



Department of Energy  
Washington, DC 20585

QA: L

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for Yucca Mountain Site  
Characterization Project  
U.S. Geological Survey  
1261 Town Center Drive  
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EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT  
(DR)YM-97-D-002 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA)  
AUDIT OQA-SA-96-029 OF SCOTT SPECIALTY GASES

The OQA staff has evaluated the amended response to DR YM-97-D-002. The amended response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to that date. Please send a copy of extension requests to Deborah G. Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Daniel A. Klimas at (702) 794-1495.

*R.W. Craig*  
for Donald G. Horton, Director  
Office of Quality Assurance

OQA:JB-0331

Enclosure:  
DR YM-97-D-002

cc w/encl:  
J. O. Thoma, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
T. H. Chaney, USGS, Denver, Co  
D. J. Sinks, OQA/USGS, Denver, CO  
A. M. Whiteside, OQA/USGS, Denver, CO

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

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**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
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<sup>8</sup>  Performance Report  
 Deficiency Report  
NO. YM-97-D-002  
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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: Quality Assurance Requirements and Description (QARD), DOE/R/W-0333P, Revision 5, Scott Speciality Gases (SSG) Quality Manual	2 Related Report No. OQA-SA-96-029
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3 Responsible Organization: U.S. Geologic Survey/SSG	4 Discussed With: Thomas H. Chaney/Ric Schmeltekopf
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5 Requirement/Measurement Criteria:

- 1) QARD, Section 5.0, Paragraph 5.2, states: "Work shall be performed in accordance with controlled implementing documents."
- 2) SSG Quality Manual, Section 17, states: "...appropriate training records are maintained to demonstrate the acquired level by every employee."
- 3) SSG Quality Manual, Section 5, states: "SSG will (1) maintain a list of vendors carefully selected on ability to meet Scott's specification requirements; (2) ensure purchase orders contain all necessary specifications."
- 4) SSG Operating Procedure No. 100, Revision 0, Number 4, states: "When a procedure is reviewed and no changes are to be made, the reviewer will write a memo stating no changes are required. The memo will be placed in the procedures manual."

(See page 3)

6 Description of Condition:

Contrary to the above requirements:

- 1) SSG has not developed implementing procedures for the following activities: procurement document control; control of purchased items and services; calibration; receiving inspection of raw/bulk material and audits.
- 2) There is no documented training available for any employee.
- 3) There is no list of vendors; procurement documents (i.e., Colorado Department of Agriculture) do not contain all necessary specifications.
- 4) There is no evidence that procedure revisions requiring no changes have memos placed in the manual or that the documented review was accomplished as required.
- 5) There is no evidence of compliance to the SSG Quality Manual, Section 16, "Internal Quality Audits." The last formal audit that was conducted was performed by the SSG Corporate Office in January 1992.
- 6) The calibration certificate provided by SSG does not contain this information.

7 Initiator Daniel A. Kilmas <i>Daniel Kilmas</i> Date 10/2/96	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Action: (Not required for PR)

Correct noted deficiencies. Develop and implement required procedures. Provide documented training to program and procedure changes.

11 QA Review: QAR <i>Daniel Kilmas</i> Date 10/2/96	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA manager Issuance Approval: (QAR for PR)	Signature <i>James B. Bayliss for RES</i>	Date 10/18/96
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22 Corrective Action Verified QAR	Date	23 Closure Approved by: (N/A for PR)	AOQAM	Date
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CHAR BY TO HARRON 7/30/97

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

*See continuation page.*

15 Extent of Condition: (Not required for PR)

*See continuation page.*

16 Root Cause Determination: (Not required for PR)

Required

Yes

No

*See continuation page.*

17 Action to Preclude Recurrence: (Not required for PR)

Required

Yes

No

*See continuation page*

18 Corrective Action Completion Due Date:

*See continuation page.*

19 Response by:

Initial

Amended

Date

Phone

*See continuation page*

20 Response Accepted

QAR *Handl. for D. Klimas* Date *1/6/97*

21 Response Accepted (N/A for PR):

AOQAM *R.W. Cell*

Date *1/17/97*

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**5 Requirement/Measurement Criteria: (continued)**

- 5) SSG Quality Manual, Section 16, "Internal Quality Audits," states:  
SSG shall:
- schedule audits on the basis of status and importance of an activity
  - carry out audits by qualified personnel
  - use auditors independent of the activity being audited
  - inform responsible people in the area audited about results
  - arrange timely corrective action in case of deficiencies
  - conduct follow-up audit to verify implementation and effectiveness of the corrective action taken
  - record all audit results
- 6) USGS Purchase Order Number 1434-CR-96-SA-00515, Attachment 7, Section III, states in part: "...The information specified below shall be included on or with the Certificate of Calibration (g) Identification of calibration standard and NIST traceability, and the calibration procedure or method used."

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12/18/96 Response to Deficiency Report DR No. YM-97-D-002 [Scott Specialty Gases (SSG)]

**Block 14: Remedial Actions:**

**Deficiency Item 1:** "SSG has not developed implementing procedures for the following activities: procurement document control; control of purchased items and services; calibration; receiving inspection of raw/bulk material and audits."

**Deficiency Item 2:** "There is no documented training available for any employee."

**Deficiency Item 3:** "There is no list of vendors; procurement documents (i.e., Colorado Department of Agriculture) do not contain all necessary specifications."

**Deficiency Item 4:** "There is no evidence that procedure revisions requiring no changes have memos placed in the manual or that the documented review was accomplished as required."

**Deficiency Item 5:** "There is no evidence of compliance to the SSG Quality Manual, Section 16, "Internal Quality Audits." The last formal audit that was conducted was performed by the SSG Corporate Office in January 1992."

**Response:** Items 1 through 5 resulted from a policy change initiated by the Corporate office of Scott Specialty Gases, requiring the Longmont facility of SSG to implement an ISO 9000 Quality Program. Although the manual that was used by the auditor to evaluate SSG has not been fully implemented, SSG has indicated that every effort is being made to develop implementing procedures and to place them in effect. The time frame for having procedures in place, providing training and fully implementing this new program is estimated for July 31, 1997.

**Deficiency Item 6:** "The calibration certificate provided by SSG does not contain this information."

**Response:** Item 6: For all gases purchased under Purchase Order 1434CR-95-SA-0273, the USGS has requested SSG to provide the identification of the calibration standard with NIST traceability, and to document the method used on the certificate of calibration supplied with the gas.

**Block 15: Extent of Condition:** Upon receipt of each tank of mixed gases, the USGS scientists verify the gas standard during calibration of the gas chromatograph. Regression curves are developed from these calibrations and the new gas mixture is accepted if consistent with other standards. In addition, after calibration, an atmospheric sample (gas) is analyzed using the gas chromatograph and results are checked against known, accepted atmospheric concentrations as published in standard reference materials. These comparisons are carried out periodically using the gas mixture and the regression data are documented in the gas chromatograph log books.

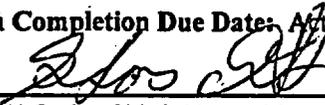
If gas mixture did not fit an acceptable profile of the USGS regression curve, the vendor's product would not be used. The vendor would be contacted and the standard returned for replacement.

All standards obtained from SSG since 1989 have been found to be acceptable using the above verification process to determine acceptability.

**Block 16: Root Cause Determination:** N/A

**Block 17: Action to Preclude Recurrence:** The implementation of an ISO 9000 Program at SSG should preclude recurrence of the identified deficiencies. No immediate need for a restriction on the use of the gases or vendor, due to the fact that the gas products can be verified through technical verification of the mixture.

**Block 18: Corrective Action Completion Due Date:** Actions noted in Blocks 14 and 17 to be completed by July 31, 1997.

**BLOCK 19 RESPONSE BY:** 

**DATE:** 12/19/96

**R.W. Craig, Chief, Yucca Mountain Project Branch**

12/19/96  
CRAIG TO WERTON

**ORIGINAL**

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**Revised Response to YM-97-D-002  
Scott Specialty Gases**

**BLOCK 14**

**REVISED RESPONSE:** The USGS will impose attached the QA accepted requirements in a new purchase order with SSG to require that 1.) all gas mixtures be prepared in accordance with SSG's Standard Operating Procedure, 2.) a certificate of analysis be supplied along with all gases, 3.) Colo. Dept. of Agriculture will continue to be used for calibration of SSG's weights, and 4.) records of internal analyses, round robin results, and third party audits are available for inspection.

Deficiency Items 1-6 will be addressed by the new procurement resulting from the Requisition Request No. 8RQ4889-8015 with SSG and the satisfactory implementation of those requirements.

**BLOCK 15: EXTENT OF CONDITION:** There is no impact on quality for the gases that have been procured prior to the initiation of this deficiency as the USGS performs a 100% verification of the gas upon receipt of the gas in accordance with YMP-USGS Technical Procedure HP-160. All gases have been found acceptable.

**BLOCK 16: ROOT CAUSE:** N/A

**BLOCK 17: ACTION TO PREVENT RECURRENCE:** The satisfactory implementation of the SSG QA program should preclude recurrence of the identified deficiencies.

**BLOCK 18 CORRECTIVE ACTION DUE DATE:** June 19, 1998

**BLOCK 19 RESPONSE BY:** *T. H. Chaney* **DATE:** 10/14/97  
T. H. Chaney, Chief, Engineering Assurance

*initial 7 Mike to Horton*

**QUALITY ASSURANCE REQUIREMENTS FOR USGS PROCUREMENTS  
WITH SCOTT SPECIALTY GASES, INC.**

**10/14/97**

**I. INTRODUCTION**

The services quoted upon or furnished for this procurement are for use by the Yucca Mountain Project Branch, U.S. Geological Survey (YMPB USGS) in connection with the Civilian Radioactive Waste Management Program sponsored by the U.S. Department of Energy (DOE).

The services shall be provided in accordance with the Scott Specialty Gases, Inc. (SSG) documented Quality Assurance (QA) program, accepted by the DOE Office of Quality Assurance (OQA) prior to the start of work. OQA acceptance of the SSG QA program is predicated on the degree of compliance with the QA Requirements described below in Section II and SSG's agreement to meet the terms described in Section III.

**II. SUPPLIER'S QA PROGRAM**

SSG's documented QA program shall address the topics listed below to the degree appropriate for the nature, scope and complexity of the activity and shall provide justification for the non-applicability of a topic.

NOTE: The QA program could take the form of a QA manual that contains a QA program description and implementing documents or a series of implementing documents with a matrix that reflects how the following topics are addressed:

**1.0 Organization**

A description of SSG's organizational structure and responsibilities for the personnel verifying quality achievement must be provided. Personnel who perform verification of quality achievement must be independent from those performing the work.

**2.0 QA Program**

SSG shall assure that personnel are familiar with procedures and/or instructions pertaining to the work to be performed prior to initiating the work. SSG shall ensure that training is documented according to SSG procedures.

**3.0 Procurement Control**

SSG weights shall be calibrated by the Colorado Department Of Agriculture (CDA) and the SSG procurement document shall state that CDA shall calibrate the weights according to the OCRWM approved QA program for CDA. If SSG procures calibration services from a supplier other than CDA, SSG shall notify the YMPB USGS prior to supplying gas mixtures for this order.

**QUALITY ASSURANCE REQUIREMENTS FOR USGS PROCUREMENTS  
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**4.0 Instructions, Procedures and Document Control**

The gas mixing process and analyzation of gas mixtures shall be performed in accordance with a documented approved implementing procedure(s).

The gas mixture shall be prepared by standard gravimetric methods using balances with NIST traceable calibrations. SSG shall provide the YMPB USGS with any revisions to the SSG procedure(s) for gas mixing process and analysis of gas mixtures prior to implementation for YMPB USGS procurements.

The process used for preparation, review, approval and control of implementing documents shall be described. This process must include: methods used for ensuring that only the latest revision is used at the work place; and, methods used to ensure that documents are reviewed for applicability, correctness, adequacy, completeness, accuracy and compliance with established requirements.

**5.0 Control of Measuring and Test Equipment (M&TE)**

SSG weights shall be calibrated by the CDA in accordance with the CDA QA program approved by OCRWM.

The CDA methods used to calibrate the SSG weights shall be described to assure that the M&TE, including the equipment that contains software or programmable hardware, is adjusted and maintained as a unit at prescribed intervals, or prior to use, against reference standards having traceability to nationally recognized standards. Calibration standards shall have a greater accuracy than that required of the M&TE being calibrated. If a standard with greater accuracy does not exist or is unavailable, calibration standards with equal accuracy is acceptable if it can be shown to be adequate for the requirements. This acceptance shall be documented by SSG.

Calibrated M&TE shall be uniquely identified to provide traceability to calibration data. The use of M&TE shall be documented. Measures shall be established to prevent the use of out-of-calibration M&TE. When M&TE is found to be out-of-calibration the validity of results using that equipment since its last calibration shall be evaluated.

M&TE shall be properly handled and stored to maintain accuracy.

**QUALITY ASSURANCE REQUIREMENTS FOR USGS PROCUREMENTS  
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**6.0 Corrective Action**

Deviations from technical and quality implementing documents shall be reported to the appropriate YMPB USGS contact who shall determine the extent of the condition and take corrective actions as soon as practical. SSG shall not proceed with quality-affecting activities on YMP gas standards until YMPB USGS provides the corrective actions to the deviation or otherwise authorizes SSG to proceed.

**7.0 QA Records**

SSG shall supply a Certificate of Analysis identifying the delivered gas composition.

The Certificate of Analysis shall be legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply, and traceable to the purchase order number.

Corrections to the Certificate of Analysis shall be made by drawing a single line through the changed or incorrect information and inserting the new or correct information. The correction shall include the initials or signature of the individual authorized to make the correction and the date the correction was made.

Records of SSG participation in Round-Robin testing, internal QC sample analyses, third-party audits, and NIST-traceable calibrations shall be maintained by SSG and available for review.

**8.0 Audits**

Planned and scheduled internal audits to verify compliance with the QA program requirements and to determine effectiveness of the QA program shall be performed by SSG at least annually as described in the SSG QA program.

**ACCEPTANCE METHOD**

The YMPB USGS upon receipt of a gas mixture will analyze the gas mixture following technical procedure HP-160, R2 (or current revision) to verify that it meets the purchase order specifications. The gas mixture must be within  $\pm 5\%$  of the requested composition for acceptance.

**QUALITY ASSURANCE REQUIREMENTS FOR USGS PROCUREMENTS  
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**III. GENERAL TERMS AND CONDITIONS**

1. If SSG subcontracts any part of the scope of work the YMPB USGS shall be notified prior to issuance of the SSG sub-tier procurement document, except for those procurements of calibration services with CDA as described in Section II, item 3.0.
2. SSG shall notify the YMPB USGS technical contact when a calibrated instrument used on USGS YMPB orders is found to be defective or out-of-calibration.
3. SSG shall notify the YMPB USGS technical contact when SSG identifies any nonconformances (deviations) from the procurement document. Nonconformances where the proposed disposition is "repair" or "use-as-is" are required to be submitted to the YMPB USGS technical contact for review and concurrence.
4. SSG will identify any spare or replacement parts or assemblies and the appropriate technical and QA requirements/information required for ordering them.
5. The Purchaser (YMPB USGS) or Purchasers Representative (U.S. Department of Energy/U.S. Nuclear Regulatory Commission or their representative) have the right to inspect and evaluate (audit/surveil) the work performed or being performed under the purchase document, and the premises where the work is being performed, at all reasonable times and in a manner that will not unduly delay the work. If the Purchaser or Purchasers Representative performs inspection or evaluation on the premises of SSG or a subcontractor, SSG shall furnish and shall require subcontractors to furnish, at no increase in contract price, all reasonable facilities and assistance for the safe and convenient performance of these duties.

NOTE: Procurement requirements with SSG are regulated by U.S. Department of Energy (DOE) requirements for the Yucca Mountain Project. Therefore, regulations impose audits of SSG at a minimum of every three years. More frequent audits may be imposed at the discretion of DOE. Additionally, the YMPB USGS is required to conduct annual evaluations of a supplier's QA program and of services received from a supplier.

6. YMPB USGS verification activities shall not relieve SSG of the responsibility for verification of quality achievement.
7. SSG shall provide the YMPB USGS with any revisions to their QA program documents that apply to the work being performed prior to implementation of those requirements for YMPB USGS orders.