

Department of Energy

Washington, DC 20585

JAN 10 1997

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
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Las Vegas, NV 89134

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-002
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT
OQA-SA-96-029 OF SCOTT SPECIALTY GASES

The OQA staff has evaluated the response to DR YM-97-D-002. The 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 the date. Please send a copy of extension requests to Deborah Sult, OQA/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Daniel A. Klimas at (702) 794-1495.

Donald G. Horton, Director
Office of Quality Assurance

OQA:MRD-0673

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
- Records Processing Center = "7"

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
WASHINGTON, D.C.**

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/RW-0333P, Revision 5, Scott Speciality Gases (SSG) Quality Manual

2 Related Report No.

OQA-SA-96-029

3 Responsible Organization:

U.S. Geologic Survey/SSG

4 Discussed With:

Thomas H. Chaney/Ric Schmeltekopf

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

Date 10/2/96

9 Is condition an isolated occurrence?

Yes No Unknown; Must be Yes if PR

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

Date 10/2/96

12 Response Due Date

20 working days from issuance

13 Affected Organization QA manager Issuance Approval: (QAR for PR)

Printed Name

Signature

Jane B Baylock for RES

Date 10/10/96

22 Corrective Action Verified

QAR

Date

23 Closure Approved by: (N/A for PR)

AOQAM

Date

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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 *Small* for D. KUMAS Date 1/6/97

21 Response Accepted (N/A for PR):

AOQAM

Date

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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.

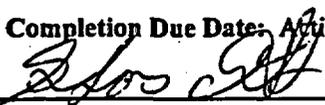
If gas mixture did not fit an acceptable profile of the USGS regression curve, the vendor's product would not be used. The vendor would be contacted and the standard returned for replacement.

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

DATE: 12/19/96

12/19/96 CRAIG TO STURTON