



Department of Energy  
Washington, DC 20585

JANUARY 6, 1994

Dr. Michael C. Brady  
Department Manager  
Transportation System Development Department  
Sandia National Laboratories  
Albuquerque, NM 87185

Subject: Issuance of Corrective Action Requests (CARs) HQ-94-001, HQ-94-002, and HQ-94-003  
Resulting from OCRWM QA Audit HQ-94-01

Dear Dr. Brady:

Enclosed are CARs HQ-94-001, HQ-94-002, and HQ-94-003 which document the deficiencies identified during OCRWM Quality Assurance Audit HQ-94-01 of Sandia National Laboratories (SNL) Cask Systems Development Program (CSDP). The audit report detailing the audit results will follow under separate cover. You are requested to provide a response to the CARs to the OCRWM Office of Quality Assurance by the response due date entered in block 11 of the CAR form.

The responses must be signed by the responsible manager and include a concise statement of the corrective action to be taken, the names of the responsible individuals, and the scheduled completion dates. Please submit your original responses on CAR continuation sheets. A copy of a continuation sheet and preferred response format are provided.

The response shall address the required actions of block 12 of the CAR form. If the required response due date cannot be met, a written extension should be requested by you to this office.

If you have any questions, please contact Mr. Marlin Horseman of QATSS/HQAD at (703) 841-0043 or myself at (202) 586-1238.

Sincerely,

Robert W. Clark, Director  
Headquarters Quality Assurance  
Division

Enclosures

070087

102.7  
WM-11  
NH03



cc:

D. Dreyfus, RW-1  
T. Johnson, RW-3.1  
D. Horton, RW-3  
R. Spence, RW-3.2  
J. Carlson, RW-43  
B. Lake, RW-431  
M. Horseman, QATSS/HQAD  
K. Ransom, QATSS/HQAD  
R. Morgan, M&O/Vienna  
S. Zimmerman, Carson City, NV  
C. Schank, Churchill Co., NV  
D. Betchel, Clark Co., NV  
E. von Teisenhausen, Clark Co., NV  
J. Hoffman, Esmeralda Co., NV  
L. Fiorenzi, Eureka Co., NV  
B. Mettam, Inyo Co., NV  
R. Michener, Inyo Co., NV  
G. Derby, Lander Co., NV  
J. Pitts, Lincoln Co., NV  
M. Baughman, Lincoln Co., NV  
V. Poe, Mineral Co., NV  
L. Bradshaw, Nye Co., NV  
W. Offutt, Nye Co., NV  
P. Niedzielski-Eichner, Nye Co.  
K. Hooks, NRC  
J. Woodward, SNL  
T. Mills, SNL



**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

<sup>3</sup> CAR NO.     --Q-94-002      
DATE.     \*\*24/93      
PAGE.     CF      
              QA    

**CORRECTIVE ACTION REQUEST**

<sup>1</sup> Controlling Document QARD DOE RW-0214 Rev. 3, SNL CSDP QA Manual Rev. E      <sup>2</sup> Related Report No. HQ-94-01

<sup>3</sup> Responsible Organization SNL CSDP      <sup>4</sup> Discussed With M.C. Brady/K. Seager/R. Baehr/T. Mills

<sup>5</sup> Requirement:

1. SNL CSDP PD 1.4, Para. 3.3.17 requires the CSDP QA Coordinator to establish and maintain current the CSDP QA Manual
2. QARD, Para. 2.8 requires the development of position descriptions for tasks involving quality affecting work and requires the verification of education and experience of personnel performing quality affecting work.
3. RW-0214, Para. 6.1 states in part: "In addition to the elements identified in NQA-1 Supplement 6S-1, Section 2, the control system for document preparation, review, approval, and issuance shall include:"
  - a) Resolution of review comments considered mandatory by the reviewing organization.
  - b) Documentation, resolution, and maintenance of review comments. (Continued on Page 2)

<sup>6</sup> Adverse Condition:

1. The CSDP QA Manual has not been kept current and does not meet QARD 214, Rev. 3
2. Contrary to the above requirements, SNL CSDP has not developed detailed position descriptions or verified the education and work experience of personnel performing quality affecting work. There is not a procedure requiring verification of relevant education and experience.
3. Department 6320 "Report Procedures" Rev. Nov. 1991 is not under the SNL QA Program for review, approval, and issuance as a quality affecting procedure. The subject document fails to meet the QARD requirements in the following areas:
  - Qualification of review personnel.
  - Specification of review criteria.
 (Continued on Page 2)

<sup>9</sup> Does a significant condition adverse to quality exist? Yes x No           <sup>10</sup> Does a stop work condition exist? Yes      No x : If Yes - Attach copy of SWO If Yes, Circle One: A B (C) D

<sup>11</sup> Response Due Date: 2/11/94 *Per 02/20/93*

<sup>12</sup> Required Actions:     Remedial     Extent of Deficiency     Preclude Recurrence     Root Cause Determination

<sup>13</sup> Recommended Actions:

1. The CSDP Manual should be revised to reflect current SNL practices and conform to DOE/RW-0333P, Rev. 0 requirements.

(Continued on Page 2)

<sup>7</sup> Initiator Thomas R. Swift      <sup>14</sup> Issuance Approved by: [Signature]  
Thomas R. Swift      Date 12/8/93      QADD [Signature]      Date 12/20/93

<sup>15</sup> Response Accepted      <sup>16</sup> Response Accepted  
QAR      Date      QADD      Date

<sup>17</sup> Amenable Response Accepted      <sup>18</sup> Amenable Response Accepted  
QAR      Date      QADD      Date

<sup>19</sup> Corrective Actions Verified      <sup>20</sup> Closure Approved by:  
QAR      Date      QADD      Date

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

**1 Requirement: (continued)**

3. (cont) SNL QA Manual section 6.7 states: SAND documents are subject to review in accordance with SNL Dept. 6320 procedures.  
  
PD 3.3, Para. 6.0 states that CSDP controlled documents including document reviews are to be maintained as QA records.
4. NQA-1 basic requirement 16 requires conditions adverse to quality to be identified and corrected.
5. The QARD states that NQA-1 Basic Requirement 7 and Supplement 7S-1 apply with amendments.
6. NQA-1, Supplement 17S-1, Section 4.4 requires that QA records be stored to prevent damage or destruction from natural disasters, environmental conditions, and biological agents.
7. CSDP PD 1.5 Paragraph 3.3.3 requires that the Transmittal Form be used when records are forwarded to the Records Management Center.

**2 Adverse Condition: (Continued)**

3.
  - Processing mandatory and non-mandatory comments.
  - Retention of review comments and resolutions.
  - Review of documents for adequacy, completeness, and correctness prior to approval and issuance. (NQA-1: 6S-1).
  - Identification of QA records.
4. PD 5.2 is only used to correct significant conditions adverse to quality. There is no formal process to correct conditions adverse to quality which are not considered significant. Consequently, repetitive occurrences cannot be monitored.
5. The CSDP QA Program (PD) does not address NQA-1 verification criteria for methods of acceptance of Certificate of Conformances or Receipt Inspection records. (QARD Para. 7.3)
6. Storage requirements as required by the QARD and NQA-1 are not identified in SNL CSDP documents.
7. The Transmittal Form is not being used.

**3 Recommended Actions: (Continued)**

2. Develop and implement procedures for developing position description and verification of education and experience.
3. Only "Remedial" and "Preclude Recurrence" actions are required for Adverse Condition 3. As noted in the audit report SNL is performing many of these actions for technical reports and procedures. In addition to revising the procedure to meet all requirements, SNL needs to incorporate and implement the requirements under their QA program.
4. Only "Remedial", "Extent of Deficiency", and "Preclude Recurrence" actions are required for Adverse Condition 4. Revise procedures to incorporate requirements and evaluate past activities to determine if any conditions adverse to quality exist.
5. Only "Remedial" and "Preclude Recurrence" actions are required for Adverse Conditions 5 and 6. For Adverse Conditions 5 and 6 incorporate QARD requirements into the applicable procedures.
6. Only "Remedial" and "Preclude Recurrence" actions are required for Adverse Condition 7.

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**CAR NO.** HQ-94-003  
**DATE:** 11/24/93  
**PAGE:** 1 **OF**       
**QA**

**CORRECTIVE ACTION REQUEST**

**<sup>1</sup> Controlling Document** SNL CSDP PD 1.4, 3.2, 5.2, 5.3, 5.9 and QARD RW-214, Rev. 3 **<sup>2</sup> Related Report No.** HQ-94-01

**<sup>3</sup> Responsible Organization** SNL CSDP **<sup>4</sup> Discussed With** R. Baehr/T. Mills

**<sup>5</sup> Requirement:**

- SNL CSDP PD 1.4, Para. 3.3.20 requires the QA Coordinator to conduct surveillances in accordance with CSDP PD 5.9, Surveillances. SNL CSDP PD 5.9, para. 2.1 requires surveillances to be conducted to assess the quality of items or activities and to verify compliance with quality-related aspects and programmatic considerations of the CSDP.
- SNL PD 5.3, Para. 3.1.1 requires that the SNL CSDP QA Program and external organizations be audited annually.

**<sup>6</sup> Adverse Condition:**

- There have been only 2 surveillances performed on CSDP OCRWM quality affecting work and activities since mid 1990 which is not sufficient to assess quality.
- Contrary to "Requirement 2", Gram, Inc. has never been audited and no CSDP QA audit was performed in FY 1993.

**<sup>9</sup> Does a significant condition adverse to quality exist?** Yes x No       
**If Yes, Circle One:** A B **(C)**

**<sup>10</sup> Does a stop work condition exist?** Yes      No x; If Yes - Attach copy of SWO  
**If Yes, Circle One:** A B C D

**<sup>11</sup> Response Due Date:** 2/11/94

*RW 12/20/93*

**<sup>12</sup> Required Actions:**  Remedial  Extent of Deficiency  Preclude Recurrence  Root Cause Determination

**<sup>13</sup> Recommended Actions:**

- Perform surveillances as required to supplement the audit program or provide documented rationale for not performing surveillances.
- Evaluate the acceptability of previous Gram Inc. services.

**<sup>7</sup> Initiator** *Thomas R. Swift*  
*Ken* Kenneth McFall **Date** 12/8/93 **<sup>14</sup> Issuance Approved by:** *Ken McFall* **Date** 12/20/93

**<sup>15</sup> Response Accepted** QAR **Date** **<sup>16</sup> Response Accepted** QADD **Date**

**<sup>17</sup> Amended Response Accepted** QAR **Date** **<sup>18</sup> Amended Response Accepted** QADD **Date**

**<sup>19</sup> Corrective Actions Verified** QAR **Date** **<sup>20</sup> Closure Approved by:** QADD **Date**

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CAR NO.	_____
DATE:	_____
PAGE:	_____ OF _____
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**CORRECTIVE ACTION REQUEST (Continuation Page)**

Blank area for the continuation of the Corrective Action Request.

Format for Corrective Action Response

The CAR response shall include the following information:

1. Corrective Action Response for CAR # \_\_\_\_\_
  - A. Remedial Action - Actions taken to correct specific deficiencies noted.  
(Required for all CARs)
  - B. Investigative Action - Actions taken to determine the extent of the condition.  
(Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)
  - C. Root Cause Determination - Identification of the root cause of the condition.  
(Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)
  - D. Corrective Action to Preclude Recurrence - Actions taken to address the root cause and preclude recurrence of the condition.  
(Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)
2. For each action above, identify the name of the individual assigned responsibility for completion and the anticipated (or actual, if complete) completion date.
3. Response Approved: \_\_\_\_\_ Date: \_\_\_\_\_  
Responsible Manager