Department of Energy
Washington, DC 20585

QA: QA

MAR 25 2003

Robert Stoner
Bechtel SAIC Company, LLC
1180 Town Center Drive, M/S 423
Las Vegas, NV 89144

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT (DR) BSC(O)-02-D-099 REGARDING THE FAILURE TO CAPTURE THE INDEPENDENT TECHNICAL REVIEW RECORDS FOR SOFTWARE DEVELOPMENT

The Office of Quality Assurance staff has evaluated the corrective action of DR BSC(O)-02-D-099 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Donald J. Harris at (702) 794-1467.

R. Dennis Brown, Director
Office of Quality Assurance

OQA:JB-0853

Enclosure:
DR BSC(O)-02-D-099

cc w/encl:
N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV (2 cys)
S. W. Lynch, State of Nevada, Carson City, NV
L. W. Bradshaw, Nye County, Pahrump, NV
D. T. Krisha, BSC, Las Vegas, NV
D. R. Tommela, BSC, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
D. J. Harris, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
W. J. Arthur, III, DOE/ORD (RW-2W), Las Vegas, NV
B. M. Terrell, DOE/ORD (RW-40W), Las Vegas, NV
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

8 ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION REPORT
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document (Document ID and Revision or Date)	2. Related Report No.:
AP-SI.1Q, Rev. 3, ICN 3, Software Management	N/A
3. Responsible Organization:	**4. Discussed With:**
Bechtel SAIC Company, LLC	Sam Archuleta, David Calloway, Mike Eshleman, Steve Splawn

5. Requirement

Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Rev. 10.

1) Section 6.2.3 Reviewing Documents. 'Documents shall be reviewed in accordance with the requirements of subsection 2.2 10 Document Review.

2) 2.2.10 Document Review

Implementing documents and documents that specify technical or quality requirements shall be reviewed to the following requirements and for any additional requirements specified by the applicable section of the QARD.

6. Description of Condition:

Block 6 Description of Condition:

1. Contrary to the cited requirements, the Administrative Procedure AP-SI.1Q fails to provide for objective evidence (records) that mandatory comments resulting from the independent technical review of the software requirements documents were resolved or objective evidence that the QA program was properly executed.

2. Contrary to the Cited Requirements:

AP-SI.1Q requires an independent technical review of the Software Activity Plan, Requirements Documents, Design Document, Installation Test Plan, Validation Test Plan, Validation Test Report and User Manual. The only objective evidence of the technical review is the signature of the the independent technical reviewer on the cover sheet of each document. However, there is no objective evidence that mandatory comments existed or were resolved satisfactory or objective evidence that the QA program was properly executed as a record, other than the independent technical reviewer's signature.

Has work been stopped? ☐ Yes ☒ No

7. Initiator:	9. Does a stop work condition exist?
Donald J. Harris (Printed Name) Donald J. Harris (Signature) 3/27/02 (Date)	☐ Yes ☒ No ☐ N/A If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

Revise AP-SI.1Q to require objective evidence of the independent technical review as a nonpermanent record.

11. QA Review:	12. Response Due Date:
DONALD J. HARRIS (Printed Name) Donald J. Harris (Signature) 3/27/02 (Date)	10 Working Days after Issuance

13. QAM Issuance Approval.

Printed Name Ram Murthy Signature James B Blaylock for Date 4/9/02

14. Corrective Actions Verified/Closure	15. QAM Closure Approval:
DONALD J. HARRIS (QAR Printed Name) Donald J. Harris (Signature) 3/6/03 (Date)	R Dennis Brown (Printed Name) R Dennis Brown (Signature) 3/24/03 (Date)

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Block 5 Requirements (cont)

2) 2.2.10 Document Review (continued)

F. Mandatory comments resulting from the review shall be documents and resolved before approving the document.

3) 17.2.1 Classifying Quality Assurance Records

B. Documents that do not meet the requirements for lifetime QA records, but provide objective evidence that the QA program has been properly executed shall be classified as nonpermanent QA records.

NOTE: NUREG-1804, Draft 2, Review Plan for Safety Analysis Report, Consider: 1) Acceptance Criterion 6, Controlled documents are required to include as a minimum, design documents, including documents related to computer software, etc. 2) Acceptance Criterion 17, Quality Assurance records that furnish evidence of quality must be specified, prepared and maintained, results of reviews, inspections, test, audits, material analyses, monitoring of work performance, maintenance and modification procedures and related inspection results, reportable occurrences, computer software, and etc. Nonpermanent records are those documents prescribing the planning, execution and auditing of activities affecting quality.

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2. Check if Amended ☐

3 Extended Processing

☑ No ☐ Yes (If yes, submit Extended Processing request)

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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)
N/A - the AP-SI.1Q procedure is currently undergoing revision and will have this issue addressed within the new version.

Date when process will meet requirements: _____

5. Immediate Remedial Actions Completed:
DAR-D3867 generated to request a change to the AP-SI.1Q procedure in order to incorporate the recommended action.

6. Plan for Determining the Extent of Condition:
The AP-SI.1Q procedure needs to be ICN'd or rev'd in order to resolve the DR issue. No additional procedures need to be modified.

7. Due Date for Submittal of Completed Response:	8. Response by: (Responsible Manager)
June 30, 2002	Robert E. Snow for [signature] 4-23-02 Printed Name / Signature / Date
9. QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject	10. QAM Concurrence:
DONALD HARRIS Donald Harris 5/2/02 Printed Name / Signature / Date	RAM MURTHY James Blaylock for 5/2/02 Printed Name / Signature / Date

02 260 7/11/02

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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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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)
Since AP-SI.1Q is the only procedure which deals with independent review of software requirements documents, no other procedures were considered in conducting this extent of condition determination. AP-SI.1Q was carefully reviewed and no other instances of failure to provide for objective evidence were identified.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)
This non compliance does not impact waste isolation and safety, or other work.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)
The procedure in question, AP-SI.1Q is undergoing substantial revision and restructuring . The new procedure(s) are expected to become effective no later than 10/1/2002. The requirements for retaining the objective evidence of independent technical review(s), as specified in this DR, will be incorporated into the appropriate sections of the new procedure(s). DAR-D3867 was developed, submitted, and accepted to track this issue to closure.
To address this requirement, prior to issuance of the new procedure(s), an e-mail will be sent to all software coordinators directing them to retain the objective evidence of the independent technical review comments/resolution and to provide the documentation to SCM for inclusion in the records package for submission to RPC.

7. ☐ Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16 4Q)
☑ Apparent Cause

The specific records retention requirements related to independent technical review of software and associated documentation were not detailed in the current or previous versions of AP-SI.1Q.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)
Send out informative email with details regarding the DR and the actions to take to prevent the recurrance of the problem.

Change the AP-SI.1Q procedure to incorporate the records retention requirement for independent technical reviewer comments.

9. Due Date for Completion of Corrective Action:	10. Responsible Manager:
03/01/2003	R. E. Stoner [signature] 7-10-02 Printed Name Signature Date
11. QAR Evaluation. ☒ Accept ☐ Partially Accept ☐ Reject	12. QAM Concurrence:
Donald J HARRIS [signature] 7/16/02 Printed Name Signature Date	RAM MURTHY [signature] 8/1/02 Printed Name Signature Date

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REQUEST FOR EXTENDED PROCESSING

3. Extended Actions: (Identify those corrective actions planned for completion beyond 100 days from issuance of the DR/CAR)
The revision process for AP-SI.1Q will not be completed within the 100 day 'normal processing' period. Additionally, training for the new procedures will be required and cannot be initiated before the new procedure(s) have been completed and complete the AP-5.1Q review process.

Expected Completion Date: 03/01/2003

4. Justification: (Provide an explanation as to why the required actions cannot be completed within 100 days)
Reallocation of resources has impacted the schedule for completing procedure revision activities. In addition, the amount of time needed to conduct the formal AP-5.1Q review, resolve comments, and finalize the document(s) has been reevaluated. Finally, development of training and providing the training was not considered in original schedules for responding to this DR.

5. Impact: (Provide an impact statement to indicate what affect not completing within 100 days will have relative to waste isolation and safety, and impact to other work, if any)
This deficiency does not impact waste isolation, safety, or other work. Not completing the corrective actions within the 100 day normal processing period will not impact waste isolation, safety, or other work

Approvals

6. Responsible Manager:			7. Senior Manager:		
R. E. Stoner	7/10/02 RS	~~07/08/2002~~	D. R. Tommela	DRTommela 7/10/02 DRT	~~07/08/2002~~
Printed Name	Signature	Date	Printed Name	Signature	Date
8. DOE Project Management:			9. DOQA:		
J.R. Dyer	8/9/02		Ram Murthy	8/9/02	
Printed Name	Signature	Date	Printed Name	Signature	Date

10. Director, OCRWM: (required for scheduled completion dates one year or more from initial issue)

N/A	N/A	
Printed Name	Signature	Date

02 1/28/03

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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)
Since AP-SI.1Q is the only procedure which deals with independent review of software requirements documents, no other procedures were considered in conducting this extent of condition determination. AP-SI.1Q was carefully reviewed and no other instances of failure to provide for objective evidence were identified.
No change since 7/10/02 response.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)
This non compliance does not impact waste isolation and safety, or other work.
No change since 7/10/02 response.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)
The procedure in question, AP-SI.1Q is undergoing substantial revision and restructuring . The new procedure(s) are expected to become effective no later than 10/1/2002. The requirements for retaining the objective evidence of independent technical review(s), as specified in this DR, will be incorporated into the appropriate sections of the new procedure(s). DAR-D3867 was developed, submitted, and accepted to track this issue to closure.
To address this requirement, prior to issuance of the new procedure(s), an e-mail will be sent to all software coordinators directing them to retain the objective evidence of the independent technical review comments/resolution and to provide the documentation to SCM for inclusion in the records package for submission to RPC.
(See continuation page for additional response)

7. ☐ Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16 4Q)
☑ Apparent Cause

The specific records retention requirements related to independent technical review of software and associated documentation were not detailed in the current or previous versions of AP-SI.1Q.
No change since 7/10/02 response.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)
Send out informative email with details regarding the DR and the actions to take to prevent the recurrance of the problem.

Change the AP-SI.1Q procedure to incorporate the records retention requirement for independent technical reviewer comments.
(See continuation page for amended response)

9. Due Date for Completion of Corrective Action:	10 Responsible Manager
03/01/2003	D. R. Tommela DR Tommela 01/28/2003 Printed Name Signature Date
11. QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject Re evaluated for significance! DONALD J HARRIS Donald J Harris 1/30/03 Printed Name Signature Date	12. QAM Concurrence: DENNIS BROWN James Blaylock for 1/30/03 Printed Name Signature Date

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Block 6 - Added response: Software Coordinators were not identified prior to the effective date of the procedures since the Software Coordinator is a new role developed for the new procedure suite; consequently the e-mail was not sent.

Block 8 - Amended response: The AP-SI.1Q/2Q/3Q procedures became effective on January 13, 2003. The procedures state that the Independent Verification and Validation reviews shall be performed in accordance with AP-2.14Q, "Review of Technical Products and Data". References to AP-2.14Q can be found in AP-SI.3Q, Subsection 5.1, where it states that "All IVV activities will be performed in accordance with AP-2.14Q, Review of Technical Products and Data...". Training has also included instruction that AP-2.14Q will be used during the IVV review processes. The approved lesson plans for the training classes contain at least one slide each that docuemnts the requirement for using AP-2.14Q for the IVV review processes.

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Block 4, Extent of Condition:

Verified AP-SI.1Q, Software procedure was the only procedure that required an independent technical review of Software.

Block 5, Impact:

Concur with BSC/SAIC that this noncompliance does not impact waste isolation, safety or other work.

Block 6, Remedial Action:

1. Verified DAR-D3867 was generated to request the change of the AP-SI.1Q procedure prior to 8/23/02.
2. Verified the proposed action to e-mail all Software Coordinators, directing the coordinators to retain objective evidence of the independent technical review comments and their resolution and submit to SCM for inclusion into the records package, was not accomplished due to no Software Coordinators being identified prior to issuance of the new suite of software procedures.

Block 7, Apparent Cause:

Verified the specific records retention retention requirements related to independent technical reviews of Software was not detailed in the current or the last few versions of AP-SI.1Q.

Block 8, Action to Preclude Recurrence:

1. Verified AP-SI.1Q, Rev. 4, ICN O, *Software Management,* AP-SI.2Q, Rev. 2, ICN 0, *Qualification of Level A Developed or Modified Software* and AP-SI.3Q, Rev. 0, ICN 0, *Software Independent Verification and Validation,* all became effective on January 13, 2003. These procedures require that the Independent Verification and Validation Reviews shall be performed in accordance with AP-2.14Q, *Review of Technical Products and Data*
2. Verified AP-SI.3Q, Rev. 0, ICN 0, addresses Independent Verification and Validation in Section 3.3 and Section 5.1.
3. Verified the approved training lesson plans:
   LPTEC03-001, Rev. 2, AP-SI.1Q, AP-SI.2Q and AP-SI..3Q, Software Developer and User Training segments, LPTEC03-002, Rev. 2, AP-SI.1Q, 2Q and 3Q, review the Independent Verification and Validation Reviews shall be performed in accordance with AP-2.14Q, *Review of Technical Products and Data*
4. Verified training on the above lesson plans at various locations has occurred for 603 personnel as of 3/6/03. Additional classes are scheduled for March and April, 2003.

Based on the above verifications, it is recommended that this DR be closed.

Donald J. Harris, QAR — 3/6/03

3/6/03

Template AP161-2

Rev 3/25/02