



Department of Energy

Washington, DC 20585

QA: QA

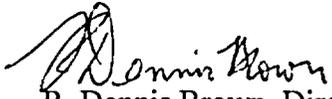
APR 29 2003

D. R. Tommela
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-187 RESULTING FROM THE FAILURE TO IMPLEMENT REQUIRED COMMENT RESOLUTION PROCESS

The Office of Civilian Radioactive Waste Management staff has verified the corrective actions of DR BSC(O)-02-D-187 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either Kerry M. Grooms at (702) 794-1367 or Samuel E. Archuleta at (702) 794-1476.


R. Dennis Brown, Director
Office of Quality Assurance

OQA:KMG-1097

Enclosure:
DR BSC(O)-02-D-187

cc w/ encl:
R. W. Minning, DOE/HQ (RW-50E), FORS
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
M. J. Mason, BSC, Las Vegas, NV
S. E. Archuleta, NQS, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
Alesia Boone, DOE/ORD (RW-32W), Las Vegas, NV
B. M. Terrell, DOE/ORD (RW-40W), Las Vegas, NV



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WASHINGTON, D.C.

8. DEFICIENCY REPORT
 CORRECTIVE ACTION REPORT
NO BSC(0)-02-D-187
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)
AP-5.1Q, Rev. 3, ICN 2

2. Related Report No.
N/A

3. Responsible Organization:
BSC, Chief Information Officer

4. Discussed With
Paula Thompson, Jake Wooley

5. Requirement:
Section 5.5.4a) requires the Preparer: "Review comments for possible incorporation into the plan or procedure, document responses on the Comment Sheets, and complete the appropriate blocks on the Review Record."

Section 5.5.4d) requires the Preparer: "Forward a comment resolution package consisting of the modified plan or procedure and as applicable the requirements matrices (QA organization and ES&H RC only), and a copy of the Review Record and Comment Sheet(s) to the Reviewers for acceptance of the comment resolutions and concurrence with the modified plan or procedure...."

6. Description of Condition:
Contrary to the above requirements the Draft B comment resolutions for AP-SI.1Q, Rev. 4, ICN. 0, AP-SI.2Q, Rev. 0, ICN 0, and AP-SI.3Q, Rev. 0, ICN 0 were sent back out to reviewers on September 13, 2002, on Excel spreadsheets instead of the Comment Sheets and without the Review Records.

Has work been stopped? Yes No

7. Initiator:
Alesia Boone
Printed Name Signature Date
Alesia Boone 9-17-02

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

10. Recommended Actions:
NONE.

11. QA Review:
S. E. ARCHULETA
Printed Name Signature Date
S.E. Archuleta 9-30-02

12. Response Due Date.
10 Working Days after Issuance

13. QAM Issuance Approval:
Printed Name Signature Date
Dennis Brown 11/07/02 *James Blaylock* *11/07/02*

14. Corrective Actions Verified/Closure
S.E. Archuleta
Printed Name Signature Date
S.E. Archuleta 4-22-03

15. QAM Closure Approval:
Printed Name Signature Date
R. Dennis Brown *R. Dennis Brown* *4/23/03*

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)

During review of Draft B AP-SI.1Q Rev 4, AP-SI.2Q Rev 0, and AP-SI.3Q spreadsheets were used to facilitate tracking the large number of reviewer comments and the responses from staff supporting the review activity. The extent of condition is difficult to quantify since anecdotal information suggests that this practice is not uncommon and records of this type are not retained. These spread sheets were then used as an informal transmission of information in preparation for discussions of comments and responses with reviewers. Again, an informal exchange of information prior to a meeting is a fairly standard courtesy and records do not exist to document the extent of this condition. Finally, inclusion of the formal Review Record with the informal discussion materials is not believed to be typical, but again documentation is not retained to permit determination of the extent of condition.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)
Despite the use of spreadsheets and the absence of the Review Record during early comment resolution discussions, QA records submitted to the Records Processing Center at the completion of the review process for these three procedures were complete, correct, and signed/dated as required. Consequently, this noncompliance has no impact on waste isolation and safety and no impact on other work.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)
No additional remedial actions are necessary. Records, including procedure drafts, submitted review comment sheets, responses to comments, resolution documentation for all drafts have been maintained on the appropriate forms as required by AP-5.1Q and have been submitted to Document Review, Document Control, and to Records for processing.

7. Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16.4Q)
 Apparent Cause
Apparent cause is some confusion on the part of some reviewers to whom informal materials were e-mailed as a courtesy prior to a comment resolution meeting so that reviewers could be prepared to discuss the responses provided. The transmission email did not unambiguously characterize the communication as informal. Apparently some reviewers concluded that the materials attached to this e-mail were intended as the formal response to their comments and therefore expected the formal Comment Sheets and the Review Record..

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)
Informal or courtesy copies of responses are identified as such when sent by email in order to avoid the apparent confusion. Formal comment resolution packages include the appropriate material, as defined in AP-5.1Q.

*Approved by response dated 12/10/02
DGO 12/23/02*

9. Due Date for Completion of Corrective Action:
12-05-02

10. Responsible Manager:
David R. Tommela *DR Tommela* 12/5/02
Printed Name Signature Date

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

12. QAM Concurrence:

Printed Name Signature Date

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)

During review of Draft B AP-SI.1Q, Rev 4, AP-SI.2Q, Rev 0, and AP-SI.3Q, Rev 0, spreadsheets were used to facilitate tracking the large number of reviewer comments and the responses from staff supporting the review activity. Anecdotal information suggests that this practice is not uncommon and records of this type are not retained. These spread sheets were then used as an informal transmission of information in preparation for discussions of comments and responses with reviewers. Again, an informal exchange of information prior to a meeting is a fairly standard courtesy. It is believed that this is the only instance wherein the informal information was interpreted to be a formal response.

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

Despite the use of spreadsheets and the absence of the Review Record during early comment resolution discussions, QA records submitted to the Records Processing Center at the completion of the review process for these three procedures were complete, correct, and signed/dated as required. Consequently, this noncompliance has no impact on waste isolation and safety and no impact on other work, and in the end all records were in full compliance with AP-5.1Q.

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

No additional remedial actions are necessary. Records, including procedure drafts, submitted review comment sheets, responses to comments, resolution documentation for all drafts have been maintained on the appropriate forms as required by AP-5.1Q and have been submitted to Document Review, Document Control, and to RPC for processing.

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

The apparent cause is deemed to be a communications failure. The transmission email did not unambiguously characterize the communication as informal. Some reviewers apparently concluded that the materials attached to this e-mail were intended as the formal response to their comments.

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

Personnel assigned to this organization who might be designated as review coordinators or reviewers have been instructed to ensure compliance with governing procedures, and have been cautioned to ensure that when informal information is transmitted during the comment resolution process, such informal information is clearly characterized as such. See attached email.

9. Due Date for Completion of Corrective Action:
 12/10/02

10. Responsible Manager:
 D. R. Tommela DRTommela 12/10/02
 Printed Name Signature Date

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

12. QAM Concurrence:
 RDENNIS BROWN James B. Brown 12/23/02
 Printed Name Signature Date

SAM E. ARCHULETA Sam Archuleta 12/11/02
 Printed Name Signature Date

112/10/2002

 David Tommela
12/10/2002 07:29 AM

QA:QA D60

To: Paula Thompson/YM/RWDOE@CRWMS, Steve Splawn/YM/RWDOE@CRWMS, Brett
Platko/YM/RWDOE@CRWMS, Virgil Rochester/YM/RWDOE@CRWMS, Richard
Atkisson/YM/RWDOE@CRWMS
cc: Sam Archuleta/YD/RWDOE@CRWMS, James Whitcraft/YM/RWDOE@CRWMS
Subject: Software Procedure Reviews

User Filed as: ExclAdminMgmt-14-4/CA:WA D60
12/11/02

All,

Recently, spreadsheets were used to facilitate tracking a large number of comments used during an AP-5.1Q review. The spreadsheets were then used as an informal transmission of information. The email used to send the spreadsheets did not clearly categorize the informal nature of the information, and BSC(O)-02-D-187 was generated as a result. Please ensure compliance with governing procedures for the document review process (AP-5.1Q), and ensure that when informal information is transmitted during the process, such as email or spreadsheets, that the informal information is clearly identified as informal so as to avoid miscommunication.

I will appreciate your attention to this requirement.

Dave

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

During verification of corrective actions reported on your amended initial response dated 12/10/02, additional deficient conditions have been noted. and will require your attention. The deficient conditions are described below.

AP-5.1Q, Section 5.5.6c) requires that when changes "other than editorial changes are made to the plan or procedure during the comment resolution process," the preparer is obliged to "obtain re-concurrence from each reviewing organization/discipline affected by the corrections."

A review of the review records packages for AP-SI.1Q, AP-SI.2Q, and AP-SI.3Q was conducted for the purpose of verifying the corrective actions reported on the amended initial response, signed on 12/10/02. While that review did verify as accurate the corrective actions taken to address the original condition, it also resulted in the discovery of deficiencies in the maintenance of version control during the comment resolutions for the above named procedures. Within the review records packages for each of the procedures, there was considerable evidence that reviewers did not review the same draft of the procedure for re-concurrence, as required by the cited section of AP-5.1Q.

For example, the version of AP-SI.1Q that was reviewed by OQA during the review process was Draft D, dated 10/23/02. After changes were made to that draft, the concurrence review was conducted on the changed version which was designated as Draft E, dated 11/05/02. There was no evidence in the review packages that other organizations had reviewed that version of the draft. Similar conditions existed in the review packages for AP-SI.2Q and AP-SI.3Q. The review records packages thus indicate that there was a lack of version control during the review process for any of the three procedures in question.

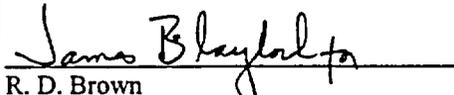
The three procedures were signed on 11/14/02 and became effective on 1/13/03.

Please provide an amended response to address the additional conditions within ten working days.



Sam E. Archuleta
QA Representative

1-16-03
Date



R. D. Brown
QA Manager

1/29/03
Date

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)

During review of Draft B AP-SI.1Q, Rev 4, AP-SI.2Q, Rev 0, and AP-SI.3Q, Rev 0, spreadsheets were used to facilitate tracking the large number of reviewer comments and the responses from staff supporting the review activity. Anecdotal information suggests that this practice is not uncommon and records of this type are not retained. These spread sheets were then used as an informal transmission of information in preparation for discussions of comments and responses with reviewers. Again, an informal exchange of information prior to a meeting is a fairly standard courtesy. It is believed that this is the only instance wherein the informal information was interpreted to be a formal response.

See Continuation Page for Additional (Amended) Response.

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

Despite the use of spreadsheets and the absence of the Review Record during early comment resolution discussions, QA records submitted to the Records Processing Center at the completion of the review process for these three procedures were complete, correct, and signed/dated as required. Consequently, this noncompliance has no impact on waste isolation and safety and no impact on other work, and in the end all records were in full compliance with AP-5.1Q.

Additional (amended) response: No changes to previous response.

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

No additional remedial actions are necessary. Records, including procedure drafts, submitted review comment sheets, responses to comments, resolution documentation for all drafts have been maintained on the appropriate forms as required by AP-5.1Q and have been submitted to Document Review, Document Control, and to RPC for processing.

Additional (amended) response: No changes to previous 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 apparent cause is deemed to be a communications failure. The transmission email did not unambiguously characterize the communication as informal. Some reviewers apparently concluded that the materials attached to this e-mail were intended as the formal response to their comments.

Additional (amended) response: Some Review Records did not accurately reflect the draft date on the document; it appears that a typographical errors could have been made on the Review Records and could account for the appearance of loss of version control.

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

Personnel assigned to this organization who might be designated as review coordinators or reviewers have been instructed to ensure compliance with governing procedures, and have been cautioned to ensure that when informal information is transmitted during the comment resolution process, such informal information is clearly characterized as such. See attached email.

Additional (Amended) Response: Actions to preclude recurrence will be applied during the review of AP-SI.4Q. A different review coordinator has been assigned to this review. AP-5.1Q training has been verified for the review coordinator. Special attention will be applied to version control and to the annotation of review records. These controls will be reassessed at the completion of this review for application in future procedure developments and reviews.

9. Due Date for Completion of Corrective Action:
 15 April 2003

10. Responsible Manager:

D. R. Tommela

Printed Name

DR Tommela 2/5/03
 Signature Date

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

12. QAM Concurrence:

Sam E. Archuleta

Printed Name

Sam Archuleta
 Signature

Signature

Date

R. D. Brown

Printed Name

R. D. Brown
 Signature

Signature

2/13/03

Date

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Block 4, Continued:

Additional (amended) response: The records packages for the procedures were reviewed. Several reviewers provided updated review records by crossing out the previous draft identification and initialing and dating the change/correction. Several reviewers did this several times, causing the review record to potentially be unreadable, and it appears that some review records did not accurately reflect the date of the draft being reviewed. Additionally, it appears that at least one draft had several different dates associated with it, thereby allowing for the appearance of loss of version control.

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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 corrective actions for development, review and implementation of procedure AP-SI.4Q will not be complete until 31 March 2003

Expected Completion Date: 15 April 2003

4. Justification: (Provide an explanation as to why the required actions cannot be completed within 100 days)
AP-5.1 compliance will be verified by the development of a new procedure AP-SI.4Q. The procedure is in review currently and scheduled to be complete by the end of March.

5. Impact: (Provide an impact statement to indicate what affect not completing within 100 days will have relative to waste generation and safety, and impact to other work, if any)
NONE

**Deficiency closed prior to obtaining
signatures and, therefore,
are no longer applicable.**

Deborah J. Opilowski, CAC
4/22/03

Approvals

6. Responsible Manager:
Steve Splawn [Signature] 2/5/03
Printed Name Signature Date

7. Senior Manager:
Dave Tommela [Signature] 3/15/03
Printed Name Signature Date

8. DOE Project Management:
N/A
Printed Name Signature Date

9. DOQA:
N/A
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

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Verification of corrective action commitments as stated in Block 8 of the Amended Response dated February 5, 2003 was completed on April 17, 2003.

Verified the assignment of a different Review Coordinator for the review of AP-SI.4Q, Software Independent Verification and Validation (IVV) of Legacy Code. Also verified that the new Review Coordinator had completed training in AP-5.1Q, Plan and Procedure Preparation, Review and Approval prior to initiating the review process for AP-SI.4Q.

AP-SI.4Q was signed on April 14, 2003 and will be effective on May 15, 2003. In order to verify the balance of corrective action commitments, i.e., the assessment of version control and the proper annotation of review records, the entire review package that was configured for transmission to the Records Processing Center (RPC), was reviewed. The records package documents the reviews by each reviewer for each of the four drafts of the procedure. Documents observed were Comment Sheets and Review Records for each of the drafts, including Draft D, which was the concurrence draft. Also reviewed were the final signed procedure, each of the drafts, the IVV Report Template, the complete training package, and the various commitment letters which support the development of the procedure.

In the observation of each reviewer's package, it was evident that strict version control had been closely maintained as the development of the procedure progressed through four drafts. In the review of 13 review packages, not one instance of noncompliance was found. All of the mandatory comments on each of the Comment Sheets had been properly initialed and dated. All of the Review Records properly identified the correct draft document, and all Review Records had been signed by the appropriate individual. There were no instances where an official reviewer had failed to submit the required, signed documents.

IMPACT: Concur with the impact as stated in Block 5 of the Amended Response dated February 5, 2003.

Based on the verification of committed corrective actions and verification of the effectiveness of those actions, closure of this DR is recommended.



Sam E. Archuleta
QA Representative

4-17-03
Date