



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
"QA"

NN1.881205.0072

DEC 05 1988

Joseph E. Stiegler, Acting
Technical Project Officer for Yucca Mountain Project
Sandia National Laboratories
P.O. Box 5800
Organization 6310
Albuquerque, NM 87185

REQUEST FOR AMENDED RESPONSES TO YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE (QA) STANDARD DEFICIENCY REPORTS (SDRs) 170, 172 AND 179, REVISION 0, GENERATED AS A RESULT OF YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QA AUDIT 88-06 OF SANDIA NATIONAL LABORATORIES (SNL) (NN1-1989-0567)

The Project Office has evaluated your responses to SDRs 170, 172, and 179, Revision 0, generated as a result of Project Office QA Audit 88-06 and has determined that amended responses are required. A summary of each evaluation is contained below. You are requested to submit the amended responses to this office within 10 working days of this letter, and to send the original copy of each amended response to Nita J. Brogan of Science Applications International Corporation, (SAIC), Las Vegas, Nevada.

SDR - 170 Revision 0

The response did not address how or when SNL design subcontractor QA programs would incorporate the requirement cited in the SDR.

SDR - 172 Revision 0

The response did not address measures to ensure SNL design subcontractors are in compliance with the requirement cited in the SDR.

SDR - 179 Revision 0

The Project Office is of the understanding that significant calculations performed under SNL Department Operating Procedure (DOP) 3-3, "Analysis Definition Requirements," would be segregated from the design process described in SNL Procedure DOP 3-5, "Design Control and Verification." The response provided does not clearly indicate this situation. SNL is requested to clarify the response.

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If you have any questions, please contact Wendell B. Mansel of my staff at FTS 544-7945 or Gerard Heaney of SAIC at FTS 544-7739.

N. Valtura for

James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-926

Enclosures:
SDRs 170, 172, and 179, Rev. 0

cc w/encls:

- Ralph Stein, HQ (RW-30) FORS
- L. H. Barrett, HQ (RW-3) FORS
- J. H. Hines, NWQA, AL
- S. W. Zimmerman, NWPO, Carson City, NV
- J. J. Holonich, NRC, Washington, DC 
- John Gilray, NRC, Las Vegas, NV
- R. R. Richards, SNL, 6310, Albuquerque, NM
- S. H. Klein, SAIC, Las Vegas, NV
- J. W. Estella, SAIC, Las Vegas, NV
- O. D. Smith, SAIC, Las Vegas, NV
- H. H. Caldwell, SAIC, Las Vegas, NV
- E. P. Ripley, SAIC, Las Vegas, NV
- K. B. Johnson, SAIC, Las Vegas, NV
- J. E. Therien, SAIC, Las Vegas, NV
- S. B. Ailes, SAIC, Las Vegas, NV
- B. A. Tabaka, SAIC, Las Vegas, NV
- N. J. Brogan, SAIC, Las Vegas, NV
- Gerard Heaney, SAIC, Las Vegas, NV
- P. T. Prestholt, NRC, Las Vegas, NV
- R. W. Gray, MED, NV
- C. P. Gertz, YMP, NV
- M. B. Blanchard, YMP, NV
- W. R. Dixon, YMP, NV
- L. P. Skousen, YMP, NV
- E. L. Wilmot, YMP, NV
- W. B. Mansel, YMP, NV
- C. E. Hampton, YMP, NV
- A. C. Williams, YMP, NV
- N. A. Voltura, YMP, NV
- A. L. Baca, YMP, NV

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization	1 Date 8/3/88		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 3		
	3 Discovered During WMPO Audit 88-06		3a Identified By S. Dana		3b Branch Chief Concurrence Date N/A		
	4 SDR No. 170		Rev. 0				
	5 Organization SNL		6 Person(s) Contacted R. Hill		7 Response Due Date is 20 Working Days from Date of Transmittal		
	8 Requirement (Audit Checklist Reference, if Applicable) The NNWSI QA Plan, NVO-196-17, Rev. 5, Section III, "Scientific Investigation and Design Control," Para. 2.2.1, states "Applicable design input such as criteria letters, design bases, performance and regulatory requirements,						
	9 Deficiency Contrary to the above requirements, no objective evidence could be provided to support that SNL QA has reviewed or approved design inputs (i.e., Design Investigation Memos) and design output documents (i.e., SAND Reports/Letter						
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Revise appropriate SNL procedures to incorporate the requirements contained in Block 8 above.						
	Completed by Organization in Block 5	11 QAE/Lead Auditor Date <i>7-11-88</i>		12 Branch Manager <i>[Signature]</i>		13 Project Quality Mgr. Date <i>James Blaylock 8/18/88</i>	
		14 Remedial/Investigative Action(s) Investigation concerning the impact of the 470 stated deficiencies and consideration of the design process indicates the following: In an iterative design process, such as that for the repository, the inputs (requirements) provide the basis for a given design, and these designs are reviewed against (cont'd.)					
		15 Effective Date <u>N/A</u>					
Completed by Org. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence The cause of this deficiency was that the cited provisions of NVO 196-17 had not been incorporated into an approved version of the SNL NNWSI QAPP nor its implementing procedures. Action to preclude recurrence consists of: (cont'd.)						
	17 Effective Date <u>see text</u>						
	18 Signature/Date <i>Thomas [Signature]</i> 26/8/88						
Comp. by Orig. QA Org.	19 Response <input type="checkbox"/> Accept <input checked="" type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date <i>D. Heaney 11-16-88</i>		Branch Manager/Date <i>[Signature]</i>		
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date		
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date		
	22 Remarks						
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date			
				PQM/Date			

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ENCLOSURE



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 170

Rev. 0

Page 2 of 3

8 Requirement (continued)

codes, standards, manufacturer's design data, and quality standards shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization."

Para. 2.7.1 states that design output documents shall "Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction or release to another organization for use in other design activities. As a minimum the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the WMPO. (Refer to audit checklist Item No. 3-10)

9 Deficiency (continued)

Reports) for QA Level II design activities.

10 Recommended Actions (continued)

2. Complete the required reviews and investigate to determine what impact the lack of QA review and approval has had on SNL design input and output documents.
3. Reinstruct appropriate personnel to revised procedural requirements. Provide objective evidence of the reinstruction with response to this SDR.
4. Ensure design subcontractor QA programs incorporate the requirements contained in Block 8 above.

14 Remedial/Investigative Action(s) (cont'd.)

the design inputs, and refinements of either the design or the requirements result. Due to this iterative nature of this design process, the products under question will still receive pre-ACD, ACD, LAD, and FD&C design reviews. Therefore, there is no apparent benefit for SNL QA to review either the inputs or outputs of design which is already completed and published. There is no QA impact on the design products which have not been released for procurement, manufacture, construction, or controlled release in other design activities. Consequently, no remedial action to address the specific deficiencies cited is to be taken. By the nature of the Project design process and implementation of actions stated in 16, below, any negative impact of the cited deficiencies will be eliminated.

16 Cause of the Condition & Corrective Action to Prevent Recurrence (cont'd.)

- Revising the SNL QAPP to incorporate these requirements (such a revision has already been forwarded for approval by WMPPO).
- Revising the affected implementing design-related procedures to incorporate these requirements (R. R. Hill, 12/15/88).
- Conducting training for design personnel to cover the new requirements (R. R. Hill, 1/31/89).

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date 8/3/88	2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
3 Discovered During WMPO Audit 88-06	3a Identified By S. Dana	3b Branch Chief Concurrence Date	4 SDR No. 172 Rev. 0
5 Organization SNL	6 Person(s) Contacted R. Hill/H. MacDougal	7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) The NNWSI QA Plan, NVO-196-17, Rev. 5, Section II, "Quality Assurance Program," Para. 2.2.4, states "The requirements contained in this document apply to QA Levels I and II items and activities unless otherwise noted"			
9 Deficiency Contrary to the above requirement, SNL has delineated less restrictive design verification requirements for QA Level II activities than for QA Level I activities in the SNL-NNWSI-QAPP, Rev. 0, Section 3. QA Level II requirements			
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Revise the SNL QAPP and appropriate implementing procedures to incorporate the requirements in Block 8 above.			

Aprvl.

11 QAE/Lead Auditor Date <i>James Blaylock 8/11/88</i>	12 Branch Manager Date <i>R. Hill 8/11/88</i>	13 Project Quality Mgr. Date <i>James Blaylock 8/18/88</i>
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Completed by Organization in Block 5

14 Remedial/Investigative Action(s) Remedial Action: For less restrictive design verification requirements: Revise the SNL NNWSI QAPP to eliminate differentiation in design verification for QA Level I and II. (This revision has already been submitted to YMPO for approval - SNL NNWSI QAPP, Rev. B.)	15 Effective Date <u>12/15/88</u>
16 Cause of the Condition & Corrective Action to Prevent Recurrence The cause of both deficiencies was an effort to provide some meaningful and reasonable "grading" or differentiation between QA Level I and II design activities; an effort which was approved by the Project Office in Rev. 0 of the SNL QAPP. This situation is not one which must be precluded from recurrence, therefore, no corrective action is needed.	
17 Effective Date <u>N/A</u>	

Completed by Org.

18 Signature/Date <i>Monroe</i> 10/6/88	
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Comp. by Orig. QA Org.

19 Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	<input checked="" type="checkbox"/> Amended Response	QAE/Lead Auditor/Date <i>S. Heaney 11-16-88</i>	Branch Manager/Date <i>R. Hill 1/6/89</i>
20 Amended Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	<input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date	Branch Manager/Date
22 Remarks				
23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date	



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 172

Rev. 0

Page 2 of 2

8 Requirement (continued)

herein...Deviations within applicable criteria are permissible for Level II items and activities provided that adequate justification has been documented and approved by WMPO." (Refer to audit checklist Item Nos. 3-10 and 3-11.)

9 Deficiency (continued)

are less restrictive for (1) methods of design verification and (2) personnel qualifications for performing design verifications without appropriate documented justification and approval from WMPO. Additionally, SNL DOP 3-4, "Design Investigation Control," Rev. B, contains less restrictive requirements for the review and approval of QA Level II Design Investigation Memos (DIMs) as QA is required to only review and approve QA Level I DIMs.

10 Recommended Actions (continued)

2. Reinstruct appropriate personnel to revised procedural requirements. Provide objective evidence of the reinstruction with response to the SDR.
3. Investigate to determine what impact the less restrictive requirements for Level II design activities has had.
4. Ensure design subcontractor QA programs are in compliance with revised SNL QAPP requirements.

14 Remedial/Investigative Action(s) (cont'd.)

For less restrictive requirements for review and approval of DIMs: Revise DOP 3-4 to require QA review of QA Level II DIMs. Conduct appropriate training. (R. R. Hill, 12/15/88.)

Investigative Action: Investigation revealed that the implementing procedure for design verification, DOP 3-5, does not, in fact, include the differentiation "allowed" in Rev. A of the SNL QAPP. In addition, there have been no QA Level II design products subjected to design verification and approved. Therefore, there is no adverse impact of either the less restrictive design verification allowed by the SNL QAPP or the lack of QA review of QA Level II DIMs.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date <u>8/3/88</u>	2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
3 Discovered During WMPO Audit 88-06	3a Identified By T. Watson	3b Branch Chief Concurrence Date N/A	4 SDR No. <u>179</u> Rev. <u>0</u>
5 Organization SNL	6 Person(s) Contacted R. Steinbaugh	7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) SNL DOP 3-5, "Design Control and Verification," Rev. 0, Para. 4.1.3.4, states "If a significant calculation is to be performed as part of design, the PI shall adhere to the requirements of DOP 3-3, Analysis Definition Requirements.			
9 Deficiency Complex calculations used in the design of complex systems such as the ventilation system, underground excavations and shaft design analysis are currently being performed as routine calculations under SNL DOP 3-10, "Routine			
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Review to determine which calculations are significant and perform those calculations in accordance with DOP 3-3.			

11 QAE/Lead Auditor Date <u>8-11-88</u>	12 Branch Manager <u>[Signature]</u>	Date <u>AUG 11 1988</u>	13 Project Quality Mgr. Date <u>James Blayford 8/15/88</u>
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14 Remedial/Investigative Action(s) Remedial action is not required since: 1) issuing a PDM and redoing the calculations as required by DOP 3-3 would not alter the results, 2) results were used to support a Level III document, i.e., the SCP/CDR, and 3) calculations performed will be superseded by new calculations specific to supporting the Advanced Conceptual Design.	15 Effective Date <u>N/A</u>
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16 Cause of the Condition & Corrective Action to Prevent Recurrence Cause: 1) DOP 3-5 unspecific as to definition of significant calculations, and 2) at the time these calculations were initiated, DOPs 3-3, 3-4, 3-5, and 3-10 did not exist. Corrective Action ...see next sheet	17 Effective Date <u>1/1/89</u>
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18 Signature/Date <u>[Signature]</u> <u>10/18/88</u>	
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19 Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	<input checked="" type="checkbox"/> Amended Response	QAE/Lead Auditor/Date <u>B. Heaney 11-16-88</u>	Branch Manager/Date <u>[Signature] 10/16/88</u>
20 Amended Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	<input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date	Branch Manager/Date

22 Remarks				
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23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date	
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WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 179

Rev. 0

Page 2 of 2

8 Requirement (continued)

If routine calculations are performed as part of a design task, the investigator or analyst shall adhere to the analysis and calculation requirements for routine design calculations in DOP 3-10, Routine Design Calculations (or their equivalent)." (Refer to audit checklist Item No. T-32)

9 Deficiency (continued)

Design Calculations."

Discussion: For SNL to perform a complex (Scientific Analysis and Calculation) a Problem Definition Memo (PDM) is required to be issued in accordance with DOP 3-3, "Analysis Definition Memo." During the course of the audit, it was observed that there have not been any PDMs issued to the subcontractor who is performing the complex calculations described above.

10 Recommended Actions (continued)

2. Investigate to determine if the use of the inappropriate procedure to perform the calculations has caused any adverse impact on the quality of the work products.
3. Reinstruct appropriate personnel to procedural requirements. Provide objective evidence of the reinstruction with response to the SDR.

16 Correction Action

Corrective Action: 1) for consistency with DOP 3-5, modify definition 3.8 of DOPs 3-3 and 3.9 of DOP 3-4 to read--"Significant Calculation--a scientific or engineering calculation or analysis that involves a mathematical or numerical model of a physical process or phenomena," and 2) modify DOP 3-4 to allow significant calculations to be done under the charter of a DIM. This will require that DOP 3-4 be made more specific in terms of requirements for significant calculations. Conduct necessary training (R. R. Hill, by 1/1/89).