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U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

SCIENCE APPLICATIONS INTERNATIONAL CORPORATION

LAS VEGAS, NEVADA

AUDIT YMP-93-05
FEBRUARY 1-4, 1993

Prepared by: Robert B. Constable Date: 03.15.93
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Donald G. Horton
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ENCLOSURE

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMP-93-05, the audit team determined that Science Applications International Corporation (SAIC) is satisfactorily implementing an effective QA program in accordance with the Technical and Management Support Services (T&MSS) Quality Assurance Program Description (QAPD) document and implementing procedures for QA Program Elements 4.0, "Procurement Document Control," 7.0, "Control of Purchased Items and Services," 10.0, "Inspection," 14.0, "Inspection, Test and Operating Status," 15.0, "Control of Nonconforming Items," 19.0, "Software Quality Assurance," and 20.0, "Scientific Investigation Control."

There was no implementation for QA Program Elements 3.0, "Design Control" and 8.0, "Identification and Control of Items, Samples and Data."

The technical portion of the audit revealed no discrepancies and technical activities evaluated, were considered to be satisfactorily implemented.

The audit team identified three deficiencies during the course of the audit. All of these deficiencies were corrected prior to the post-audit meeting.

2.0 SCOPE

The audit evaluated compliance to and the effectiveness of the T&MSS QA Program as described in the T&MSS QAPD, Revision 7, and implementing quality and technical procedures.

The QA program elements/requirements evaluated during the audit, in accordance with the published audit schedule, were:

QA PROGRAM ELEMENTS

- 3.0 Design Control
- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items, Samples, and Data
- 10.0 Inspection
- 14.0 Inspection, Test and Operating Status
- 15.0 Control of Nonconforming Items
- 19.0 Software Quality Assurance
- 20.0 Scientific Investigation Control

The following QA program element was not reviewed during the audit because T&MSS has no activities to which this QA program element applies:

- 11.0 Test Control

TECHNICAL AREAS

Work Breakdown Structure (WBS) Number	Title
1.2.13.4.2	Air/Quality/Meteorology

3.0 AUDIT TEAM AND OBSERVERS

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

Individual	QA Program Element/Requirement or Technical Area
Robert B. Constable, Audit Team Leader, Yucca Mountain Quality Assurance Division (YMQAD)	
Donald J. Harris, Auditor, YMQAD	4, 7, and 8
Frank J. Kratzinger, Auditor, YMQAD	10, 14, and 15
John R. Matras, Auditor, YMQAD	19
Kenneth T. McFall, Auditor, YMQAD	20
Dale S. Ambos, Technical Specialist, U.S. Geological Survey	WBS 1.2.13.4.2
Donald Chery, Observer, U.S. Nuclear Regulatory Commission (NRC)	
John W. Gilray, Observer, NRC	
Kenneth Hooks, Observer, NRC	
Bruce Mabrito, Observer, NRC	
Englebrecht von Tiesenhausen, Observer, Clark County	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at T&MSS offices in Las Vegas, Nevada, on February 1, 1993. A daily debriefing and coordination meeting was held with T&MSS management and staff, and daily audit team/observer meetings were held to discuss issues and potential deficiencies. The audit was concluded with a post-audit meeting held at T&MSS offices in Las Vegas, Nevada, on February 4, 1993. Personnel contacted during the audit are listed in Attachment 1 to this report. The list includes an indication of those who attended the pre- and post-audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, in general, the QA program for T&MSS was being fully implemented and for this reason was determined to be satisfactory except for the following QA program elements.

- There was no implementation for QA Program Elements 3.0, "Design Control," 8.0, "Identification and Control of Items, Samples and Data," and 11.0, "Test Control."

5.2 Stop Work or Immediate Corrective Actions or Additional Actions

None

5.3 QA Program Audit Activities

Details of the QA program audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

5.4 Technical Activities

The study plan for meteorological monitoring, selected supporting procedures, and data products were examined during the audit. Scientific personnel demonstrated through knowledge of the objectives of this study and are executing the technical tasks outlined in the plan in a satisfactory manner.

Details of technical areas examined during the audit are provided in Attachment 2.

5.5 Summary of Deficiencies

The audit team identified three deficiencies during the audit. All three deficiencies were corrected prior to the post-audit meeting. Therefore, there were no Corrective Action Requests (CAR) issued as a result of the audit. A synopsis of deficiencies corrected during the audit are identified below.

5.5.1 Corrective Action Requests

None

5.5.2 Deficiencies Corrected During the Audit

A deficiency which is considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. T&MSS procedure Work Instructions WI-QA-008, Revision 0, Paragraph 4,4, "Certification of Inspection Personnel," requires that the QA Manager provide the Training Department with inspector certifications and associated documentation for the purpose of tracking training requirements and recertification dates for QA personnel. This requirement was not being complied with.

   It was determined that the above requirement is inappropriate and should not have been stated in a procedure. Interim Change Notice (ICN) 1 to procedure WI-QA-008, Revision 0, was issued to remove the above requirement from the procedure.

2. T&MSS procedure Standard Procedure SP 1.23, Revision 4, Paragraph 5.8.1.h, "Nonconformance Reporting," requires that Conditional Release Numbers be included in the Nonconformance Report (NCR) Log.

   Contrary to this requirement, Conditional Release Numbers, when applicable, were not included in the NCR Log reviewed during the audit. This deficiency was corrected during the audit by adding Conditional Release Numbers to the NCR Log.

3. T&MSS procedure SP 1.25, Revision 5, ICN 1, "Acceptance of Items and Services," requires an annotation in the remarks section of the Receiving Inspection Reports (RIR) to indicate that an Accept Tag was attached to items.

   Contrary to this requirement, required annotations were not being made in the remarks section of RIRs. This requirement was determined to be unnecessary and was deleted during the audit by issuance of ICN 2 to SP 1.25, Revision 5.

5.5.3 Follow-up of Previously Identified CARs

None, all CARs previously issued to T&MSS have been closed.

6.0 RECOMMENDATIONS

The following recommendation resulted from the audit and is presented for consideration by T&MSS management.

Currently, SP 1.28, Revision 6, ICNs 1 and 2, Section 6.0, "Records," contains form N-QA-107. However, Section 7.2, "Forms referenced in this procedure," does not list form N-QA-107. It is recommended that form N-QA-107 be included in Section 7.2 at the next revision of the procedure.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Audit Details
Attachment 3: List of Objective Evidence Reviewed During the Audit

ATTACHMENT 1

Personnel Contacted During the Audit

Name	Organization/Title	Pre-audit Meeting	Contacted During Audit	Post-audit Meeting
Bostian, R. S.	SAIC/APM	X		
Brown, J. R.	SAIC/Procurement	X	X	X
Chandler, D. K.	SAIC/Deputy Proj. Mgr.	X		
Clark, J. E.	SAIC/REFP	X	X	X
Conway, Z. J.	SAIC/Site Technician		X	
Croft, L. D.	SAIC/Mgr. EFPD	X	X	X
Donaldson, G. A.	SAIC/M&TE Custodian		X	
Estella, J. W.	SAIC/Staff Advisor			X
Foley, M. I.	SAIC/Senior Staff	X		
Fransioli, P.	SAIC/Meteorologist	X	X	X
Gonzales, J. R.	SAIC/APM	X		X
Harbert, K. R.	SAIC/SQA Analyst	X	X	X
Harper, J. B.	SAIC/QA Mgr.	X	X	X
Harris, M. W.	SAIC/APM, ERP	X		X
Helms, R. G.	SAIC/Senior Staff	X		
Johnson, K. B.	SAIC/Dept. QA Mgr.	X	X	X
Jones, G. W.	SAIC/Site Technician		X	
Keele, R. P.	SAIC/QA Advisor			X
Keyes, A. E.	SAIC/Purchasing Mgr.	X	X	X
Lee, D. D.	SAIC/CM		X	
MacNabb, W. V.	SAIC/Division Mgr.	X		
Malone, Mike	SAIC/Quality Engineer			X
Moran, T. A.	SAIC/Site Technician		X	
Nolan, S. P.	SAIC/Audits Supervisor			X
Osenbaugh, W. E.	SAIC/Procurement Sr. Buyer	X	X	X
Pelletier, J. F.	SAIC/QA Specialist		X	X
Prince, J. K.	SAIC/RFPD Mgr.	X	X	
Prowell, G. H.	SAIC/Meteorologist	X	X	X
Rinderman, R. R.	SAIC/Lead Quality Engineer	X	X	X
Rochester, V. M.	SAIC/ISD Mgr.	X		
Sorensen, C. D.	SAIC/REFP Mgr.	X	X	X

Personnel Contacted During the Audit
(Continuation)

Name	Organization/Title	Pre-audit Meeting	Contacted During Audit	Post-audit Meeting
Spence, R. E.	DOE/Director YMQAD			X
Tait, T. D.	SAIC/APM	X		
Temple, A. L.	SAIC/QA Specialist		X	
Weaver, J. D.	SAIC/APM	X		

APM = Assistant Project Manager
CM = Configuration Management
DOE = U.S. Department of Energy
EFPD = Environmental Field Programs Department
ERP = Environmental and Regional Programs
ISD = Information Systems Department
M&TE = Measuring and Test Equipment
RFPD = Radiological Field Program Division
REFP = Radiological/Environmental Field Programs
SQA - Software Quality Assurance

ATTACHMENT 2

Audit Details

The following is a summary of the QA program activities covered during the audit. A list of objective evidence reviewed, by document identification and title, is given in Attachment 3.

3.0 DESIGN CONTROL

There was no activity in this QA program element for the timeframe of the scope of this audit. Therefore, QA Program Element 3.0 is considered as no implementation.

4.0 PROCUREMENT DOCUMENT CONTROL

The evaluation of this QA program element was based on the examination of objective evidence to determine compliance with selected requirements taken from implementing procedure SP 1.28. The selected requirements are listed below:

- The purchase package shall consist of the Purchase Requisition (PR) Form 1-932-023, checklist for Preparation/Review of Quality Affecting Procurement Documents (TMSS/293) and a procurement quality specification based on the requirements indicated on Form TMSS/293.

- The Responsible Manager and QA Representative shall review the procurement package and sign and date the package.

- The correct project number shall be entered and appropriate management level approved the PR package (reference signature authority matrix).

- The potential supplier shall be identified on the Qualified Supplier's List (QSL) prior to issuance of the procurement document.

- The Purchase Order (PO) shall be consistent with the requirements of the PR and bid analysis, and shall be reviewed by the requester or Contract Administration Manager, and documented the review on the PO review section of the checklist.

- QA shall review the PO to ensure the QA requirements are consistent with the PR and the PO and checklist shall be signed and dated by QA.

- Upon issuance of a subcontract/PO for support services, technical advisory service, or professional service work, the procurement organization shall provide the training manager the names of the responsible technical organization and each individual identified to perform work.

- If non-administrative changes/cancellations are necessary, the original PR form shall be changed in pen and ink and initialed and dated by the requester. If canceled, line through PR and mark "canceled" and return PR to purchasing.

- Additional management approval signature(s) shall be required when changes cause the purchase value to exceed the signature authority of the previous signatories.

- Initials and dates of persons or their representatives reviewing the original requirement for technical and QA acceptability shall be included for changes.

- When changes/cancellations are necessary after the PO award, when the proposed changes modify the cost, technical or QA requirements of the items or services requested, and the items or services have not been shipped or performed by the supplier at the time of the proposed changes, a PR which details the changes shall be processed in the same manner as the original PR. The new PR shall indicate clearly that it is a change order and shall indicate the original PO number on the face of the document.

- When there is a cancellation due to a suppliers removal from the QSL, the requester shall evaluate the impact of the procurements on quality.

- Where the procurement involves a violation of the QA program, the requester shall document and process the deficiency in accordance with Administrative Procedure AP-1.37. If the procured item or service involves a nonconformance, it shall be documented and processed as a nonconformance in accordance with SP 1.23.

- When the procurement organization is verbally notified to have a supplier cease work by the requester, procurement contacts and instructs the supplier to cease work until further notice. Upon receipt of an approved PR, the procurement organization shall process the PR package in accordance with this procedure.

- QA monitors the extent of verification activities, i.e., source inspections, surveillances and audits, including designated hold points and notification time. These verification activities shall be conducted as early as practicable in the life of the contract.

- The responsible technical organization coordinates with the QA Manager to assure qualified personnel perform appropriately identified verification activities, such as inspections (including verification of critical characteristics), surveillances and audits during the period of contract performance.

- QA shall conduct the required performance evaluations of suppliers on the QSL to determine supplier's QA program effectiveness.

- QA/requester performed receipt inspection and acceptance of items or services in accordance what SP 1.25.

- QA notifies procurement when PO package can be closed and forwards to procurement any documentation needed to support closure.

- Procurement, upon receipt of documentation for PO closure, compiles the records to close the PO and transmits to the Local Records Center (LRC).

- The procurement records package shall include the following:

  - The Procurement Requisition Package shall consist of:

    1) SAIC Form 1-932-023, PR (include changes/cancellations)

    2) Form N-QA-107 (as applicable)

    3) Form TMSS/293, Standard Quality Assurance Clauses (was not established until Revision 5)

    4) Technical requirements or technical basis/justification for QA and QA Commercial-Grade Items and Services procurement (as applicable)

    5) Form TMSS-008, checklist for Preparation/Review of Quality Affecting Procurement Documents

  - PO, SAIC Form 9-932-018 (include changes/cancellation).

  - Requested supplier QA documentation, including acceptance of requirements.

  - Supplier generated NCRs.

  - RIR (as applicable).

  - Basis for Acceptance of Services (as applicable).

Based on verification of compliance to the requirements listed above, QA program Element 4.0 was considered to be satisfactorily implemented.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

The evaluation of this QA program element was based on the examination of objective evidence to determine compliance with selected requirements taken from the following implementing procedures: Operating Procedures OP 1.3, OP 1.7, SP 1.25, SP 1.65, SP 1.72 and WI-QA-006. The selected requirements are listed below.

OP 1.3

- A supplier evaluation audit in accordance with OP 1.1, "Quality Assurance Audits," shall be performed for each supplier.

- When a supplier evaluation audit was not performed, Block 16 of the Supplier Evaluation Report (SER) shall be annotated to explain the reason for not performing the audit and specific action or inspection performed to assure compliance with SP 1.28.

- Appropriate elements of forms TMSS/018 or TMSS/019/10, shall be evaluated based on the requirements of the procurement documents.

- The QA Manager shall sign Block 17 of the SER to signify approval of the information.

- SER TMSS/016, in addition to the appropriate audit report, shall document the results of the supplier audit.

- Suppliers shall be re-evaluated annually for those suppliers shown on the QSL in accordance with OP 1.7.

- The following indicators or attributes shall be considered when performing the annual supplier evaluations:

  - Status of current QA program and procedures
  - Status of national certificates
  - Supplier correspondence (Technical)
  - Trend indicators, RIRs, past acceptance testing, and NCRs
  - Previous audits and surveillances
  - Available industry information

- The annual supplier evaluations shall be documented on the SER.

- That for unfavorable annual evaluations, that the using organization and purchasing shall be notified.

- Suppliers qualified by audit shall be re-scheduled for a triennial audit based on the date of the original audit.

- QA records packages shall be submitted to the LRC and that the package contains an SER, as a minimum and as applicable.

- Supplier Evaluation Checklist Cover Sheet (TMSS/017)
- Supplier Evaluation Checklist (Items) (TMSS/018)
- Supplier Evaluation Checklist (Calibration Services) (TMSS/019)

OP 1.7

- The QSL shall be arranged in alphabetical order and consists of QSL, Form TMSS/004, Index, Form TMSS/005, Cover Sheet, Form TMSS/006.

- Verify from the SERs and the QSL, that the annual evaluation of triennial audits were performed prior to QSL issuance.

- The QSL forms shall reflect the year, quarter and revision number.

- Revisions of the QSL between quarters shall utilize a QSL Change Notice (CN).

- The QSL CN shall describe the changes to the QSL, which includes revision to the Index, added or deleted QSL forms, a new Cover Sheet, and directions for revising the QSL document.

- The effective date on the QSL Cover Sheet shall include the applicable revision number.

- The records shall be submitted to the LRC within 10 working days of their completion for the following:

  - Qualified Suppliers List Change Notice (TMSS/003)
  - Qualified Suppliers List (TMSS/005)
  - Qualified Suppliers List Index (TMSS/005)
  - Qualified Suppliers List Cover Page (TMSS/006)

SP 1.25

- Supplier furnished items shall be procured from a supplier identified on the QSL and that the supplier approval was current at the time of the procurement.

- Item acceptance activities as required by the RIR for receiving inspection or source verification shall be performed.

- The required inspections shall be performed using the applicable procurement documents, RIR and procedure Exhibit 5, acceptance by receiving inspection.

- Acceptance by Certificate of Conformance shall be based on the procurement documents, RIR, Exhibit 3 acceptance by Certificate of Conformance for items procured.

- Acceptance by source verifications shall be indicated in the "Acceptance Method" block of the RIR and the applicable procurement documents, RIR, and Exhibit 4, Acceptance by Source Verification.

- For those items source verified, the receiving location shall complete and document the inspection of the remaining characteristic following arrival at the receiving location.

- RIR or each line item inspected shall contain a "SAT" in the "Results" block.

- The RIR "Remarks" section shall be annotated to indicate an accept tag was attached.

- Quantity received shall be entered on the RIR and "UNSAT" shall be entered for each line item inspected which was unsatisfactory. The NCR number shall be recorded in the "Remarks" section.

- Acceptance of items by post receipt testing shall be performed to the criteria contained on Exhibit 5 and the method indicated on the RIR.

- Acceptance of Calibration Services shall be in accordance with the Procurement Package, Section 5.1.2 of the procedure with the results documented on forms TMSS/038 (Basis for Acceptance) and TMSS/094 (RIR).

- The QA staff shall perform a verification of the requester acceptance of services and documented it on forms TMSS/038 and TMSS/094.

SP 1.65

- The department manager shall assign a custodian who is competent in the subject matter of the Vendor Manuals/Vendor Technical Information (VMs/VTIs) to be responsible for the review and approval.

- The custodian shall document the results of the review of the VM/VTI on TMSS/095/2, Document Review and Comment (DRC) form and TMSS/098/1, Document Concurrence/Approval form.

- QA shall document their review and concurrence on TMSS/095/2 and TMSS/098/1 forms.

- For those VM/VTIs requiring to be controlled, the custodian shall stamp the first page with an approval stamp that contains at a minimum, signature/date to document, prior to issue, the review by the technical reviewer and approval by department manager and QA.

- The custodian shall contact the vendor/supplier of approved VM/VTIs on an annual basis and assured that the project has been informed of all changes to the VM/VTIs since the last contact. Inform the Contract Services Organization of the results of the communications. Results of their contact shall be documented in a memorandum.

- The requisitioner shall determine the need for a VM/VTI and includes the following information in the requisition and PO:

  - Number of copies of VM/VTI required.
  - Instructions to send the VMs/VTIs with the items ordered.
  - Organization name and address where changes to the VM/VTI should be sent.

- Revised VM/VTI shall be reviewed the same as the original.

- Update to VM/VTI shall be submitted to the Document Control Center (DCC) for control in accordance with SP 1.34.

- The DCC shall issue controlled copies of VM/VTI to the site DRC in accordance with SP 1.34.

SP 1.72

- Responsible manager upon identification of an item procured as "QA-N/A," which is desired for use in QA service, shall assign a staff member the responsibility of preparing an Item Upgrade Request.

- The assigned staff member (preparer) shall initiate the Item Upgrade Request form (TMSS/307). The following information is required as a minimum for Part I of the form (attach additional documentation as necessary):

  - Item description per the manufacturer's published product description (for example, catalog number) and method of establishing item identity.

  - Identification of original procurement documents, if possible.

  - Current and proposed item usage and location.

  - Item specification (including critical characteristics and technical and functional requirements).

  - Acceptance criteria.

  - Identification of preparer.

- The preparer shall sign as preparer in Part I of the form and forwards to the responsible manager.

- The responsible manager shall review the Item Upgrade Request. If unacceptable, coordinates with preparer to produce an acceptable Part I. If acceptable, sign Part I and forwarded to the QA Manager.

- The assigned QA staff member shall review Part I of the Item Upgrade Request for completeness with respect to technical information required to determine inspection and documentation requirements. If acceptable, enter the inspection and documentation requirements on the Item Upgrade Request form and sign Part II of the form. If unacceptable, return to the responsible manager for additional information.

- The QA staff shall conduct an interim inspection and documented results in Part III of the Item Upgrade Request form.

- It is mandatory that during this activity, the following shall be determined and documented:

  - The item does not show detectable damage.
  - The item is that described on the Item Upgrade Request form.
  - The item meets inspection acceptance criteria.

- The responsible manager shall perform acceptance testing and documents results as required. Acceptance testing shall be accomplished as necessary to assure conformance with the manufacturer's published requirements, as appropriate, and the user-defined critical characteristics.

- The QA staff shall conduct a quality engineering review of the item acceptance process:

  - Review the Item Upgrade Request form and associated documentation to assure completeness and accuracy.

  - Assure that the results of acceptance testing, if required, support item acceptance.

  - Assure that the critical characteristics of the item are confirmed.

  - Assure that documentation of the results of QA item acceptance on Part III of the Item Upgrade Request form. Acceptance requires marking "yes" or "N/A" on the form.

- If the item is found to be nonconforming, indicate in Part III. Document the condition and identify the item by tagging or other means as nonconforming in accordance with SP 1.23 and resubmit the item, as applicable, and the documentation and Item Upgrade Request form to the responsible manager.

- If the item is found acceptable or dispositioned such that the item may be used in QA service, complete and sign Part III of the Item Upgrade Request form and continue with this procedure.

- The QA Manager shall approve the release of the item for service by signing Part IV of the Item Upgrade Request form and forwarding to the responsible manager.

- The responsible manager shall approve the release of the item for service by signing Part IV of the Item Upgrade Request form.

- The responsible manager shall prepare a QA records package and submit it in accordance with SP 1.36 and in accordance with Section 6.0 of this procedure and provide an information copy to the QA Manager.

WI-AQ-006

- A site technician/field operation Supervisor shall perform acceptance testing and records anomalies on a Gaseous Analyzer Acceptance Test Form (GAATF), form TMSS/080.

- A site technician/field operation Supervisor shall perform the following:

  - Operated the equipment for an initial adjustment period, as specified by the operation manuals. Indicate on the GAATF how long the equipment was allowed to run once the initial adjustment run is complete.

  - Perform a multipoint calibration of each analyzer in accordance with the following WIs:

    1) WI-AQ-007 for the ozone analyzer.
    2) WI-AQ-008 for the carbon monoxide analyzer.
    3) WI-AQ-009 for the nitrogen oxide analyzer.
    4) WI-AQ-010 for the sulfur dioxide analyzer.

  - The performance characteristics and design features of the equipment given in the analyzer operating manuals have been met and record this information on the GAATF.

  - Enter comments on performance characteristics, design features, equipment adjustments, or other pertinent information on the GAATF.

- If any nonconformances are noted, identify them in accordance with SP 1.23.

- Use a Miscellaneous Acceptance Test Form (MATF), for TMSS/124, for any components not specifically included in other acceptance test forms.

- Carefully repack any equipment to be shipped to the field in its original shipping carton.

- Forward a copy of the acceptance test results to QA in accordance with SP 1.25.

- A performance audit shall be performed by a multipoint calibration of each analyzer using a separate calibrator and gas standards. Compare this calibration to the previous calibration and document on the Gaseous Analyzer Performance Audit Form (GAPAF) and the appropriate form for the type analyzer:

  - Ozone Audit Data Sheet and Procedure Summary, form TMSS/140.

  - $S0_2$ and CO Audit Data Sheet and Procedure Summary, form TMSS/141.

  - $NO_x/NO/NO_2$ Audit Data Sheet and Procedure Summary, form TMSS/139, and record anomalies encountered during the audit on the appropriate GAPAF.

- The Task Manager shall review the results of the performance audit to determine whether any data from a given analyzer needs to be invalidated, as a result of errors in flow rates, or a performance audit calibration curve which diverges 25 percent or more from the previous calibration curve, and documented the review on the appropriate GAPAF within 10 days of the audit and provide the GAPAF to the Data Manager.

- The Data Manager shall annotate the data record to reflect invalidated data.

- The following records shall be submitted to the LRC in accordance with SP 1.36:

  - GAATFs, form TMSS/080.
  - MATFs, form TMSS/124.
  - Ozone Audit Data Sheet and Procedure Summaries, form TMSS/140.
  - $S0_2$ and CO Audit Data Sheet and Procedure Summaries, form TMSS/141.
  - $NO_x/NO/NO_2$ Audit Data Sheet and Procedure Summaries, form TMSS/139.

Review of implementation for the above listed procedures indicated that QA Program Element 7.0 was satisfactorily implemented, except for one deficiency in implementation of SP 1.25 which was corrected during the audit (see Section 5.5.2.3). Areas covered by procedures SP 1.65 and SP 1.72 had no implementation.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

The evaluation of this QA program element was to be based on the examination of objective evidence to determine compliance with select requirements taken from the following implementing procedure SP 1.12. The selected requirements are listed below.

- The RFPD Manager shall evaluate and documented the hazards of possessing radioactive material and recommended appropriate measures to assure compliance with radiological safety regulations. Recommendations may include training, storage, radiation surveys, posting, and As Low As Reasonably Achievable considerations.

- The RFPD Manager shall review the procurement documentation for compliance, if appropriate controls are being implemented, he shall sign and date to indicate review and approval for procurement and completes a "Procedure Compliance Documentation" form per SP 1.31.

- The RFPD Manager shall provide user with information on packaging criteria, labels, labeling specifications, shipping form(s), and other controls as appropriate to the specific shipment classification and regulatory agency criteria.

- The user shall package the material and initiate documentation in accordance with regulations. Minimum documentation includes:

  - Shipper's Certification for Radioactive Material (SCFRM). Exhibit 1 provides an example of SCFRM.

  - Packing list with identification that references the SCFRM.

- The RFPD staff shall verify by reviewing the documentation of the radioactive material being shipped meets or exceeds the quantities in 49 CFR for "normal form Type A," and sends the documentation to the REFP Manager for concurrence of the shipment.

- The REFP Manager shall sign and date the SCFRM.

- The user shall submit a record package in accordance with SP 1.36 containing the following to the LRC concurrent with, or at a maximum, within 10 working days.

  - Packing list

  - SCFRM

  - Memo, report, or similar documentation required for preparation and/or authorization to ship.

A review of QA Program Element 8.0 and discussions with cognizant T&MSS personnel for the above listed requirements indicated that there was no implementation of QA Program Element 8.0.

10.0 INSPECTION

Objective evidence generated as a result of implementation of procedure WI-QA-008 was evaluated to determine compliance to specific requirements which are listed below:

- The QA Manager documents on form TMSS/144 the completion of training, testing, and/or experience and signifies the method of qualification.
- The certification candidate has undergone a visual acuity examination for near vision, far vision, and color vision.
- The person administering the vision tests was qualified to do so.
- The QA Manager evaluates the results of the visual acuity examinations and approves the results on form TMSS/236.
- The QA Manager completes the candidate's Certification Record, form TMSS/144, and maintains associated documents in the candidate's training files.
- Conducts annual visual acuity examinations.
- The QA Manager documents proficiency evaluations on form TMSS/144 and maintains the proficiency evaluation in the candidate's training file.

A review of the objective evidence for QA Program Element 10.0 indicated that this area is being satisfactorily implemented, except for one deficiency in implementation of WI-QA-008 which was corrected during the audit (see Section 5.5.2.1).

14.0 INSPECTION, TEST AND OPERATING STATUS

Objective evidence generated as a result of implementation of SP 1.25 was evaluated to determine compliance to specific requirements which are listed below:

- A procedure (SP 1.25) provides for identifying the status of inspection and test activities to ensure that required inspections and tests are performed and to ensure that unacceptable items are not inadvertently installed, used, or operated.
- Provisions have been made for the use of status indicators, as appropriate, and that authority for application and removal of status indicators is defined.
- Examples of status indicators are provided in the procedure.

A review of the objective evidence for SP 1.25 indicated that the requirements of QA Program Element 14.0 are being satisfactorily implemented.

15.0 CONTROL OF NONCONFORMING ITEMS

Objective evidence generated as a result of implementation of procedure SP 1.23 was evaluated to determine compliance to specific requirements which are listed below:

- The QA staff maintains an NCR Log which contains the following information:
  - NCR number
  - Initiation date
  - Brief description of the nonconformance
  - Organization responsible for disposition/correction of nonconformance
  - Validation/invalidation dates
  - Trend analysis code
  - Disposition approval dates
  - Conditional release numbers, as applicable
  - QA concurrence date of conditional release
  - Disposition completion dates
  - QA closure date
- The QA Manager or Department Manager signs and dates valid NCRs in Block 14.
- The QA staff logs appropriate information in the NCR Log and files and retains NCR copy until original is received.
- A staff member signs and dates the disposition in Block 17.
- If the disposition is acceptable, the Department Manager signs and dates in Block 18.
- The QA Manager reviews the NCR and determines if the nonconformance is a significant condition adverse to quality by checking YES or NO in Block 15.
- The QA Manager reviews the disposition to assure all QA requirements have been addressed and signs and dates in Block 19.
- For a revision to an NCR, the person initiating a change: (1) revises the necessary blocks of the NCR to effect the changes, (2) signs and dates the form, and (3) submits it to the same organization that accepted the original for their acceptance signatures on the revised NCR form.

- For implementation of the disposition, the staff member signs/dates the original NCR in Block 21, returns NCR, support documentation and Hold Tags removed to the QA organization.

- The QA staff signs and dates closure of the NCR in Block 22.

- The QA staff assigns trend analysis codes to valid NCRs in Block 23.

With exception of one deficiency in implementation of SP 1.23 which was corrected during the audit (see Section 5.5.2.2), objective evidence indicated that the requirements of QA Program Element 15.0 are being satisfactorily implemented.

19.0 SOFTWARE QUALITY ASSURANCE

The evaluation of this QA program element was based on the examination of objective evidence to determine compliance with selected requirements taken from implementing procedures SP 1.52, SP 1.53, SP 1.55, and SP 1.56.

- There is a Configuration Management Log (CML) established for tracking all quality-affecting software and contains the required information.

- The following documents are developed: Software Requirements Specification, Software Application Record, and User Manual. After approval, these documents are then entered into the CML and placed into the Software Development folder.

- The first step in the software lifecycle is the development of the Change Request Form and Software Classification form. When these documents are received, they are placed into the Software Development folder by the CM Librarian.

- The System Software Conversion, Datalogger, ENVICOM, ENVAID, WROSE, PLOTCALL and BEEMET were used to evaluate the above requirements.

As a result of evaluating the above implementing procedures the requirements for QA Program Element 19.0 have been satisfactorily implemented.

20.0 SCIENTIFIC INVESTIGATIONS

The evaluation of this QA program element was based on the examination of objective evidence to determine compliance with selected requirements.

Objective evidence generated as a result of implementation of the following procedures was evaluated to determine compliance to specific requirements: SP 2.2, WI-MET-002, WI-MET-003, WI-MET-006, WI-MET-001, and WI-MET-007.

- Develop a scientific investigation planning document if such a document does not exist. Include all information in Exhibit 1 of SP 2.2 that is relevant plus additional information of a similar nature that may be appropriate to the subject investigation.

- Compile a scientific implementation package, if not already available, which contains:

  - QA Grading Report

  - Environmental Investigation Implementation Package Approval memorandum (see Exhibit 2 of SP 2.2), or equivalent approval sheet for other investigations.

  - Scope of work

  - WBS element reference

  - Any other information needed to fully describe and control the investigation to be implemented

  - Schedule(s)

- The investigation implementation methodology may take two forms: technical procedures or scientific notebooks. The investigation shall use one or a combination of these two methods.

- Prepare and issue new or revised technical procedures in accordance with SP 1.1, and in accordance with the information provided in Exhibit 3 of SP 2.2.

- Conduct the investigation in accordance with the approved scientific investigation package.

- Monitor the scientific investigation by reviewing and approving the investigation package.

- If a change in the scientific investigation planning document is required, draft the changes and process the planning document in accordance with Sections 5.1.5 through 5.1.8 of SP 2.2.

- If a revision to the investigation implementation package is required, proceed with Steps 5.1.9 through 5.1.12 of SP 2.2.

- Prepare a report on scientific investigations in accordance with the requirements outlined in Exhibit 6 of SP 2.2.

- Initiate the report in accordance with SP 1.62 or SP 1.35 as appropriate.
- Approve and validate the Technical Data Information Form and associated report.
- Ensure that the following record is submitted to the LRC within 10 days of approval and authentication, in accordance with SP 1.36:
  - Meteorological Reports to the State of Nevada
- Establish reporting schedule requirements.
- Submit completed Data Transmittal packages to the technician within 3 working days of completing the package; the package is to be complete within 5 working days of the beginning of the calendar month. The package includes:
  - Data Transmittal, form TMSS/108
  - Meteorological Site Routine Visit Checklist, form TMSS/110
  - Strip Charts and any hard-copy printouts
- Calibrations of devices are to be performed annually. Performance checks are to be performed on active monitoring systems once during each calendar quarter.

A review of the above listed procedural requirements indicated that QA Program Element 20.0 was satisfactorily implemented.

Technical Activities

WBS 1.2.13.4.2; Study Plan 8.3.1.12.2.1, Revision 0

The study plan for meteorological monitoring, selected supporting procedures, and data products were examined during the audit. Scientific personnel demonstrated thorough knowledge of the objectives of this study and are executing the technical tasks outlined in the plan in a satisfactory manner. Procedures for implementing the study objectives were found to be complete and concise. The abrupt departures of two technical support personnel resulted in a manpower shortage in recent months. However, a new person, added in December 1992, was learning rapidly and quickly becoming knowledgeable on technical procedures.

Despite the turnover in technical personnel, attention to the field instrumentation was not neglected. In fact, four new weather stations were added to the original five effective July 1, 1992. Sound technical rational, based on potential air flow dispersion pathways to the accessible environment from Yucca Mountain, was used in selecting these four additional sites. All sites were visited every three days and performance checks and independent

performance audits were performed quarterly as scheduled. During the audit, technical personnel demonstrated the performance check on wind speed and direction sensors and also the performance check on a tipping-bucket rain gauge installed at Site 9. Operational instrument checks were satisfactorily demonstrated at Sites 8 and 9. Forms TMSS/110 and TMSS/285 were reviewed to verify that site visits, performance checks and performance audits were being completed.

Another goal of this audit was to trace the data trail from field instruments to the final report. T&MSS personnel demonstrated ODESSA data cartridge exchange at Site 1 and the handling of the cartridge until it was downloaded at the Las Vegas, Nevada office. Data from the other eight sites were similarly handled. Raw data were entered into a database for each site and then reformatted into readable columns. Data retrieval is done every two weeks. Quarterly reports were prepared to meet State of Nevada requirements for air quality monitoring. Five reports have been sent to the State of Nevada since the last audit. The primary output parameter of this program is the determination of atmospheric stability. This parameter will be used in an atmospheric dispersion model in the future to predict potential contaminant movement toward or into the accessible environment.

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

QA Program Element 4.0, "Procurement Document Control"

Procedure: SP 1.28, Revision 6, ICNs 1 and 2, "Procurement of Quality Affecting Items and Services"

Purchase Requisitions:

R5892483	R5947507	R5836802, Modifications R5892438 and R5892441
R5892438	R5732896	R5836860, Modification R5892461
R5836860	R5836846	

Purchase Orders:

39-930294-94	39-930328-94	39-930147-94
39-930031-94	39-930248-94	39-930270-94
39-930246-94		

Supplier Evaluation Reports:

Climatronics Corp. (12-1-92)
R. M. Young (7-16-92)
SAIC RadeCo (8-5-92)
Atmospheric Instrument Research (7-16-92)

Receiving Inspection Reports:

39-930248-1-A	39-930270-1-A	39-930246-1-A

Basis for Acceptance of Services (TMSS/094 Form) for RIRs 39-930248-1-A and 39-930270-1-A

Certificates of Calibration for POs:

39-930270-94, Part Nos. 101257 and 101258, and
39-930246-94, Model 18801

QA Program Element 7.0, "Control of Purchased Items and Services"

Procedures:

OP 1.3, Rev. 3, ICN 1, "Supplier Evaluation"
OP 1.7, Rev. 3, "Development and Maintenance of Qualified Suppliers List (QSL)"
SP 1.25, Rev. 5, ICN 1, "Acceptance of Items and Services"
SP 1.65, Rev. 1, "Control of Vendor Manuals and Vendor Technical Information"
SP 1.72, Rev. 0, "Upgrade of Items procured as Non-Quality Affecting"
WI-AQ-006, Rev. 0, ICNs 1 and 2, "Air Quality Monitoring: Receiving, Acceptance Testing and Performance Auditing of Gaseous Monitoring Equipment"

Supplier Audits:

A91-025	A91-045	A91-055	A92-015
A92-035	A92-045	A92-065	

Annual Performance Evaluations:

Amersham Corporation, 11/11/92
Ludlum Measurements, Inc., 8/27/92
Ringard Metrology, 10/7/92
John Fluke Mfg. Co., 9/30/92
REECo Inc., 6/4/92

Interoffice Memorandum:

M92-4645, J. Harper to Distribution, Subject: Removal of TMA/Eberline, Albuquerque, New Mexico from the QSL

M93-4647, J. Harper to Douglas E. Cover, SAIC Campus Point A, Subject: T&MSS Quality Assurance Qualified Suppliers List 93-01, Rev. 1

Purchase Orders:

39-930248-94	39-930270-94	39-930246-94
39-930151-94	39-930143-94	39-920601-94

Checklists for Preparation/Review of Quality Affecting Procurement Documents (TMSS/008) and RIRs (TMSS/038) for POs:

39-930294	39-930228	39-930147	39-930003
39-920601	39-930143	39-930151	39-930270
39-930246	39-930248		

Receiving Inspection Reports:

39-930248-1-A	39-930270-1-A	39-930246-1-A
39-930151-1-A	39-920601-1-A	

Certificates of Calibration and Bases for Acceptance of Services (TMSS/094) for RIRs:

39-930143-1-A	39-930248-1-A

QSL 93-01, Rev. 1, dated 1/27/93

QA Program Element 8.0, "Identification and Control of Items"

Procedure: SP 1.12, Rev. 1, "Possession, Procurement, Shipment, and Receipt of Radioactive Material"

QA Program Element 10.0, "Inspection"

Procedure: WI-QA-008, Rev. 0, ICN 1, "Certificate of Inspection Personnel"

Certification Files Reviewed:

F. H. Loffus	R. R. Rinderman	K. B. Johnson
S. P. Nolan	M. Malone	

Forms: TMSS/144 and TMSS/236 for each of the above inspection personnel.

QA Program Element 14.0, "Inspection, Test, and Operating Status"

Procedure: SP 1.25, Rev. 5, ICN 1, "Acceptance of Items and Services"
(Reviewed for inclusion of requirements and forms)

QA Program Element 15.0, "Control of Nonconforming Items"

Procedure: SP 1.23, Rev. 4, "Nonconformance Reporting"

Nonconformance Reports:

92-001	92-007	92-011	92-015	92-020
92-026	92-031	92-038	92-043	92-034
92-042	92-044	93-001		

Nonconformance Log Book

QA Program Element 19.0, "Software Quality Assurance"

Procedures:

SP 1.52, Rev. 1, "Quality-Related Software Management Process"
SP 1.53, Rev. 0, "Software Verification and Validation"
SP 1.55, Rev. 0, "Software Documentation and Review"
SP 1.56, Rev. 0, "Software Configuration Management"

Software Documentation:

Change Request Form (CRF)
- 91.008 ENVICOM/ENVAID
- 92.001 ENVICOM
- 92.004 DEEMET 1.0.A
- 92.005 WROSE 1.0.A
- 92.002 DATALOGGER 1.0.B
- 93.002 DATALOGGER
- 93.003 WROSE 2.11
- 93.004 PC 208 DATALOGGER
- 93.001 SODAR

Software Classification Form (SCF)
- 92.014Q BEEMET 3.01.A
- 92.017Q WROSE 2.01.A
- 92.042Q CONVERSION 1.0.A
- 92.008Q CONVERSION
- 93.001Q SODAR

Software Requirements Specification (SRS)
- 93.001 SODAR
- 91.002 ENVICOM 5.0.A AND TEST PLAN
- 91.001 ENVAID 5.0.A

User Manual (UM)
- 92.001 DATALOGGER 1.0.B
- 92.002 ENVICOM 5.0.A
- 93.001 EXCEL 4.0.A
- 93.003 ENVAID 5.0.A
- 92.004 BEEMET 3.0.1.A W/WROSE 2.0.1.A W/PLOTCALL

Configuration Management Log
- No. UM-92
- No. SRS-91
- No. SRS-92

No. UM-93
No. SCF-92
No. CRF-93
No. UAF-92
No. UAF-93
No. SRS-93

Quality Finding/Management Corrective Action Report Quality Finding Report QFR 92-021, Rev. 0

QA Program Element 20.0, "Scientific Investigations"

Procedures:

SP 2.2, Rev. 3, "Scientific Investigation Control"
WI-MET-001, Rev. 2, "Tests, Checks, and Audits of Meteorological Equipment"
WI-MET- 002, Rev. 3, "Routine Operations and Maintenance of Meteorological Equipment"
WI-MET-003, Rev. 3, "Meteorological Monitoring: Instructions for Processing Current Data"
WI-MET-006, Rev. 0, "Meteorological Monitoring: Reporting Formats"
WI-MET-007, Rev. 0, "Meteorological Monitoring: Instructions for Processing Past Data"

Documents:

Scientific Investigation Implementation Package for Characterizing Wind Patterns Relative to Population Centers, WBS 1.2.13.4.2

Document Concurrence/Approval/Cancellation Forms for WBS 1.2.13.4.2

DRCs for WBS 1.2.13.4.2 from:

- C. D. Sorensen, 3/12/92
- L. D. Croft, 3/6/92
- K. B. Johnson, 3/2/92

DRCs TMSS/095, for WI-MET-002 from:

M. W. Harris, 5/10/92
C. L. Sellards, 5/15/92
G. W. Jones, 5/26/92
F. H. Loftus, 5/13/92
G. H. Prowell, 5/13/92

Reviewer Qualifications Statements for:

- C. D. Sorensen, 2/28/92
- L. D. Croft, 2/28/92
- J. B. Harper (K. B. Johnson), 2/28/92

Interoffice Memorandum, P. Fransioli to D.. Sorensen, dated 2/28/92 concerning the review of the Wind Pattern SIIP

Quality Assurance Grading Report for WBS 1.2.13.4.2

Ambient Air Monitoring Report, Monitoring Period 4: June 1992 supplement

Ambient Air Monitoring Report July-September 1992

Ambient Air Monitoring Reports sent to the State of Nevada for Air Quality permit to construct No. 2693: July 1991, October 1991, January 1992, April 1992, and July 1992.

Data Transmittal Forms TMSS/108, Rev. 2 for transfer of Site data for:

1/5/93	9/1/92	12/28/92	8/18/92
12/8/92	8/7/92	11/19/92	8/4/92
11/3/92	7/20/92	10/20/92	7/17/92
10/5/92	7/2/92	9/23/92	6/8/92

Meteorological Site Routine Visit Checklist TMSS/110, Rev. 2

Nevada Test Site (NTS) Office	1/5/93-1/13/93
Yucca Mountain	1/8/93-1/21/93
Coyote Wash	1/8/93-1/21/93
Alice Hill	1/8/93-1/21/93
40 Mile Wash	1/8/93-1/21/93
WT-6	1/5/93-1/18/93
Sever Wash	1/5/93-1/20/93
Knothead Gap	1/8/93-1/21/93
Gate 510	12/30/92-1/8/93

Strip Charts:

NTS-60, 10 meter, Wind Direction, 0-540
Start 1522 Pacific Standard Time (PST), 1/28/93
End 1452 PST, 2/1/93

NTS-60, Site 1, 60 meter, Wind Speed, 0-44.7 meters/second
Start 1213 PST, 1/21/93
End 1432 PST, 2/1/93

NTS-60, Dewpoint, Temperature C, -50 to +50
Start 1509 PST, 1/28/93
End 1433 PST, 2/1/93

NTS-60, Air Temperature C, 10 meter, -50 to +50
Start 1348 PST, 1/28/93
End 1433 PST, 2/1/93

NTS-60, Delta T, 10 meter versus 60 meter, -5 to +5 C
Start 1208 PST, 1/21/93
End 1433 PST, 2/1/93

NTS-60, Barometric Pressure, 855 to 905 millibars
Start 1358 PST, 1/26/93
End 1433 PST, 2/1/93

NTS-60, Site 1, Dewpoint, Temperature C, -50 to +50
Start 1210 Pst, 1/21/93
End 1450 PST, 1/28/93

NTS-60, Site 1, 10 meter, Wind Direction, 0-540
Start 1212 PST, 1/21/93
End 1320 PST, 1/28/93

NTS-60, Site 1, Temperature C, -50 to +50
Start 1016 PST, 1/25/93
End 1628 PST, 1/27/93

NTS-60, Air Temperature C, -50 to +50
Start 1209 PST, 1/21/93
End 0828 PST, 1/25/93

NTS-60, Barometric Pressure, 855 to 905 millibars
Start 1207 PST, 1/21/93
End 1304 PST, 1/26/93

NTS-60, 60 meter, Wind Direction, 0-540
Start 1211 PST, 1/21/93
End 1458 PST, 2/1/93

NTS-60, Site 1, 10 meter, Wind Speed, 0-44.7 meters/second
Start 1214 PST, 1/21/93
End 1432 PST 2/1/93