interface Document, Revision 0, it was noted that paragraph 7.33, SEG/QA-18.3, *Management Assessment*, stated that management assessments are not required by 10CFR71; therefore this procedure does not apply to GESCO. 10CFR71, Subpart H, Section 71.105, contains the requirement that the licensee shall review the status and adequacy of the QA program at established intervals. Also, the GESCO QA Plan, Section 4.2, requires that the QA Manager assess the adequacy of implementation of the quality plan throughout the duration of the project. The GESCO/SEG Quality Assurance Interface Document was revised during the audit to include provisions for management assessments.

2. MPC-CD-02-010 - During review of the GESCO/SEG Quality Assurance Interface Document, Revision 0, it was noted that paragraph 7.34, *Stop Work Authorization*, and paragraph 7.35, *Document Review*, indicated that the documents were stand alone procedures for GESCO use in implementing portions of the QA program. The GESCO/SEG Quality Assurance Interface Document was revised during the audit to indicate that the documents were supplement procedures issued in accordance with the SEG QA Program.

3. SEG/QA-4.1 - There was no evidence that Technical and QA Reviews had been performed on Change Notices to POT 86-RCB-18524 and 86-RCB-18525. This was corrected on August 24, 1995, by the Project Administrator preparing new Change Notices for 86-RCB-18524 and 86-RCB-18525 and obtaining the required technical and QA Reviews.

4. SEG/QA-6.1 - There was no evidence that a Document Change

Notice (DCN) had been prepared for Revision 3 to SEG/QA-2.1. This was corrected on August 22, 1995, by issuance of DCN 95-547.

5. SEG/QA-6.1 - There was no evidence of an Access List posted on the file cabinet containing Document Changes Notices. This was corrected on August 25, 1995, by placing an access list on the file cabinet.

6. SEG/QA-6.1 - An incorrect DCN number had been entered on the cover sheet of QAP-129, Revision 1. This was corrected on August 23, 1995, by placing the correct DCN number on the cover sheet and reissuing the cover sheet to all applicable document holders.

7. SEG/QA-15.1 - SEG's President had not been placed on the Distribution List for the Quality Assurance Action Item Listing as required by Paragraph 5.1.1 of SEG/QA-15.1. On August 23, 1995, a new Monthly NCR Status Distribution List was generated that included SEG's President's name.

8. SEG/QA-15.1 - The Quality Assurance Action Item Listings had not been generated and issued to SEG's senior management for the months of June and July as required by Paragraph 5.1.1 of SEG/QA-15.1. On August 23, 1995, a memorandum was issued to file from SEG's NCR Coordinator explaining the reasons why the monthly status reports had not been issued. SEG's Quality Assurance Department was upgrading to a new software and all the old data had to be entered into the new software manually.

9. SEG/QA-15.2 - The 10CFR Part 21 postings at several locations throughout SEG's Oak Ridge, TN facilities made reference to a procedure that no longer existed (SEG/QA-2.3). On August 22, 1995, a memorandum was issued to the Vice President, QA informing her that as of 3:00 p.m. on August 22, all 10CFR Part 21 posting documents at the SEG Oak Ridge, TN facilities had been corrected. The above was satisfactorily verified by reauditing the deficient postings.

10. SEG/QA-15.1- The NCR log that SEG maintains to track MPC related deficiencies was not being maintained current. This concern was addressed and subsequently corrected by SEG's NCR Coordinator, by reviewing all NCRs issued and generating a more comprehensive MPC specific NCR log. This was satisfactorily verified by auditing the revised SEG Nonconformance Reports Log.

11. SEG/QA-17.1 - There was no evidence that Records Flow Schedules (RFSs) had been prepared for the MPC Document. This was corrected on August 25, 1995, when a draft copy of RFSs were submitted to MPC Department Managers by the MPC Program Manager for review and comment.

12. SEG/QA-17.1 - There was no evidence that access to Quality Records (e.g., NCRs, Surveillance Reports, Quality Trend Reports) was controlled. This was corrected on August 24, 1995, by moving the file cabinet containing the NCRs, Surveillance Reports, and Quality Trend Reports to a controlled area; adding a locking device; and posting an access list onto the file cabinet.

13. SEG/QA-4.1 - There was no evidence that copies of Procurement Documents were being mainlined in accordance with SEG/QA-17.1, *Quality Records Management*. This was corrected on August 25, 1995, by the Project Administrator submitting copies of the following Procurement Documents to the appropriate records file:

    POT 86-RCB-18524
    POT 86-RCB-18525
    POT 86-RCB-18526
    POT 86-RCB-18527
    POT 86-RCB-18528
    POT 86-FCB-18522
    POT 86-FCB-18523

    Change Notice for POT 86-RCB-18524
    Change Notice for POT 86-RCB-18525

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by GESCO management:

1. It is recommended that Purchase Requisitions and Purchase Orders clearly identify all attachments.

2. It is recommended that a legend be attached to each pareto chart included in the SEG Trend Reports so that the user could more easily interpret the information being presented.

3. It is recommended that forms associated with procedures be controlled, so as to eliminate the confusion created when using multiple versions of the same form.

4. It is recommended that all active record files be consolidated into one location.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

ATTACHMENT 1
Personnel Contacted During the Audit

				MEETINGS	
NAME	ORGANIZATION/TITLE		CONTACT	PRE	POST
C. Betts	QATSS	Auditor	x	x	x
D. Boyt	M&O	Observer		x	x
R. Clark	DOE	Observer, HQAD			x
J. Fillmore	SEG	Doc. Contrl Admin. Asst.	x		
D. Franks	M&O	Observer		x	x
K. Gordon	SEG	Records/Security Analyst	x		
L. Hodges	SEG	Mgr, Quality Verification	x	x	x
J. Hopper	GESCO	Program Manager		x	
T. Huling	SEG	Doc. Contrl Admin. Asst.	x		
M. Kavchak	SEG	VP, Quality Assurance	x	x	x
P. Kumar	DOE	Observer		x	
D. Lewis	SEG	Quality Specialist	x		
R. Mitchell	SEG	Quality Specialist	x		
M. Mitchell	SEG	Project Administrator	x	x	x
R. Peck	QATSS	Audit Team Leader	x	x	x

ATTACHMENT 1
Personnel Contacted During the Audit

				MEETINGS	
NAME	ORGANIZATION/TITLE		CONTACT	PRE	POST
J. Pride	SEG	Executive VP	x	x	x
D. Reid	NRC	Observer		x	x
C. Ross	GESCO	Project QA Manager	x	x	x
B. Roy	SEG	VP, Engineering			x
D. Threatt	QATSS	Auditor	x	x	x
J. Walsh	QATSS	Auditor	x	x	x

ATTACHMENT 2
Summary Table of Audit Results

AUDIT HQ-SA-95-001 DETAIL SUMMARY								
ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	HQAD CARs	CDA	HQAD PR/DR	RECOMM	COMPLIANCE	OVERALL
1	QA PLAN SECTION 4.1	Pgs. 1-3						SAT
	QMSM PART A SECTION 1.0	Pg. 4						
2	QA PLAN SECTION 4.2	Pgs. 1-3		No. 1,2	95-P-003			UNSAT
	QMSM PART A SECTION 2.0	Pgs. 3-5						
	SEG/QA-2.1	Pgs. 5-7			95-D-006			
	SEG/QA-2.2	Pgs. 7-8						
4	QA PLAN SECTION 4.4	Pgs. 1-2						UNSAT*
	SEG/QA-4.1	Pgs. 3-8		No.3				

ATTACHMENT 2
Summary Table of Audit Results

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	HQAD CARs	CDA	HQAD PR/DR	RECOMM	COMPLIANCE	OVERALL
5	QA PLAN SECTION 4.5	Pgs. 1-3						SAT
	QMSM PART B SECTION 2.0	Pgs. 4-5						
	SEG/QA-5.1	Pgs. 6-8			95-D-007			
6	SEG/QA-6.1	Pgs. 1-8		No. 4,5,6		No. 1		SAT
7	QA PLAN SECTION 4.7	Pgs. 1-2						UNSAT*
	QMSM PART B SECTION 4.0	Pgs. 3-4						
	SEG/QA-7.2	Pgs. 5-9						
	SEG/QA-7.3	Pgs. 9-11						

ATTACHMENT 2
Summary Table of Audit Results

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	HQAD CARs	CDA	HQAD PR/DR	RECOMM	COMPLIANCE	OVERALL
15	QA PLAN SECTION 4.15	Pg. 1						MARGINAL
	QMSM PART B SECTION 11.0	Pg. 1						
	SEG/QA-15.1	Pgs. 2-5		No. 7, 8	95-D-002 95-P-002			
	SEG/QA-15.2	Pgs. 6-8		No. 9				
	SEG/QA-15.3	Pg. 9		No. 10		No. 2		
16	QA PLAN SECTION 4.16	Pg. 1						UNSAT
	QMSM PART B SECTION 12.0	Pg. 1						
	SEG/QA-16.1	Pgs. 2-9	95-C-014		95-D-005	No. 3		
17	QA PLAN SECTION 4.17	Pg. 1						MARGINAL
	SEG/QA-17.1	Pgs. 2-5		No. 11,12,13				
	SEG/QA-17.2	Pgs. 6-13			95-D-003 95-D-004	No. 4		

ATTACHMENT 2
Summary Table of Audit Results

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	HQAD CARs	CDA	HQAD PR/DR	RECOMM	COMPLIANCE	OVERALL
18	QA PLAN SECTION 4.18	Pg. 1						UNSAT
	QMSM PART B SECTION 15.0	Pgs. 2-3						
	SEG/QA-18.1	Pgs. 3-8						
	SEG/QA-18.2	Pgs. 8-11	95-C-015		95-D-008			
TOTAL		89 pages	2	13	2/7	4		UNSAT

CARs ..... Corrective Action Requests
CDA ..... Corrected During Audit
PR/DR ..... Performance/deficiency Report
RECOMMEND . Recommendations
COMPLIANCE . Procedures Implemented
OVERALL..... Summary of Element

* (note)..... Elements four and seven were determined to be unsatisfactory based upon the corroboration by the audit team of seven existing deficiencies generated by the CRWMS M&O and GESCO.