



Department of Energy

Washington, DC 20585

QA: L

AUG 27 1997

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 12, Room 1249, M/S 423
Las Vegas, NV 89134

EVALUATION OF AMENDED 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 (SSG)

The OQA staff has completed its review of your revised response dated July 30, 1997, to
DR YM-97-D-002. The review has resulted in the following questions and comments:

1. The revised response is unacceptable for the following reasons:

- Revised response to Deficiency Item 1 is unacceptable: SSG needs to have
procedures for procurement and calibration, since the need to pass down technical
and quality requirements remains, even if they are using a supplier on the Office of
Civilian Radioactive Waste Management (OCRWM) Qualified Suppliers' List. A
method for handling Measuring and Test Equipment (M&TE) found "Out of
Calibration" is still required to comply with OCRWM requirements. The
requirement for development of implementing procedures for receiving, inspection,
and audit was not addressed, therefore, the original response commitment still
applies.
Revised response to Deficiency Item 2 is unacceptable: Documented evidence of
qualification and training is necessary to ensure individuals are kept abreast of the
latest program and procedure requirements and that new hires are properly trained
and qualified.
Revised response to Deficiency Item 3 is unacceptable: The deficiency is that the
procurement documents did not contain adequate quality and technical
requirements, and there was no list of approved suppliers, as required by their
Quality Assurance (QA) program.
Revised response to Deficiency Item 4 is unacceptable: The deficiency is that
procedure revisions and procedure reviews are not being accomplished as required
by their QA program. The requirements are that documents will be controlled.
Revised response to Deficiency Item 5 is unacceptable: The day-to-day
involvement by a lab manager and the small size of the staff in an organization of
this size does not mitigate the requirement to perform the required internal audits.
The agreement of the Workshop held June 11 and 12, 1997, did not in any way
consider this type of organization a "mom and pop" shop.
Deficiency Item 6: This was not addressed in the revised response, therefore, the
original response still applies.

Handwritten notes: //, NH33, WM-11, 102.7

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NM-11 PDR

AUG 27 1997

2. Why was this revised response submitted when your original response to the DR in December 1996 provided adequate corrective and remedial action commitments, and was found acceptable by OQA? Because the revised response is unacceptable, OQA will initiate action to verify effective implementation of the corrective action of the original response, which had a completion date of July 31, 1997, unless a request for extension is received.

An amended response to DR YM-97-D-002 is required to be submitted to this office within ten working days of this letter. Any extension to these dates must be requested in writing, with appropriate justification prior to the respective due date. Please send the original of your amended response and a copy of extension requests to Deborah G. Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, NV 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Daniel A. Klimas at (702) 734-0853.

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

OQA:JB-2164

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

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
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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 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 Daniel Kilmas 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 James B. Baylock for RES 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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Chaney to Horizon 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):

AQAM *R.W. Co* 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.

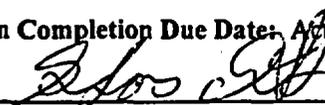
If gas mixture did not fit an acceptable profile of the USGS regression curve, the vendor's product would not be used. The vendor would be contacted and the standard returned for replacement.

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