



## Department of Energy

Washington, DC 20585

QA: QA

JUL 03 2002

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### VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORTS (DR) BSC(O)-02-D-120 AND BSC(O)-02-D-122 RESULTING FROM THE OFFICE OF QUALITY ASSURANCE (OQA) AUDIT BSC-ARC-02-09

The OQA staff has evaluated the corrective actions of DRs BSC(O)-02-D-120 and BSC(O)-02-D-122 and determined the results to be satisfactory. As a result, the DRs are considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Christian M. Palay at (702) 794-1486.

Ram B. Murthy, Acting Director  
Office of Quality Assurance

OQA:JB-1415

Enclosures:

1. DR BSC(O)-02-D-120
2. DR BSC(O)-02-D-122



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cc w/encl:

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**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
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8.  Deficiency Report  
 Corrective Action Report  
 No. BSC(0)-02-D-120  
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 QA: QA

**DEFICIENCY REPORT/CORRECTIVE ACTION REPORT**

1. Controlling Document: (Document ID and Revision or Date)  
 AP-2.14Q, Revision 2, ICN 0

2. Related Report No.:  
 BSC-ARC-02-09

3. Responsible Organization:  
 BSC Science & Engineering Testing

4. Discussed With:  
 Rochelle E Rucinski, Roxanna Vandillen

5. Requirement:  
 AP-2.14Q, Section 5.2.2 d) states "If Reviewer's mandatory comments, if any, have been resolved and the concurrence draft of the technical product or data is acceptable, complete the concurrence section of the Review Record (a concurrence signature is necessary on the Review Record even if no comments were made. The concurrence signature assures that changes incorporated were made by other reviewers, have been reviewed by the person providing no comments, and that they concur with the latest draft)."

6. Description of Condition:  
 Contrary to the above requirement, the concurrence sections for the technical reviews of the following DTNs were found to be incomplete (i.e., no concurrence signature of the reviewer):

1. SN0108F3409100.005
2. SN0202F3409100.006
3. MO0109EBSCT3CD.010

Has work been stopped?  Yes  No

7. Initiator:  
 Christian M. Palay

9 Does a stop work condition exist?  
 Yes  No  N/A  
 If Yes, Check One:  A  B  C  D

Printed Name: Christian M. Palay  
 Signature: *Chris Palay*  
 Date: 5-15-02

10. Recommended Actions:  
 None.

11. QA Review:  
 Christian M. Palay

12 Response Due Date:  
 10 Working days after issuance.

Printed Name: Christian M. Palay  
 Signature: *Chris Palay*  
 Date: 5-15-02

13. QAM Issuance Approval:  
 Ram B. Murthy

Printed Name: Ram B. Murthy  
 Signature: *James Blaylock Jr*  
 Date: 6/5/02

14. Corrective Actions Verified/Closure:  
 Christian Palay

15. QAM Closure Approval:  
 Ram MURTHY

Printed Name: Christian Palay  
 Signature: *Chris Palay*  
 Date: 6-27-02

Printed Name: Ram MURTHY  
 Signature: *James Blaylock Jr*  
 Date: 7/3/02

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2. Check if Amended   
Check if also Initial Response

3. Extended Processing  
 No  Yes (if yes, submit  
Extended Processing request.)

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1. DR/CAR No.: BSC(O)-02-  
D-120  
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QA:

**DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE**

4. Extent of Condition: (Amended response will be required if all Extent of Condition Investigations are not complete and documented herein)  
Discussions with personnel close to the situation determined that the identified non-compliance condition was a common practice within the EBS  
Geoengineering Testing Department for the technical review of notebook-generated data sets in which there were:

- 1) No mandatory comments,
- 2) No other technical reviewers for the particular data set, and
- 3) No revised version of the data set with which to "concur."

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)  
There is no impact to waste isolation or safety, or impact to other work. This is because there is no impact to data because of the reasons identified in  
block 4. In addition, the data were derived from AP-SIII.1Q, that requires only the use of the criteria from AP-2.14Q. The use of the review record forms  
from AP-2.14Q was optional.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)  
It was determined that no remedial actions would be productive, based on the fact that there was no negative impact to quality as a result of the non-  
compliance and no negative impact to quality as a result of leaving the review records "as is".

7.  Root Cause (For a significant CAQ, attached results of formal root cause determination prepared in accordance with AP-16.4Q)  
 Apparent Cause  
The apparent cause of the deficiency was a misinterpretation of the procedural requirements regarding the review of notebook-generated data sets,  
within the EBS Geoengineering Testing Department. AP-2.14Q, Subsection 5.2, *Comment Resolution and Concurrence*, requires that the review record  
concurrence section be signed even if there are no mandatory comments. However, in the event of no comments, "comment resolution and  
concurrence" activities are usually not performed.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)  
On 6/3/02, an email was sent to the EBS Geoengineering Testing Department, and its support staff, reminding them of the procedural requirement  
associated with the completion of the concurrence section of the AP-2.14Q review records in the event of no mandatory comments.

9. Due Date for Completion of Corrective Action:

6/20/02

10. Responsible Manager:

Tom Doering  
Printed Name

Dennis Thomas  
Signature

KEM BSC/HA 6/20/02

4/20/2002  
Date

11. QAR Evaluation:  Accept  Partially Accept  Reject  
 Re-evaluated for significance

Christian Palay  
Printed Name

Chris Palay  
Signature

6-24-02  
Date

12. QAM Concurrence:

RAM MORTY  
Printed Name

James Blylock  
Signature

6/26/02  
Date

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WASHINGTON, D.C.

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 SWO

No: BSC(O)-02-D-120

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**CONDITION ADVERSE TO QUALITY CONTINUATION PAGE**

**Verification of Corrective Action for Deficiency Report (DR) BSC-02-D-120**

The Quality Assurance Representative (QAR) performed the following verification of commitments documented within the complete response (dated 6/20/02) for this DR:

**8. Actions to Preclude Recurrence:**

In this block of the response, BSC committed that an e-mail was sent on 6/3/02 to the EBS Geoengineering Testing Department staff. This e-mail served as a reminder to complete the concurrence sections of the AP-2.14Q Review Records even in the case of "no comments". This e-mail was verified by hard copy and it was confirmed that this was sent to the EBS Geoengineering Staff. The hard copy e-mail was further confirmed to contain specific guidance as to remind the staff to complete the concurrence sections from their AP-2.14Q Review Records.

As this was the only commitment from the complete response requiring verification, the QAR recommends closure of DR BSC-02-D-120 based on the above evaluation

<i>Christian Palay</i>	<i>Chris Palay</i>	<i>06-27-02</i>
QAR Printed Name	QAR Signature	Date

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8.  Deficiency Report  
 Corrective Action Report

No. BSC(O)-02-D-122

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QA: QA

**DEFICIENCY REPORT/CORRECTIVE ACTION REPORT**

1. Controlling Document: (Document ID and Revision or Date) AP-SIII.1Q, Revision 1, ICN 1		2. Related Report No.: BSC-ARC-02-09	
3. Responsible Organization: BSC Science & Engineering Testing		4. Discussed With: Cliff Howard, Michael Schuhen, Rochelle E Rucinski, Andrew Burningham	
5. Requirement: AP-SIII.1Q, Section 5.5.4 b) states: "Resolve the comments with the Technical Reviewer. Obtain a signed statement of acceptance of comment resolution from the Technical Reviewer and attach that statement in the scientific notebook, as close to the end of the segment reviewed as possible. If the notebook is full, reference the comment resolution acceptance statement as part of the record package for the notebook."			

6. Description of Condition:  
Contrary to the above requirement, there is no objective evidence that the Principal Investigator of SN-SNL-SCI-024-V1 resolved the comments from the Technical Reviewer (Dated 4/23/02, on page 128 of the Scientific Notebook).

Discussion:

One of the comments from the Technical Review indicates that some level of corrective action is needed regarding a thermocouple already installed that had failed calibration. The required annual record segment was submitted to records per AP-SIII.1Q, Section 6.1 "QA Records" on April 29, 2002 without any documented resolution to the comment.

Has work been stopped?  Yes  No

7. Initiator: Christian M. Palay <i>Chris Palay</i> 5-15-02		9 Does a stop work condition exist? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	
Printed Name	Signature	Date	

10. Recommended Actions:  
None.

11. QA Review: Christian M. Palay <i>Chris Palay</i> 5-15-02		12 Response Due Date: 10 Working days after issuance.	
Printed Name	Signature	Date	

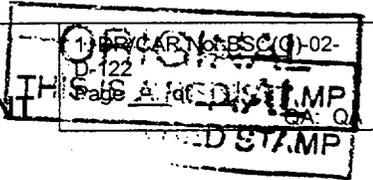
13. QAM Issuance Approval: Printed Name Ram B. Murthy Signature <i>James Blyskal</i> Date 6/15/02			
14. Corrective Actions Verified/Closure: <i>Christian Palay</i> <i>Chris Palay</i> 6-27-02		15. QAM Closure Approval: Printed Name RAM MURTHY Signature <i>James Blyskal</i> Date 7/3/02	
QAR Printed Name	Signature	Date	

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2. Check if Amended   
Check if also Initial Response

3. Extended Processing  
 No  Yes (if yes, submit  
Extended Processing request.)

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**DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE**

4. Extent of Condition: (Amended response will be required if all Extent of Condition Investigations are not complete and documented herein)  
Condition was an isolated incident resulting from the unique circumstances of the tunnel closure (see causal information in block 7). Other notebooks (SN-SNL-SCI-020-V1, SN-SNL-SCI-025-V1, and SN-SNL-SCI-013-V1, 2, and 3), which are "owned" by the same Principal Investigator were reviewed for a similar deficiency. No other was found.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)  
There is no impact because data collected with instrument was not used in any data submittal.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)

- 1 Technical comments were addressed and resolved.
- 2 Documentation of resolved comments will be submitted to Records as a supplement to the SN-SNL-SCI-024-V1 notebook segment submittal.
- 3 OCR SNL-2002-001 was created to identify and track the disposition of the out-of-calibration instrument.
- 4 A cross-reference between the scientific notebook segment submitted to Records and this DR will be established.

7.  Root Cause (For a significant CAQ, attached results of formal root cause determination prepared in accordance with AP-16.4Q)  
 Apparent Cause

The cause of this deficiency was an oversight of the procedural requirements of AP-SIII.1Q by the Principal Investigator. This isolated incident/procedural oversight was due to the inability to meet both the scientific notebook procedure comment resolution requirements and the records submittal timeline requirements simultaneously, due to the lack of underground access resulting from the tunnel closure.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

The Principal Investigator responsible for the non-compliance was re-trained to the scientific notebook procedure, AP-SIII.1Q, at the class offered on 5/16/2002 to managers responsible for scientific notebooks.

9. Due Date for Completion of Corrective Action:  
6/28/02

10. Responsible Manager:

Tom Doering  
Printed Name Signature

WS BSC QA 6/20/02  
6/20/2002

11. QAR Evaluation:  Accept  Partially Accept  Reject  
 Re-evaluated for significance

12. QAM Concurrence:

RAM MURPHY James Blumfeld  
Printed Name Signature Date 6/26/02

Christian Palay  
Printed Name Signature Date 06-27-02

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 SWO

No: BSC(O)-02-D-122

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**CONDITION ADVERSE TO QUALITY CONTINUATION PAGE**

**Verification of Corrective Action for Deficiency Report (DR) BSC-02-D-122**

The Quality Assurance Representative (QAR) performed the following verification of commitments documented within the complete response (dated 6/20/02) for this DR:

**6. Remedial Actions:**

The investigation for the extent of condition confirmed that SN-SNL-SCI-024-V1 was an isolated case of unresolved technical review comments. The BSC Responsible Individual for this DR committed to the following remedial actions:

1. Address the unresolved technical review comments
2. Submit their documented resolution as a supplement to the scientific notebook
3. Initiate an Out of Calibration Report (OCR) for the instrument identified as out of calibration in the technical review
4. Cross-reference the scientific notebook related records to this DR

The QAR has verified the completion of the above remedial actions via review of the record package supplementing the original record segment of SN-SNL-SCI-024-V1. The resolution of the comments was accepted by the technical review as evident by his statement in the record. The OCR was included in the package and addresses the failed instrument and confirms that the instrument had collected no data. Finally, the supplemental scientific notebook record was verified as being cross-referenced to DR BSC(O)-02-D-122.

**8. Actions to Preclude Recurrence:**

The action to preclude recurrence of this DR involved the re-training of the scientific notebook's (SN-SNL-SCI-024-V1) Responsible Manager to "AP-SIII.1Q, Scientific Notebooks for Managers". The QAR confirmed the Responsible Manager's attendance and successful completion of the class.

Based on the above evaluation, the QAR recommends closure of DR BSC-02-D-120

Christian Palay  
QAR Printed Name

Christ Palay  
QAR Signature

06-27-02  
Date