



Department of Energy

Washington, DC 20585

QA: QA

OCT 04 2002

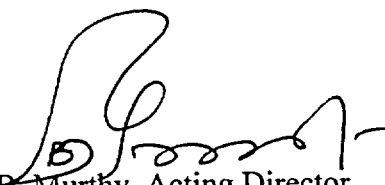
T. W. Doering
Bechtel SAIC Company, LLC
1180 Town Center Drive, M/S 423
Las Vegas, NV 89144

EVALUATION OF AMENDED RESPONSE TO, VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT (DR) BSC(O)-02-D-121 RESULTING FROM THE OFFICE OF QUALITY ASSURANCE (OQA) AUDIT BSC-ARC-02-09

The OQA staff has evaluated the amended response to, verified the corrective action of DR BSC(O)-02-D-121 and determined the results to be satisfactory. As a result, the DR is considered closed.

Disposition of this DR has resulted in no residual impact.

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-1881

Enclosure:
DR BSC(O)-02-D-121



NM5507
WM-11

T. W. Doering

-2-

OCT 04 2002

cc w/encl:

N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV
R. W. Andrews, BSC, Las Vegas, NV
G. K. Beall, BSC, Las Vegas, NV
D. T. Krishna, BSC, Las Vegas, NV
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C	8. <input checked="" type="checkbox"/> Deficiency Report <input type="checkbox"/> Corrective Action Report No BSC(O)-02-D-121 Page 1 of ____ QA QA
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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
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3 Responsible Organization BSC Science & Engineering Testing	4 Discussed With Hemi Kalia, Rochelle E Rucinski
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5 Requirement
 For the Reviewer, AP-2 14Q Section 5.1.2 f) states: "Forward the Review Record and comment documentation to the Review Coordinator."

6 Description of Condition
 Contrary to the above requirement, there is no objective evidence that 6 out of 8 Review Records for SITP-02-EBS-001 revision 00 were forwarded to the Review Coordinator (i e., the Records Package for SITP-02-EBS-001 revision 00 does not contain the Review Records).

Has work been stopped? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		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	
7. Initiator: Christian M Palay	<i>Chris Palay</i> Signature	5-15-02 Date	

10 Recommended Actions
 None

11. QA Review Christian M. Palay	12 Response Due Date 10 Working days after issuance.
Printed Name Signature Date	

13. QAM Issuance Approval Printed Name Signature Date	6/15/02 Date
--	-----------------

14 Corrective Actions Verified/Closure Christian Palay	15 QAM Closure Approval Ram Murthy
Printed Name Signature Date	Printed Name Signature Date

Submittal Page 1 of 1

2. Check if Amended

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

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1 DR/CAR No.: BSC(O)-02-
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Page
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT INITIAL RESPONSE

4. Immediate Actions Necessary to Bring the Process Under Control: (If none, provide justification statement)

PAP personnel will be informed via e-mail of the proper way to process AP-2.14Q reviews, who to contact if they have questions regarding AP-2.14Q, and who they can contact to perform AP-2.14Q functions if they do not feel comfortable performing all necessary aspects of AP-2.14Q.

Date when process will meet requirements: 6/28/02

5. Immediate Remedial Actions Completed:

A review of all AP-SIII.7Q test plan records packages was performed in order to determine if any review records were missing.

6. Plan for Determining the Extent of Condition:

The review (discussed above in Section 5) revealed that, besides the review records package for the test plan SITP-02-EBS-001 identified in the DR, nine other test plan review records packages were missing review records. They are as follows:

- SITP-02-DE-001
- SITP-02-ISM-001
- SITP-02-UZ-005, -006, -007, -009
- SITP-02-WF-006, -007
- SITP-02-WP-008

Reviewers for which no review record can be found will be contacted to determine if there is an impact to quality as a result of the missing records.

7. Due Date Submittal of Completed Response:

8/16/02

8. Response by: (Responsible Manager)

Tom Doering

Printed Name *Dennis Thomas* Signature

10. QAM Conference:

9. QAR Evaluation: Accept Partially Accept Reject

Christien Palay *Chris Palay* *6-24-02*
Printed Name Signature Date

RAM MURPHY *James Blaylock Jr* *6/26/02*
Printed Name Signature Date

Submittal Page <u>1</u> of <u>1</u> 2. Check if Amended <input type="checkbox"/> Check if also Initial Response <input type="checkbox"/> 3. Extended Processing <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (if yes, submit Extended Processing request)	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	1. DR/CAR No.: <u>BSC(O)-02-D-121</u> Page <u> </u> of <u> </u> QA: QA
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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)

All review records associated with AP-SIII.7Q Scientific Investigation Test Plans (SITPs) were reviewed for extent of condition. The records package for SITP-02-EBS-001, as documented in the deficiency report, was missing 6 of 8 review records. The records package for SITP-02-SZ-003 was missing a review record, as were those SITPs that were documented on the initial response, as follows:

- SITP-02-DE-001
- SITP-02-ISM-001
- SITP-02-UZ-005, -006, -007, -009
- SITP-02-WF-006, -007
- SITP-02-WP-008

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

No impact. Please see Attachment I for the impact statement/analysis for each review record found to be missing.

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

- 1) Documentation missing, but found, will be submitted to the Records Processing Center, and the traceability designator will reflect this deficiency report number. 2) SITP-02-EBS-001 will be cancelled. (See Attachment I for the specific actions associated with each of the missing Review Records.)

The initial response committed to an immediate action of "PAP personnel will be informed via e-mail of the proper way to process AP-2.14Q reviews, who to contact if they have questions regarding AP-2.14Q, and who they can contact to perform AP-2.14Q functions if they do not feel comfortable performing all necessary aspects of AP-2.14Q." It was determined that it was not appropriate to provide contact information in an email that was going to so many locations around the country. Instead, individuals were reminded of several important aspects of AP-2.14Q and of the importance of strict procedural compliance to this procedure.

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 is a general misunderstanding of the AP-2.14Q procedure by some of the SITP authors. Procedure AP-SIII.7Q required an AP-2.14Q review of the SITPs, and many of these individuals did not use AP-2.14Q for any other reason and had limited or no experience using AP-2.14Q

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

AP-SIII.7Q was ICN'd to no longer require the use of AP-2.14Q. This was completed on 6/28/02

9 Due Date for Completion of Corrective Action:

9/3/2002

10. Responsible Manager:

Tom Doering

Printed Name

Signature

Date

11. QAR Evaluation Accept Partially Accept Reject

Re-evaluated for significance

Christian Palay Chris Palay 8/22/02
 Printed Name Signature Date

12 QAM Concurrence

RAM MURPHY

Printed Name

Signature

Date

**Missing Review Records
Actions/Impacts**

TEST PLAN	WHICH RRs WERE MISSING?	REMEDIAL ACTION	IMPACT
SITP-02-DE-001	RISweb missing all	All missing have been provided, Package to be submitted to records	No impact because review records have now been obtained
SITP-02-EBS-001	missing 6 of 8	SITP to be cancelled.	No impact because SITP was not used and will be cancelled
SITP-02-ISM-001	EBS/John Case	None.	EBS review was not done. There is no impact based on the fact that a substantial amount of the testing was completed prior to the development of the AP-SIII 7Q test plan, and the test plan was not used in the development of the test - it was written later due to new procedural requirements. Additionally, it was reviewed by a QE reviewer and another technical reviewer.
SITP-02-SZ-003	Rev 0 Cereghino/LA, Rev 1 Knshna Iyengar; Rev. 1, ICN 1. none missing	No remedial action Package to be submitted to records	There is no impact due to the missing Rev 0 Review Record because 1) Rev. 0 was never a controlled document, and 2) Rev. 1 review was properly documented by the subject individual. There is no impact due to the missing Rev. 1 Review Record (Iyengar) due to the fact that 1) the comments were incorporated, and 2) it was not procedurally required that this individual review this test plan. It was reviewed by both a QE and a technical reviewer.
SITP-02-UZ-005	S&ET/Peters (LBNL Review was done but not submitted)	LBNL Review to be submitted to records	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer.
SITP-02-UZ-006	LA/Cereghino	No remedial action Package to be submitted to records	LA review was not done. There is no impact based on the fact that 1)Licensing was not a required reviewer per AP-SIII 7Q, and 2)This test was designed and constructed in 1997, and was nearly complete when the AP-SIII 7Q test plan was written in 2002. Therefore, the test plan was not actually used to perform the testing, but rather developed in order to meet new procedural requirements. It was reviewed by both a QE and a technical reviewer.
SITP-02-UZ-007	S&ET/Peters	None.	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer.
SITP-02-UZ-009	S&ET/Peters	None.	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer.
SITP-02-WF-006	Dana/QA	No remedial action. Package to be submitted to records.	No impact due to the one missing review record due to the fact that the Review Coordinator sent it to two QA personnel, and one did not perform review. This had no impact because it was reviewed by the other QA individual, and did not need to be reviewed by both
SITP-02-WF-007	Dana/QA	No remedial action Package to be submitted to records	No impact due to the one missing review record due to the fact that the Review Coordinator sent it to two QA personnel, and one did not perform review. This had no impact because it was reviewed by the other QA individual, and did not need to be reviewed by both
SITP-02-WP-008	S&ET/Peters	No remedial action Package to be submitted to records	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer.

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DR/CAR/QO
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No BSC(O)-02-D-121

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QA QA

CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Evaluation of Complete Response (dated 8/14/02) for Deficiency Report (DR) BSC(O)-02-D-121

The following are comments provided by the Quality Assurance Representative (QAR). The comments are linked to the specific blocks numbered on the form in the complete response (dated 8/14/02):

4. Extent of Condition:

The extent of condition documented in the complete response is well bounded and appears thorough. The extent of condition is satisfactory.

5. Impact:

The impact evaluation documented in attachment I of the complete response provided adequate justification for the no impact determination documented within the complete response. The impact evaluation is satisfactory.

6. Remedial Actions:

The planned remedial actions to be completed appear to adequately address and comply with the governing procedure. The proposed remedial actions are satisfactory.

7. Cause:

The apparent cause identifies the personnel using AP-2.14Q had a misunderstanding and/or inexperience regarding the use AP-2.14Q to review draft Scientific Investigation Test Plans (SITP). The last statement in the apparent cause is unclear what is meant by, "...many of these individuals did not use AP-2.14Q for any other reason ..". It is recommended that this statement be clarified in an amended response.

8. Action to Preclude Recurrence:

The documented action to preclude recurrence does not relate to the identified apparent cause. If the cause for this condition adverse to quality was misunderstanding and/or inexperience with the review procedure AP-2.14Q, then revising the governing SITP procedure to no longer use the review procedure does not correct the original misunderstanding or inexperience. Furthermore, it should be noted that AP-2.14Q is a widely used procedure to review other types of BSC documents. Therefore, the same personnel who misunderstood the use of AP-2.14Q to review SITPs may also misunderstand its use in their review of other documents. The action to preclude recurrence needs to address the cause of this condition adverse to quality.

Based on the above evaluation, the QAR recommends partial acceptance of this complete response to DR BSC(O)-02-D-121. *260 8/22/02*

Christian Palay
QAR Printed Name

Chris Palay
QAR Signature

August 22, 2002
Date

Submittal Page 1 of 1

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)-02-1
D-121
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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)

All review records associated with AP-SIII.7Q Scientific Investigation Test Plans (SITPs) were reviewed for extent of condition. The records package for SITP-02-EBS-001, as documented in the deficiency report, was missing 6 of 8 review records. The records package for SITP-02-SZ-003 was missing a review record, as were those SITPs that were documented on the initial response, as follows:

- SITP-02-DE-001
- SITP-02-ISM-001
- SITP-02-UZ-005, -006, -007, -009
- SITP-02-WF-006, -007
- SITP-02-WP-008

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

No impact. Please see Attachment I for the impact statement/analysis for each review record found to be missing.

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

1) Documentation missing, but found, will be submitted to the Records Processing Center, and the traceability designator will reflect this deficiency report number. 2) SITP-02-EBS-001 will be cancelled. (See Attachment I for the specific actions associated with each of the missing Review Records.)

The initial response committed to an immediate action of "PAP personnel will be informed via e-mail of the proper way to process AP-2.14Q reviews, who to contact if they have questions regarding AP-2.14Q, and who they can contact to perform AP-2.14Q functions if they do not feel comfortable performing all necessary aspects of AP-2.14Q." It was determined that it was not appropriate to provide contact information in an email that was going to so many locations around the country. Instead, individuals were reminded of several important aspects of AP-2.14Q and of the importance of strict procedural compliance to this procedure.

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

One apparent cause was a general misunderstanding of the AP-2.14Q procedure by some of the SITP authors. A second apparent cause was that AP-2.14Q was not the best procedure to use to review SITPs.

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

All PAP personnel were reminded, via e-mail, of several important aspects of AP-2.14Q and of the importance of strict procedural compliance to this procedure. This included a reminder that the review records are quality-affecting records and, as such, must be submitted to the Records Processing Center in accordance with AP-17.1Q. It also reminded personnel of what the other AP-2.14Q quality-affecting records are. Additionally, AP-SIII.7Q was ICN'd to require the use of AP-6 28Q, rather than a combination of AP-2.14Q and AP-6.28Q, for SITP reviews. AP-6 28Q is a general document review procedure, whereas AP-2.14Q is specific to the review of technical products and data.

9. Due Date for Completion of Corrective Action:

9/6/02

10. Responsible Manager:

[Signature]
Tom Doering

Printed Name

[Signature]
Signature

Date

[Handwritten]
BSC QA
09/11/02
9/10/02

11. QAR Evaluation: Accept Partially Accept Reject

Re-evaluated for significance

12. QAR Concurrence:

[Signature]
Christian Palay
Printed Name

[Signature]
Christian Palay
Signature

9-12-02
Date

[Signature]
RAM MUNITY
Printed Name

[Signature]
Signature

10/04/02
Date

Missing Review Records Actions/Impacts

TEST PLAN	WHICH RRs WERE MISSING?	REMEDIAL ACTION	IMPACT
SITP-02-DE-001	RISweb missing all	All missing have been provided Package to be submitted to records	No impact because review records have now been obtained
SITP-02-EBS-001	missing 6 of 8	SITP to be cancelled.	No impact because SITP was not used and will be cancelled
SITP-02-ISM-001	EBS/John Case	None	EBS review was not done There is no impact based on the fact that a substantial amount of the testing was completed prior to the development of the AP-SIII 7Q test plan, and the test plan was not used in the development of the test - it was written later due to new procedural requirements. Additionally, it was reviewed by a QE reviewer and another technical reviewer.
SITP-02-SZ-003	Rev. 0: Cereghino/LA; Rev. 1: Krishna Iyengar; Rev. 1, ICN 1: none missing	No remedial action Package to be submitted to records	There is no impact due to the missing Rev. 0 Review Record because 1) Rev. 0 was never a controlled document, and 2) Rev 1 review was properly documented by the subject individual. There is no impact due to the missing Rev. 1 Review Record (Iyengar) due to the fact that 1) the comments were incorporated, and 2) it was not procedurally required that this individual review this test plan It was reviewed by both a QE and a technical reviewer.
SITP-02-UZ-005	S&ET/Peters (LBNL Review was done but not submitted)	LBNL Review to be submitted to records.	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer.
SITP-02-UZ-006	LA/Cereghino	No remedial action Package to be submitted to records.	LA review was not done There is no impact based on the fact that 1) Licensing was not a required reviewer per AP-SIII.7Q, and 2) This test was designed and constructed in 1997, and was nearly complete when the AP-SIII 7Q test plan was written in 2002. Therefore, the test plan was not actually used to perform the testing, but rather developed in order to meet new procedural requirements It was reviewed by both a QE and a technical reviewer.
SITP-02-UZ-007	S&ET/Peters	None.	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer
SITP-02-UZ-009	S&ET/Peters	None	S&ET review was not done. No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer.
SITP-02-WF-006	Dana/QA	No remedial action Package to be submitted to records	No impact due to the one missing review record due to the fact that the Review Coordinator sent it to two QA personnel, and one did not perform review. This had no impact because it was reviewed by the other QA individual, and did not need to be reviewed by both.
SITP-02-WF-007	Dana/QA	No remedial action Package to be submitted to records	No impact due to the one missing review record due to the fact that the Review Coordinator sent it to two QA personnel, and one did not perform review This had no impact because it was reviewed by the other QA individual, and did not need to be reviewed by both
SITP-02-WP-008	S&ET/Peters	No remedial action. Package to be submitted to records	S&ET review was not done No impact due to the fact that S&ET manager signed-off the final SITP and that it was reviewed by both a QE reviewer and a technical reviewer

DGO
9/24/02

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DR/CAR/QO
 SWO

No: BSC(O)-02-D-121

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QA: QA

CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Verification Of Corrective Actions For Closure Of Deficiency Report (DR) BSC(O)-02-D-121

Immediate Actions Necessary to Bring the Process Under Control:

For immediate actions to preclude recurrence, the initial response (signed by Responsible Manager on 6/20/02) committed that personnel from the BSC Performance Assessment Project (PAP) would be informed of the proper way to process reviews per AP-2.14Q, *Review of Technical Products*. This information would be transmitted electronically and would include a point of contact for questions or help. However, the complete response (signed by the Responsible Manager on 8/14/02) changed the immediate actions commitment to just sending out an e-mail to PAP personnel reminding them of the critical process steps in AP-2.14Q and the importance of strict compliance with the procedure. The revised immediate action commitment was verified by the Quality Assurance Representative (QAR) via a review of a hard copy of the electronic message sent to the PAP personnel.

Additionally, the QAR verified the additional commitments in the complete response. The following are the results of the verification:

Remedial Actions

The remedial actions for the missing Scientific Investigation Test Plan (SITP) review records were under two categories: the first category (1) was if the missing records were found, and the second category (2) was if the missing records were never found. For category (1), the remedial action involved the submission of the newly found SITP review records. For category (2), no specific remedial action was taken because there was no quality impact to the SITP. The affected review records under category (2) were cross-referenced to this DR.

The QAR has verified that remedial actions were completed for those category (1) records identified in the extent of condition. For those category (2) records identified in the extent of condition, the QAR has confirmed that category (2) record packages conform to the rationale for no impacts given in the complete response. The QAR has also verified that the affected SITP review record packages have been cross-referenced to this DR.

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

The two causes for this deficiency (documented in the amended complete response signed by the Responsible Manager on 9/11/02) were (A) a general misunderstanding of the AP-2.14Q review process and (B) AP-2.14Q was not the best procedure to review SITPs. For cause (A), the immediate actions verified previously were deemed sufficient to clarify the AP-2.14Q process to the PAP personnel. For cause (B), AP-SIII.7Q was revised to utilize AP-6.28Q, *Document Review*, as the review mechanism of SITPs instead of AP-2.14Q. The QAR has reviewed the revision of AP-SIII.7Q (Revision 0 ICN 1 effective 6/28/02) and has verified that the revision now requires the utilization of AP-6.28Q instead of AP-2.14Q to review SITPs. The verification of actions to preclude recurrence is satisfactory.

Given this evaluation, the QAR recommends closure of DR BSC(O)-02-D-123.

AP-2.14Q
WR 9/25/02

Christian Palay
QAR Printed Name



QAR Signature

September 18, 2002
Date