



Department of Energy
Yucca Mountain Site Characterization
Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3
QA

NOV 15 1991

Thomas E. Blejwas
Technical Project Officer
for Yucca Mountain
Site Characterization Project
Sandia National Laboratories
P.O. Box 5800
Organization 6310
Albuquerque, NM 87185

EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-91-079 RESULTING
FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-91-07 OF
SANDIA NATIONAL LABORATORIES

The YMQAD staff has evaluated the response to CAR YM-91-079. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada.

If you have any questions, please contact Robert B. Constable at (702) 794-7945 or FTS 544-7945, or Richard L. Weeks at (702) 794-7853 or FTS 544-7853.

James B. Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-832

Enclosure:
CAR YM-91-079

cc w/encl:
K. R. Hooks, NRC, Washington,
S. W. Zimmerman, NWPO, Carson City, NV
R. R. Richards, SNL, 6310, Albuquerque, NM

cc w/o encl:
J. H. Hines, OQD, AL
J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

YMP-5 9111260208 911115
PDR WASTE PDR
WM-11

ADD: Ken Hooks

Mr. Encl.

102-7
WM-11
N403

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RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.**

14CAR NO.: YM-91-079
DATE: 8/28/91
SHEET: 1 OF 27
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAP 18-1, Revision C, ICN 03		2 Related Report No. Audit YMP-91-07	
3 Responsible Organization Sandia National Lab		4 Discussed With R. Richards	
10 Response Due 20 days from issue	11 Responsibility for Corrective Action R. R. Richards	12 Stop Work Order Y or N	
<p>5 Requirement:</p> <p>QARD, Revision 4, Section 16, Paragraph 16.0 states, "The provisions of NQA-1 Basic Requirement 16 shall apply with the following amplifications."</p> <p>QAPP, Revision E, Paragraph 16.1 states, "A corrective action system is defined herein that ensures that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical."</p> <p>QAP 18-1, Revision C, ICN 03, Sections 3.3 and 3.4 state the following:</p> <p>3.3 Finding - A statement of fact regarding noncompliance with established policies, procedures,</p>			
<p>6 Adverse Condition:</p> <p>Audit Finding and Observation Reports (AFORs) have been issued as "Observations" even though they identify a deficient condition and should be issued as a "Finding". Examples are as follows:</p> <p>NER-91-03 NER-91-04 AFORs identified in Oakridge Audit (ORNL-A91-1)</p> <p>Surveillance Reports were issued which identified conditions that were not in compliance with procedural requirements however, Deviation Reports were not issued but rather recommendations were made to document the violations. Examples are as follows:</p> <p>Surveillance Reports JVV 91-02, JVV 91-03, JVV 91-04 and CEF 91-01.</p>			
<p>7 Recommended Action(s):</p> <p>Identify the remedial action(s) to be taken to correct the deficiencies noted in Block 6. Investigate the program process, activities or documentation to determine the extent and depth of similar deficient conditions on the CAR. Identify these deficiencies and provide the measures</p>			
8 Initiator M.R. Diaz R.L. Weeks <i>Richard L. Weeks</i>	Date: 8/28/91	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <i>Catherine M. Hampton</i> 8-28-91
<p>15 Verification of Corrective Action:</p> 			
16 Corrective Action Completed and Accepted:		17 Closure Approved By:	
QAR _____ Date _____		OQA _____	

ENCLOSURE

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5 Requirements (continued)

instructions, drawings, or other applicable requirements. (Findings require a documented response specifying corrective action and verification of its accomplishment.)

3.4 Observation - A statement of opinion regarding a potential quality problem, quality assurance program weakness or practice which could lead to a finding if not corrected. (Observations require a documented response specifying corrective action.)

QAIP 10-1, Revision 0, Section 3.4.2 states, "Any activity that is found to be in noncompliance with requirements will be documented on SNL NWRT Deviation Report (DR) in accordance with QAP 16-2."

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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CORRECTIVE ACTION REQUEST
(continuation sheet)

CORRECTIVE ACTION RESPONSE:

1. Corrective Action for Deficient Condition #1 (concerning NER deficiencies)

A. Extent of Deficiency: Investigation has indicated that the deficient condition cited applies to both the New England Research audit and the Holometrix audit performed by SNL during FY91. Concerning the effect of this deficiency, it must be noted that audit results requiring corrective action were documented on the AFOR and identified either as a Finding or Observation to satisfy corrective action requirements of the QAPP para. 16.1. Both Findings and Observations require corrective action by the audited organization and follow-up by SNL is the same for both on conditions of any significance. (SNL records will verify this statement.) Therefore, with respect to corrective action required of and implemented by the auditee, there is no difference between the two conditions.

B. Root Cause: The root cause of this deficiency (identifying conditions meeting the definition of "finding" as "observations") was a desire on the part of the audit team to account for the following factors in the audit documentation:

- no quality-affecting work had been performed at one contractor (Holometrix); quality-affecting work had only recently begun at the other (NER),
- the deficiencies identified in the audits were largely the result of excessive SNL procedure requirements, rather than contractor actions,
- the knowledge that, from the audited organization's point of view, SNL findings and observations require equivalent action.

Regardless of those considerations, the subject deficiencies should have been identified as findings.

C. Remedial Action: Appropriate corrective actions have been effected for NER-91-03 and NER-91-04 (as well as the similar Holometrix deficiencies).

D. Corrective Action to Prevent Recurrence: The need to properly identify deficiencies discovered during audits as either "findings" or "observations" has been discussed with SNL QA audit personnel. It will be re-emphasized in writing. Responsible party: R. R. Richards; due 10/23/91.

Str dtd 10/18/91

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2. Corrective Action for Deficient Condition #2 (concerning audit ORNL-A91-1)

- A. Extent of Deficiency: In this situation no deficiency actually exists. At the time of the audit, Oak Ridge National Laboratory (ORNL) was on an SNL-imposed "hold" requiring ORNL to obtain SNL approval prior to initiation of contract Task 3 (quality-affecting work). The contract also contained a requirement for ORNL to perform a quality evaluation of prior work related to Task 3 prior to the SNL approval called for in Task 1. The contract then required a compliance review to determine adequacy of the ORNL QA Program and correction of any deficiencies thereof to be completed prior to any work under Task 3. The Executive Summary from the audit report, attached, clearly indicated the purpose of the audit as related to contract requirements. Additionally, QAP 18-1, para. 4.1.1.5 clearly states that audits can be conducted after award of a contract to determine the effectiveness of the implementation of a contractor QA program. It appeared prudent to perform an audit, in this case, to evaluate a contractor after award and prior to release to perform work. No quality-affecting work had been performed by ORNL at the time of the audit.

The conditions cited in our observations concerned differences between their QA implementing documents and contract requirements. There were no cases of "violations" in which requirements had not been adhered to; in actual quality-affecting work.

Considering the above, the documented situations were definitely:

- "potential quality problems,
- QA program weaknesses, or
- practices which could lead to a finding if not corrected" - which is our definition of "observation."

These observations were analogous to comments that would result from review of a QA program document; "Findings" are not utilized in such cases, and were not appropriate for the ORNL audit.

ROOT CAUSE: N/A.

REMEDIAL ACTION: N/A.

ACTION TO PRECLUDE RECURRENCE: N/A.

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3. Corrective Action for Deficient Condition #3 (concerning surveillance documentation)

- A. Extent of Deficiency: A review of all 1991 surveillances was performed and no further examples of the condition were identified. Similar conditions do not exist.
- B. Root Cause: As can be seen by evaluating the detailed information under "Remedial Action," the situations documented as recommendations in the subject surveillance reports can be categorized as:
1. less-than-effective practices that deserved to be evaluated for improvement, even though they involved no procedure violation or other quality deficiency,
 2. individual deficiencies that were corrected and verified prior to completion of the surveillance, or
 3. uncorrected deficiencies that should have been documented as such.

For the first category above, recommendations are an appropriate means of documenting the situation.

Concerning the second category, it is accepted practice in the Project to not document such situations as deficiencies, since the immediate problem has been corrected. However, it is probably not always appropriate to categorize them as "recommendations," treating them instead as "deficiencies corrected during performance of the surveillance."

For the last category above, the root cause is indeterminate, since the individual surveillor involved is no longer associated with SNL or the Yucca Mountain Site Characterization Project.

- C. Remedial Actions: The identified surveillances (JVV-91-02, 03, 04 and CEF-91-01) were reviewed to determine if the concerns/recommendations in the surveillances had any impact on quality. Each item was evaluated to determine if an unresolved quality issue existed.

The evaluation disclosed the following:

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Surveillance Report No. CEF-91-01

This surveillance identified seven recommendations. The status of these recommendations, numbered as they are in the surveillance report, is as follows:

1. DR 91-32 was issued to document this condition (open).
2. Not quality related - administrative error (typo).
3. Not quality related - administrative update; no requirement to do.
4. PDMs 72-28, 29, and 30 now reference PCA 1.0.
PDMs 75-13 and 76-08 were done to DOP 3.3, Rev. A, which did not require the listing of PCA numbers.
5. The training database was updated.
6. Training was completed.
7. TOSPAC and NORIA-SP software has been certified.
CA-DISSPLA software was addressed in DR-91-26 (closed 10/7/91).

With the exception of Recommendation No. 1 (which has now been documented on DR 91-32), all the recommendations had been addressed responsively prior to the issue of this CAR. No further actions are required.

Surveillance Report No. JVV-91-02

Three problem areas were discussed in the surveillance report. One had been documented and controlled by a Stop Work Order. Another concerned a nonmandatory Implementation Plan statement which conflicted with a procedural requirement; no procedural violation existed. The last involved unorthodox communication techniques used by YMPO to initiate SNL work. Additional documentation of these situations is not deemed necessary.

Surveillance Report No. JVV-91-03

One Deviation Report, two observations, and two recommendations were identified in the surveillance report. Both of the observations identified deficiencies that were corrected prior to completing the surveillance. It did not seem reasonable to issue DRs for these situations. Of the recommendations, one concerned training for handling SNL engineering drawings as QA records, however, the SNL work scope does not now include issuing engineering drawings. The second recommendation concerned what, at the time, was a future QARD requirement and could not then be treated as a deficiency.

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Surveillance Report No. JVV-91-04

Two "concerns" were identified in this surveillance report. One was for working to an approved Experiment Procedure that had not been issued via Document Control. Differences between the procedure in use and a current, controlled version were found to be minor and did not affect the work in progress. Also, copies of the current, controlled version were obtained at the work site prior to completion of the surveillance. For these reasons, initiation of a Deficiency Report did not appear to be appropriate at the time, nor does it now. (By means of interacting with the surveillor on this topic the affected parties became sufficiently knowledgeable concerning use of controlled documents.)

The second "concern" related to a situation that was not, at the time of the surveillance, a deficient condition. Its inclusion in the report was intended to serve as a reminder that documentation of the location of the work site should be completed prior to finishing the in-process work, in order to preclude the development of a deficient condition. (It has since been verified that the documentation of work-site location was properly completed.)

D. Corrective Action to Prevent Recurrence: To address the causes and apparent causes of this situation, cited in "Root Cause," above, the following actions will be taken: written management direction will be provided to all SNL QA audit and surveillance personnel to the effect that:

- Deficient conditions found during audits and surveillances that are not immediately corrected shall be documented as such, not as "concerns" or "recommendations."
- Deficient conditions that are immediately corrected shall be reported in audit or surveillance reports straightforwardly as such.

Responsible Party - R. R. Richards; due by 10/23/91.

Response Approved:

Thomas E. Blejwas 10/18/91
Thomas E. Blejwas, Actg. Mgr. Date
Nuclear Waste Repository
Technology
Department 6310

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Accept Response:

QAR

Date

Accept Response:

OQA

Date

Sandia National Laboratories

Albuquerque, New Mexico 87185

date: September 16, 1991

to: 6319 Staff

LIMITED-VALUE MATERIAL


from: R. R. Richards, 6319

subject: Audit Reporting Process Improvements

As documented in a number of recent (and not-so-recent) audits and surveillances, we have had difficulties with timely issuance of audit reports and AFORs. Actions we have taken in response to those audits and surveillances will improve the situation. However, there are some other straightforward actions that will help that I would like implemented immediately. These are:

- Audit documentation of all types - audit reports, AFORs, etc. - will be typed here at SNL.
- Lead auditors and other audit personnel should set the goal of having audit reports issued within three weeks of performance of the audit.
- Problems or deficiencies discovered during audits that are attributable to SNL, rather than the auditee, will be documented on DRs, CARs, or memos, instead of AFORs.

Exceptions to the above practices may be appropriate on a case-by-case basis. However, implementation of these practices on a routine basis is now the standard.

RRR:6319:mjh

Copy to:

6310 T. E. Blejwas, Actg.

6319 R. R. Richards

EXECUTIVE SUMMARY

The purpose of this audit was to perform a direct evaluation of the Oak Ridge National Laboratory (ORNL) QA Program to determine its adequacy and to identify any deficiencies or concerns requiring corrective action prior to initiating any technical work. This audit, supplementing Sandia National Laboratories (SNL's) prior review and approval activities on the ORNL QA Program Plan (QAPP), is intended to satisfy the QA compliance review requirements necessary for release of the mandatory hold point referenced in Contract 35-0023 Task 1.

The evaluation identified a number of observations (i.e., potential deficiencies) requiring corrective action by ORNL and by SNL. Several of the observations had been previously identified as "open items" requiring action. The ORNL QAPP as well as the SNL contract requires some changes, none of major significance. Agreement was reached on several changes needed in the ORNL QAPP to comply with Yucca Mountain Project (YMP) QA requirements.

The most serious problems impeding further ORNL work is the acceptance of prior work proposed by ORNL letter of June 30, 1990 and the need for an ORNL software QA plan and implementing procedures. These and other observations are documented in Audit Finding/Observation Reports (AFORs) in Appendix A for tracking purposes to ensure proper resolution.

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AMENDED RESPONSE

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CORRECTIVE ACTION RESPONSE:

1. Corrective Action for Deficient Condition #1 (concerning NER deficiencies)

A. Extent of Deficiency: Investigation has indicated that the deficient condition cited applies to both the New England Research audit and the Holometrix audit performed by SNL during FY91. Concerning the effect of this deficiency, it must be noted that audit results requiring corrective action were documented on the AFOR and identified either as a Finding or Observation to satisfy corrective action requirements of the QAPP para. 16.1. Both Findings and Observations require corrective action by the audited organization and follow-up by SNL is the same for both on conditions of any significance. (SNL records will verify this statement.) Therefore, with respect to corrective action required of and implemented by the auditee, there is no difference between the two conditions.

B. Root Cause: The root cause of this deficiency (identifying conditions meeting the definition of "finding" as "observations") was a desire on the part of the audit team to account for the following factors in the audit documentation:

- no quality-affecting work had been performed at one contractor (Holometrix); quality-affecting work had only recently begun at the other (NER),
- the deficiencies identified in the audits were largely the result of excessive SNL procedure requirements, rather than contractor actions,
- the knowledge that, from the audited organization's point of view, SNL findings and observations require equivalent action.

Regardless of those considerations, the subject deficiencies should have been identified as findings.

C. Remedial Action: Although these deficient conditions that should have been documented as "findings" were identified as observations, in fact, the resolution, implementation of corrective and remedial actions, and follow-up was pursued for these deficiencies in the same manner as if they had been identified as "findings." The resolution, implementation of actions (by NER), and follow-up (by SNL) for AFOR-0-91-03 and AFOR-0-91-04 for NER (as well as for the equivalent deficiencies for Holometrix) is completed and these AFORs are closed. No additional actions of remedial nature by NER, Holometrix, or SNL is considered necessary.

Ltr dtd 11/7/91 - Bleyman to Spencer

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D. Corrective Action to Prevent Recurrence: The need to properly identify deficiencies discovered during audits as either "findings" or "observations" has been discussed with SNL QA audit personnel. It will be re-emphasized in writing. Responsible party: R. R. Richards; due 10/23/91. (See attached memo, subject: "Guidance on Reporting of Deficient Conditions and Areas of Improvement.")

2. Corrective Action for Deficient Condition #2 (concerning audit ORNL-A91-1)

A. Extent of Deficiency: As represented in the report for audit ORNL-A91-1, the subject audit was performed to fulfill the need for a "post-award survey" or "readiness assessment" of Oak Ridge in the time period during which their QA Program was being refined but prior to them being released to perform the technical work specified in the contract. This particular timing, as described below, contributed to the condition described in this CAR. This is the only audit recently performed as such a "readiness assessment," so this is considered to be an isolated situation.

B. Root Cause: The root cause of these adverse conditions being documented as "observations" rather than "findings" is the dual nature of the conditions themselves, as described below, and the exercise of judgment in a less-than-conservative manner by the lead auditor.

Considered in different ways, the conditions cited in Observation 2 of the audit report could fit either the definition of "observation" or "finding." On one hand, the conditions in the "observation" concerned differences between the ORNL QA-implementing documents and contract requirements. At this point, it was felt significant that ORNL had not been released to implement their QA controls in technical work.

Considering that, the documented situations were seen to be:

- "potential" quality problems,
- QA program weaknesses, or
- practices which could lead (in future technical work) to a finding if not corrected" - which fits the SNL definition of "observation."

However, many of the conditions documented in Observation 2 were clearly cases in which ORNL had not adhered to contract requirements in preparing their QAPP and implementing procedures. In that sense, the "observation" included:

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- "statements of fact regarding noncompliance with established policies... or other applicable requirements" - in other words, "findings."

Faced with the situation that these conditions could fit either definition, the lead auditor considered the totality of the situation as he saw it, particularly the existence of the yet-to-be-released mandatory hold point, and elected to identify these conditions as "observations."

- C. Remedial Action: Responses were developed by both SNL and ORNL for all the individual conditions cited in the subject audit report. Subsequent to that, all work under the subject contract was halted for reasons related to funding and reassignment of responsibility for the work within YMP. Consequently, the observations were administratively closed. However, SNL to date has no evidence that the ORNL resolution actions were ever carried out and the deficient conditions actually corrected. At last report, ORNL reported that correction of their QAPP was still a future action. Therefore, SNL will initiate action to "flag" ORNL with respect to the subject work or similar work, requiring that the deficient conditions specified in the subject audit observations be adequately resolved and corrected prior to initiation of any technical work. Additionally, approval of the existing ORNL QAPP will be withdrawn until such corrections are made. Responsible party: John Friend; due date: November 15, 1991.
- D. Action to Preclude Recurrence: To address the root cause identified above, SNL will conduct a training and coaching session involving all currently qualified lead auditors wherein the situation concerning the ORNL audit will be treated as a case study for the purpose of distinguishing between "findings" and "observations" and the application of conservative judgment in indefinite situations. In order to address a contributing cause, writing of audit reports that are clear and unambiguous will also be covered during training. Responsible party: R. R. Richards; due date: December 6, 1991
3. Corrective Action for Deficient Condition #3 (concerning surveillance documentation)
- A. Extent of Deficiency: A review of all 1991 surveillances was performed and no further examples of the condition were identified. Similar conditions do not exist.

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AMENDED RESPONSE

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B. Root Cause: As can be seen by evaluating the detailed information under "Remedial Action," the situations documented as recommendations in the subject surveillance reports can be categorized as:

1. less-than-effective practices that deserved to be evaluated for improvement, even though they involved no procedure violation or other quality deficiency,
2. individual deficiencies that were corrected and verified prior to completion of the surveillance, or
3. uncorrected deficiencies that should have been documented as such.

For the first category above, recommendations are an appropriate means of documenting the situation.

Concerning the second category, it is accepted practice in the Project to not document such situations as deficiencies, since the immediate problem has been corrected. However, it is probably not always appropriate to categorize them as "recommendations," treating them instead as "deficiencies corrected during performance of the surveillance."

For the last category above, the root cause is indeterminate, since the individual surveillor involved is no longer associated with SNL or the Yucca Mountain Site Characterization Project.

C. Remedial Actions: The identified surveillances (JVV-91-02, 03, 04 and CEF-91-01) were reviewed to determine if the concerns/recommendations in the surveillances had any impact on quality. Each item was evaluated to determine if an unresolved quality issue existed.

The evaluation disclosed the following:

Surveillance Report No. CEF-91-01

This surveillance identified seven recommendations. The status of these recommendations, numbered as they are in the surveillance report, is as follows:

1. DR 91-32 was issued to document this condition (open).
2. Not quality related - administrative error (typo).
3. Not quality related - administrative update; no requirement to do.

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4. PDMS 72-28, 29, and 30 now reference PCA 1.0.
PDMS 75-13 and 76-08 were done to DOP 3.3, Rev. A, which did not require the listing of PCA numbers.
5. The training database was updated.
6. Training was completed.
7. TOSPAC and NORIA-SP software has been certified.
CA-DISSPLA software was addressed in DR-91-26 (closed 10/7/91).

With the exception of Recommendation No. 1 (which has now been documented on DR 91-32), all the recommendations had been addressed responsively prior to the issue of this CAR. No further actions are required.

Surveillance Report No. JVV-91-02

Three problem areas were discussed in the surveillance report. One had been documented and controlled by a Stop Work Order. Another concerned a nonmandatory Implementation Plan statement which conflicted with a procedural requirement; no procedural violation existed. The last involved informal, poorly documented communication techniques used by YMPO to initiate SNL work. Additional documentation of these situations is not deemed necessary.

Surveillance Report No. JVV-91-03

One Deviation Report, two observations, and two recommendations were identified in the surveillance report. Both of the observations identified deficiencies that were corrected prior to completing the surveillance. It did not seem reasonable to issue DRs for these situations. Of the recommendations, one concerned training for handling SNL engineering drawings as QA records, however, the SNL work scope does not now include issuing engineering drawings. The second recommendation concerned what, at the time, was a future QARD requirement and could not then be treated as a deficiency.

Surveillance Report No. JVV-91-04

Two "concerns" were identified in this surveillance report. One was for working to an approved Experiment Procedure that had not been issued via Document Control. Differences between the procedure in use and a current, controlled version were found to be minor and did not affect the work in progress. Also, copies of the current, controlled version were obtained at the work site prior to completion of the

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surveillance. For these reasons, initiation of a Deficiency Report did not appear to be appropriate at the time, nor does it now. (By means of interacting with the surveillor on this topic the affected parties became sufficiently knowledgeable concerning use of controlled documents.)

The second "concern" related to a situation that was not, at the time of the surveillance, a deficient condition. Its inclusion in the report was intended to serve as a reminder that documentation of the location of the work site should be completed prior to finishing the in-process work, in order to preclude the development of a deficient condition. (It has since been verified that the documentation of work-site location was properly completed.)

- D. Corrective Action to Prevent Recurrence: To address the causes and apparent causes of this situation, cited in "Root Cause," above, the following actions will be taken: written management direction will be provided to all SNL QA audit and surveillance personnel to the effect that:
- Deficient conditions found during audits and surveillances that are not immediately corrected shall be documented as such, not as "concerns" or "recommendations."
 - Deficient conditions that are immediately corrected shall be reported in audit or surveillance reports straightforwardly as such.

Responsible Party - R. R. Richards; due by 10/23/91. (See attached memo, subject: "Guidance on Reporting of Deficient Conditions and Areas of Improvement.")

Response Approved:

Thomas E. Blejwas
Thomas E. Blejwas, Acctg. Mgr.
Nuclear Waste Repository
Technology
Department 6310

11/7/91
Date

Response Accepted:

Richard L. Winkler
QAR

11/12/91
Date

Response Accepted:

James Blaylock for RRS
OQA

11/14/91
Date