

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

SUPPLIER AUDIT REPORT

OF

SCOTT SPECIALITY GASES, INC.

LONGMONT, COLORADO

**REPORT NUMBER OQA-SA-96-029
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Prepared by:

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Date:

10/24/96

Approved by:

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**Director
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Date:

10/25/96

Enclosure

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Scott Specialty Gases (SSG) revealed unsatisfactory conditions resulting in the issuance of one Deficiency Report (DR) for corrective action, related to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Not all of the required implementing procedures were in place for the scope of work and implementation was considered to be ineffective in some areas. The items furnished by SSG for this procurement are for use by the Yucca Mountain Project Branch, U.S. Geological Survey (USGS), in connection with the OCRWM managed by the U.S. Department of Energy. SSG provides reference gas standards for USGS use for their mass spectrometer.

The unsatisfactory conditions identified during the audit were discussed with SSG management and the USGS responsible management who agreed to correct the unsatisfactory conditions. Corrective actions associated with DR YM-97-D-002 will be evaluated by the Office of Quality Assurance (OQA). Verification and closure will be performed by OQA. The unsatisfactory conditions, are detailed in Section 5.0.

The results of the audit warrant a recommendation for prohibiting SSG in providing the USGS reference gas standards for use in the mass spectrometer until the noted deficiencies are corrected; however, responsibility for determination of acceptability for the use of this supplier for the items and/or services rests with the USGS subject to verification by OQA.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of the SSG's QA Program. This was accomplished by determining if the SSG QA Program meets the quality and technical requirements specified in the USGS Purchase Order Number 1434-CR-96-SA-00515, the SSG Quality Assurance Manual, and the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5, for the specific scope of work. The QA program elements determined to be applicable are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Control of Measuring and Test Equipment; Nonconformances; Corrective Action; QA Records and Audits.

3.0 AUDIT TEAM AND OBSERVERS

Daniel A. Klimas, Audit Team Leader, Yucca Mountain Quality Assurance

4.0 PERSONNEL CONTACTED DURING THE AUDIT

Ric Schmeltekopf, QA Manager, SSG
Dee Sherill, Regional Vice President, SSG
Susan Branden, Laboratory Supervisor, SSG
Edward Sacayon, Technician, SSG

5.0 SUMMARY OF AUDIT RESULTS

The SSG Quality Assurance Manual, Revision 0, dated August 1, 1995, addresses the appropriate elements of the USGS purchase order and the applicable elements of the OCRWM QARD for the intended scope of work. Not all required procedures were in place and implementation of procedures was inadequate for some areas. Implementing procedures for procurement document control; control of purchased items and services; calibration; receiving inspection of raw material; and audits have not been developed. Training for SSG employees has not been documented. There is no list of approved vendors as required by the manual and procurement documents do not contain the required quality and technical requirements. Procedure revisions are not controlled in accordance with internal procedure requirements. Internal audits are not being performed as required by the SSG program requirements. Calibration certificates do not contain all required information as requested in the purchase order.

The details of the audit, along with the objective evidence reviewed and items corrected during the audit, are contained within the audit checklist which is available from the OQA Quality Records file.

6.0 DEFICIENCIES/CORRECTED DURING THE AUDIT/RECOMMENDATIONS

The unsatisfactory conditions have been documented on DR YM-97-D-002 for corrective action and resolution. There were no conditions that were corrected during the audit and no recommendations provided to SSG.

DEFICIENCIES

1. SSG has not developed implementing procedures for the following activities as required by their QA program: procurement document control; control of purchased items and services; calibration control; receiving inspection of raw/bulk materials; and internal audits.
2. There is no documentation available that provides evidence that training of any SSG employee has occurred for the QA Program or implementing operating procedures.

3. There is no list of approved vendors as required by the QA Manual, and procurement documents do not contain the appropriate quality requirements or technical specifications.
4. There is no evidence that procedure revisions and document reviews are being controlled as required by SSG operating procedures.
5. There is no evidence of compliance to the SSG Quality Manual with regards to conducting internal audits. There has not been a formal internal audit conducted of SSG since January 1992.
6. Although this information is available, the certificates of calibration do not include the calibration standard used and traceability to National Institute of Standards and Technology, or the procedure or method used in the calibration.