



Department of Energy

Nevada Operations Office
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WBS 1.2.9.3
QA

MAR 05 1990

Thomas O. Hunter
Technical Project Officer for Yucca Mountain Project
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P.O. Box 5800
Organization 6310
Albuquerque, NM 87185

ACCEPTANCE OF RESPONSES TO STANDARD DEFICIENCY REPORTS (SDRs) 432, 433, 435, AND 444, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 89-03 OF SANDIA NATIONAL LABORATORIES (SNL)

The Project Office QA staff has evaluated and accepted your responses to SDRs 432, 433, 435, and 444, Revision 0, generated as a result of Project Office QA Audit 89-03 of SNL. The SDRs will be closed after verification of satisfactory completion of the specified corrective actions. Copies of the SDRs are enclosed for your information.

Verification of completion of your corrective action will be performed after the effective dates that were provided. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send a copy of extension requests to Nita J. Brogan, Science Applications International Corporation (SAIC), 101 Convention Center Drive, Las Vegas, Nevada 89109, and Ralph W. Gray, U.S. Department of Energy, P.O. Box 98518, Las Vegas, Nevada 89193.

If you have any questions, please contact Robert B. Constable of my staff at (702) 794-7945 or FTS 544-7945, or Amelia I. Arceo of SAIC at (702) 794-7737 or FTS 544-7737.

Donald G. Horton, Director
Quality Assurance Division
Yucca Mountain Project Office

YMP:RBC-2265

Enclosure:
SDRs 432, 433, 435,
and 444, Revision 0

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PDR WASTE
WM-11 FDC

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Add: J Kennedy 1 1


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MAR 05 1990

Thomas O. Hunter

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cc w/encl:

Ralph Stein, HQ (RW-30) FORS
D. E. Shelor, HQ (RW-3) FORS
R. R. Richards, SNL, 6310, Albuquerque, NM
A. I. Arceo, SAIC, Las Vegas, NV, 517/T-06
J. H. Nelson, SAIC, Las Vegas, NV, 517/T-04
S. W. Zimmerman, NWPO, Carson City, NV
J. E. Kennedy, NRC, Washington, DC 

cc w/o encl:

J. H. Hines, NWQA, AL
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06
J. W. Gilray, NRC, Las Vegas, NV

YMPO STANDARD DEFICIENCY REPORT

Completed by Originating QA Organization	1 Date 9/13/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During AUDIT 89-3 (SNL)		3a Identified By S. HANS		4 SDR No. 432 Rev. 0	
	5 Organization SNL		6 Person(s) Contacted R. BAEHR		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (CL# 10-1) SNL QAP-10-1 Rev. B para. 3.1.1 states in part, "The QA Coordinator will establish a schedule of surveillances of project activities based on the schedule of performance of those activities..."					
Completed by Organization in Block 5	9 Deficiency Contrary to the above, the QA Coordinator's current basis for scheduling Audits and Surveillances is : (1) procedure requirements, i.e., QAP, DOP, etc., (2) requests from PI, TPO, TL, or QA Coordinators, and (3) followup					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Develop appropriate basis for scheduling surveillance. 2. Perform training as required.					
	11 QAE/Lead Auditor/Date <i>S. Dana 9/22/89</i>		12 Division Manager/Date <i>W. O. Hunter 9-22-89</i>		13 Project Quality Mgr./Date <i>James Blaylock 9/22/89</i>	
	14 Remedial/Investigative Action(s) Remedial Action: Review the September Monthly Highlights and Status Report, identify ongoing or upcoming Level I and II activities and evaluate the need for future surveillances. If a need for surveillances is found, the activity to be surveilled will be added to the FY90 schedule; see 16 below. Responsible for action: J. Voigt. (cont'd.) 15 Effective Date <u>11/1/89</u>					
Completed by Organization in Block 5	16 Cause of the Condition & Corrective Action to Prevent Recurrence Cause: The cause of the condition was less-than-optimal use of available information resources concerning schedules for the performance of technical activities. (cont'd.) 17 Effective Date <u>12/1/89</u>					
	18 Signature/Date <i>John W. Bingham 11/1/89</i> for T. O. Hunter, Dept. Manager 6310					
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date <i>S. Dana 12/11/89</i>	Division Manager/Date <i>S. Dana 12/11/89</i>	Project Quality Mgr./Date <i>James Blaylock 12/15/89</i>	
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks <i>Accept Response 1/2/90 - YMP - JB - 1359</i> <i>Additional response dated 12/14/89 was reviewed. No impact on original evaluation. Variances 1-23-90 S. Dana 1/23/90 - 6245/90</i>					
Comp. by Orig. QA Org.	22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

ENCLOSURE

Y.M.O STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 432

Rev. 0

Page 2 of 2

9 Deficiency (continued)

audits. Additionally the QA Coordinator does not have access to schedules of project activities in order to surveill activities in a timely manner.

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

Investigative Actions:

A formal documented system to plan and schedule surveillance is being used and updates to the schedule were made based on known activities, however, technically related work other than planning and scoping activities has been very limited. Reference Attachment 1.

There is no impact on previous items or activities. No investigative corrective actions for past work is deemed necessary.

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

Corrective Action:

The FY90 (and future) QA surveillance schedule will be established and revised quarterly, by reviewing the current and future Monthly Highlights and Status Reports, and by requesting activity input from the Principal Investigators on a quarterly basis. Procedure QAP 10-1 will be revised to include an example of the document to be used to track and schedule surveillances.

This will develop an appropriate basis for scheduling surveillances.

Training was considered and determined not to be necessary as a corrective action, since the scheduling of surveillances will be performed by members of the QA staff who were involved in preparing this Corrective Action.

Amended Response SDR 432

The response stands on its own without any attachment. Delete reference to "Attachment 1."

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 9/13/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During AUDIT 89-3 (SNL)		3a Identified By S. HANS		4 SDR No. 433 Rev. 0	
	5 Organization SNL		6 Person(s) Contacted R. RICHARDS		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (CL#15-10) A. QAP 16-2, Rev. A, para. 5.1.4 states in part, "Review the DR to ensure that the condition does not warrant a CAR..."					
Completed by Originating QA Organization	9 Deficiency 15 of 39 DRs reviewed by the auditor disclosed that the determination as to whether the DR should be elevated to a CAR was made prior to obtaining enough information to make a proper decision. Therefore, it is probable that some of					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Review identified DRs to determine significance. 2. Determine if evaluation for significance is performed at appropriate step					
Aprvl.	11 QAE/Lead Auditor/Date <i>S. Hans 9/22/89</i>		12 Division Manager/Date <i>R. Richards 9-22-89</i>		13 Project Quality Mgr./Date <i>James Blaylock 9/22/89</i>	
	14 Remedial/Investigative Action(s) A Remedial Action All Deviation Reports generated to date were re-reviewed by the QA Coordinator to evaluate whether Correction Action Reports were warranted (a CAR resulting from three of the DRs was subsequently issued). Complete. (cont'd.)					
Completed by Organization in Block 5	15 Effective Date <u>11/15/89</u>					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date <u>12/15/89</u> If the evaluation cited in 14B, above, indicates that procedure change(s) are necessary, those changes will be made and training conducted (if needed) in accordance with QAP 2-5. Responsible party R. R. Richards, due 12/15/89.					
Completed by Organization in Block 5	18 Signature/Date <i>John W. Bingham</i> 11/1/89 for T. O. Hunter, Dept. Manager 6340					
	19 Response Accepted QAE/Lead Auditor/Date <i>Anneli L. Omer 2/21/90</i> Division Manager/Date <i>J. Clark 2/21/90</i> Project Quality Mgr./Date <i>James Blaylock 2/21/90</i>					
Comp. by Orig. QA Org.	20 Corrective Action Verif. Satisfactory QAE/Lead Auditor/Date Division Manager/Date Project Quality Mgr./Date					
	21 Remarks <i>Request Amended Response 1/12/90 - YMP: JB-1474</i> <i>Rec'd Amended Response, Ltr dtd 1/24/90 - LES: 6315:mb</i> <i>Request for extension of corrective action implementation date, letter Hunter to Horton dated 1/11/90. Request granted, letter YMP: RBC-1760.</i>					
Comp. by Orig. QA Org.	22 QA CLOSURE QAE/Lead Auditor/Date Division Manager/Date PQM/Date					

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 433

Rev. 0

Page 2 of 2

8 Requirement (continued)

B. QAP 16-2, Rev. A, para. 5.3.2 states in part, "QA Coordinators periodically review completed DRs and their disposition to assure proper implementation of this QAP."

9 Deficiency (continued)

the 15 DRs were not elevated to CARs because of the improper review. The 15 DRs are noted below:

DR 89-01,02,03,04,06,11,12,13,15,24,29,33,34,35,38.

10 Recommended Actions (continued)

in DR process.

3. Make changes to procedures as necessary.

4. Perform training as required.

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

B Investigative Action:

An evaluation will be conducted to determine if the evaluation of whether deviations reported on DRs constitute significant conditions adverse to quality is called for at the appropriate point in the process in QAP 16-2. Responsible party - J. V. Voigt; due 11/15/89.

Amended Response SDR 433

Change block 14 to read:

- A. Remedial Action - All Deviation Reports generated to date were reviewed by the QA Coordinator to evaluate whether Corrective Action was warranted (a CAR resulting from three of the DRs was subsequently issued). Complete.
- B. Investigative Action - An evaluation has been conducted to determine if the evaluation of whether deviations reported on DRs constitute significant conditions adverse to quality occurs at the appropriate point in the QAP 16-2 process. That evaluation indicated that it, in fact, is appropriate to determine whether the DR indicates a significant adverse condition at a point later in the process. Complete.

As a result of that evaluation, QAP 16-2 will be revised, as indicated by the evaluation. Responsible Party - R. R. Richards, due 1/19/90.

Change block 15 to read, "1/19/90."

Change block 16 to read: "The "cause" of the condition stated in block 9, above, is that the opinion of the auditor concerning the appropriate place in the QAP 16-2 process for "significance determination" differed from what was called for in the procedure. As this condition is predicated entirely on the judgment and opinion of an individual, no specific, meaningful "corrective action" can be developed. (Note: In this case, no compliance deficiency occurred; for all 39 DRs, the requirement in block 8 ["Review the DR..."] was met.)"

Change block 17 to read, "N/A."

Yucca Mountain Project Audit 89-03

Amended Response SDR 433

Change block 16 to read: "The cause of the condition cited in block 9, above, was that the Deviation Report process, as specified in QAP 16-2, required that a determination of whether a Corrective Action Report is warranted be done inappropriately early in the process. Action specified in block 14 B, above, addresses this cause.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 9/14/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 3
	3 Discovered During AUDIT 89-3 (SNL)		3a Identified By M. DIAZ		4 SDR No. 435 Rev. 0
	5 Organization SNL		6 Person(s) Contacted A. STEVENS/J. PHILLIPS		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (CL#12-3) SNL DOP 12-1, Rev.C, para. 4.3.2 states in part, " Calibration certifications shall contain as a minimum: o Identification of the calibration procedure, including revision used.				
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirements, calibration certifications of equipment or devices used on work performed by SNL 7111 Division do not contain the cited requirements in Block 8. Additionally, these records are QA records as stated				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Perform the required review of those calibration certifications in Block 8 to ensure that they contain appropriate procedure requirements.				
	11 QAE/Lead Auditor/Date <i>S. Dana 9/22/89</i>				
Completed by Organization in Block 5	12 Division Manager/Date <i>Robert G. F-22 +9</i>		13 Project Quality Mgr./Date <i>James Blaylock 9/22/89</i>		
	14 Remedial/Investigative Action(s) Calibration certificates were reviewed to determine if they contain information required in the current SNL procedure DOP 12-1. Gage calibration certifications for the period 1977 through 4/87 pre-date the development of QA procedures to cover this activity. Nevertheless, these certifications contain the (cont'd.)				
	15 Effective Date 12/1/89				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Cause: The cause for the condition is that personnel did not follow current procedures defined in DOP 12-1 and DOP 12-1 did not reflect previous agreements between the Weapons Test Seismic Investigation program and NWRT Department 6310 regarding maintenance of records from UNE tests. (cont'd.)				
Completed by Organization in Block 5	17 Effective Date 1/2/90				
	18 Signature/Date <i>T. O. Hunter, Dept. Manager 6310 11/2/89</i>				
	19 Response Accepted				
Comp. by Orig. QA Org.	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date <i>Harris Jan 2/21/90</i>		Division Manager/Date <i>JE Clark 2/21/90</i>
			Project Quality Mgr./Date <i>JE Clark 2/21/90</i>		Project Quality Mgr./Date
	21 Remarks <i>Request amended Response - 1/12/90 - YMP: 30-1474 Rec'd Amended Response. It dated 1/24/90 - LES: 6315: mb Request to extend due date, letter Hunter to Horton dated 1/11/90 Extension granted, letter YMP:RBC-1760</i>				
	22 QA CLOSURE				
		QAE/Lead Auditor/Date		Division Manager/Date	PQM/Date

YMP STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 435

Rev. 0

Page 2 of 3

8 Requirement (continued)

- o Calibration data - standards value versus device readings.
- o A quantitative statement of the accuracy of the device.
- o The printed name and signature of the person who performed the calibration."

Para. 6.0 states in part, "Calibration records resulting from this procedure include the calibration certifications. These records are QA records and will be filed in the SNL NWRT Records Management System under the appropriate file codes."

9 Deficiency (continued)

by SNL personnel. However, they have been neither filed in the SNL NWRT Records Management System nor authenticated as required (Ref. DOP 17-1, Rev. C)

10 Recommended Actions (continued)

2. Investigate to determine if an adverse impact on quality activities occurred as a result of a QA requirement being omitted from the calibration certifications.
3. After authentication of the records is performed, file those as QA records in the RMS.
4. Reinstruct applicable personnel of 6311, 7110, and 7111 Divisions to the requirements in Block 8.

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

calibration data, a statement indicating that the gage is within the quantitative accuracy limits of the manufacturer, and the date of calibration. Some calibration certificates contain the signature of the technician who conducted the calibration. Gage calibration certifications for the period 4/87 through 10/88 contain all information required by DOP 12-1 with the exception of the calibration procedure identification and the combination of printed name and signature. They contain either the signature or printed name and initials. Gage calibration certifications since 11/88 comply with DOP 12-1 requirements with one exception, namely printed name and signature. Some have a signature, and some have a printed name and initials. In all cases the signature is legible. All gage calibration certifications have been reviewed and were submitted to the SNL NWRT DRMS on 9/28/89 for inclusion in the appropriate data sets.

In addition to the gage calibration certification, similar certifications for instruments used to monitor the gage output voltages are being investigated. Preliminary investigations of the certifications indicate deficiencies essentially identical to those for the gages. All instrument calibration certifications will be renewed and submitted to the SNL NWRT DRMS by 12/1/89.

No remedial action is planned for these past certifications. The intent of the UNE seismic monitoring program (see Study Plan 8.3.1.17.3.3.2) is to collect sufficient additional UNE seismic response data under the QA program procedures to establish if any bias exists in previous data.

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

Corrective Action. Personnel have been instructed in the requirements of DOP 12-1 and calibration forms will be modified to contain all information required in DOP 12-1. TPs covering this work will be modified to reflect current requirements for records submittal to the DRMS, to require that records be sent through the appropriate 6310 contact for authentication.

Yucca Mountain Project Audit 89-03

Amended Response SDR 435

Change the last sentence of the first paragraph of block 14 to read: "All gage calibration certifications have been reviewed and properly authenticated and were submitted to the SNL NWRT DRMS on 9/29/89 for inclusion in the appropriate data sets (after acceptance as valid records). Deviation Report 90-46 was prepared to assess the impact of deficiencies in the calibration certifications."

Change the third paragraph of block 14 to read: "There are no other remedial actions (aside from those cited above) planned for these past calibration records. SNL has recognized that, generally, records associated with weapon-test seismic data collected prior to April 1987 will not, on their own, be adequate to support repository licensing application. To address this larger problem, the UNE seismic monitoring program (see Study Plan 8.3.1.17.3.3.2) has been specifically designed to collect sufficient additional UNE seismic response data at QA Level I to establish whether the past data is valid or not, as a whole, regardless of detail record deficiencies."

Add, at the end of the "Corrective Action" paragraph in block 16, "No future calibration certifications will be processed as NWRT records unless they contain all of the information required by DOP 12-1."

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 9/22/89		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2
	3 Discovered During AUDIT 89-3 (SNL)		3a Identified By A. ARCEO		4 SDR No. 444 Rev. 0
	5 Organization SNL		6 Person(s) Contacted T. O. HUNTER, E. WILMOT		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (CL# 1-1 & 1-3) NNWSI 88-9, Rev. 2, para. 1.0 states in part, "The organizational structure, lines of communication, authority and duties of persons and organizations"				
Completed by Organization In Block 5	9 Deficiency It was verified during the audit that the QA functions are performed by the QA Coordinator, and other QA personnel; however, the QA personnel are not managed by the QA Coordinator, since they report directly to the Technical Project				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective Provide a Quality Organizational Chart delineating the reporting relationship of all QA personnel and revise procedures and QA program documents if				
	11 QAE/Lead Auditor/Date <i>S. J. Jones 9/22/89</i>				
Completed by Org. QA Org.	12 Division Manager/Date <i>W. A. H. Jones 9-22-89</i>		13 Project Quality Mgr./Date <i>James Blufford 9/22/89</i>		
	14 Remedial/Investigative Action(s) Some clarification is in order. SNL employees within the SNL YMP department are considered to be on the staff of the TPO for personnel actions and salary administration. However, the QA Coordinator, assigned as Task Leader for the QA Work Breakdown Structure element, is responsible for "managing" that WBS element and the staff assigned to it in all other areas (e.g., work assignments and (cont'd.				
	15 Effective Date 11/30/89				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence NA				
Comp. by Orig. QA Org.	17 Effective Date NA				
	18 Signature/Date <i>T. O. Hunter, Dept. Manager 6310 11/1/89</i>				
	19 Response Accepted	QAE/Lead Auditor/Date <i>Amelia J. Jones 2/21/90</i>	Division Manager/Date <i>J. Clark 2/21/90</i>	Project Quality Mgr./Date <i>James Blufford 2/21/90</i>	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
Comp. by Orig. QA Org.	21 Remarks <i>Request amended Response 1/12/90 - YMP:JB-1474 Rec'd Amended Response, Ltr dtd 1/24/90 - LFS:6315:mb Request for extension of corrective action implementation completion date Letter Hunter to Horton dated 1/11/90. Extension granted, letter YMP:RBC-1760.</i>				
	22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 444

Rev. 0

Page 2

of 2

8 Requirement (continued)

performing activities affecting quality shall be clearly established and delineated in writing."

Paragraph 2.1 of the same revision states in part, "The person responsible for directing and managing the overall NNWSI Project Participant QA program shall be identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program."

Note: As interpreted by the Project Quality Assurance office the QA program includes the individuals directly performing functions of verifying adequacy and effectiveness of the SNL QA program requirements.

9 Deficiency (continued)

Officer. Furthermore, there was no QA Organizational Chart that delineates the reporting relationship between the QA Coordinator and QA personnel. It should be noted that during the audit there was no objective evidence found which would indicate that the above reporting relationship has had an adverse impact on the SNL QA program.

10 Recommended Actions (continued)

necessary.

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

reassignments, budget, planning, organizing the staff, providing direction, etc.). As contract monitor for the QA support services contract, the QA Coordinator has the same relationship with contractor employees performing QA functions. However, as is indicated in block 9, above, these relationships are not clearly delineated in writing. Therefore, SNL will issue a QA Advisory to all staff personnel to clarify any misunderstanding that may exist and will submit a request for Project Office approval of a revision to the SNL QAPP to clearly delineate the position, responsibilities, and authority that already exists. Responsible party: R. R. Richards.

Amended Response SDR 444

Add the following to the text for block 14, at the end after, "...that already exists," and before, "Responsible Party": "Additionally, to provide appropriate authority to exercise proper control over the QA Program, the QA Coordinator will provide input on performance appraisal for SNL QA personnel. This authority will be included in the revision to the QAPP mentioned above.

Change block 15 to read: "1/31/90."

Yucca Mountain Project Audit 89-03

Amended Response SDR 444

Add the following text for block 14, following, "... providing direction, etc.).": "As is the case for all Task Leaders, those staff personnel report to the QA Coordinator for activities within that WBS element." Also, add the following text at the end of block 14 after, "... that already exists," and before, "Responsible Party": Additionally, to provide appropriate authority to exercise proper control over the QA Program, the QA coordinator will perform performance appraisal for SNL QA personnel and provide that appraisal to the Director, Nuclear Waste Management and Transportation. This authority will be included in the revision to the QAPP mentioned above."

Change block 15 to read: "2-16-90."