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Office of Civilian Radioactive Waste Management
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QA: L

OCT 13 1994

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VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-91-056 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-91-01 OF LAWRENCE LIVERMORE NATIONAL LABORATORY (SCPB: N/A)

The YMQAD staff has verified the corrective action to CAR YM-91-056 and determined the results to be satisfactory. As a result, the CAR is considered closed.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Amelia I. Arceo at (702) 794-7737.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-211

Enclosure:
CAR YM-91-056

cc w/encl:

~~R. L. Johnson~~, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
J. A. Blink, LLNL, Las Vegas, NV
R. E. Monks, LLNL, Livermore, CA

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

Handwritten notes:
WM-11
NH03.1
102.7

YMP-5

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PDR WASTE
WM-11 PDR

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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

14 CAR NO.: YM-91-056
DATE: 06/07/91
SHEET: 1 OF 2
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document LLNL YMP QAPP 033-YMP-R5, Revision 0		2 Related Report No. Audit YMP-91-01	
3 Responsible Organization LLNL		4 Discussed With J. Bink	
10 Response Due 20 days after issue	11 Responsibility for Corrective Action LLNL	12 Stop Work Order Y or N N	
5 Requirement: LLNL YMP QAPP 033-YMP-R5, Revision 0, paragraph 2.0, states in part: "Independent review of all instructions, procedures, plans, and drawings are performed by the LLNL-YMP to assure technical adequacy and inclusion of appropriate quality requirements."			
6 Adverse Condition: LLNL YMP procedures have been issued that do not include some QAPP requirements. Examples are: 1. Procedure 033-YMP-QP-2.1, Revision 2, paragraph 2.1.4.5, states in part, "After LLNL approval, Document Control transmits the QAPP, SP's, SIP's, and SQAP's to the DOE Project Office for approval. These documents will be identified by Document Control as "Approved for Interim Use" until DOE Project Office approval is obtained. Documents issued as "Approved for Interim Use" may be used as though they had been approved by the DOE Project Office.", which allows SIP's to be implemented prior to DOE Project Office approval. This is contrary to LLNL QAPP 033-YMP-R 3, Revision 0, paragraph 1.3.2, which states in part, "The DOE Project Quality Assurance Manager and the appropriate DOE Project Office Branch Chief review and approve the scientific investigation planning document prior to implementation."			
7 Recommended Action(s): 1. Correct the examples identified. 2. Screen other procedures to determine the extent of the problem. 3. Matrix the QAPP requirements to the implementing procedures.			
8 Initiator Richard E. Powe <i>R. E. Powe</i> 6/12/91 A. I. Arceo <i>Amelia I. Arceo</i> 6/12/91	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <i>Catherine Langstaff</i> 10/13/91	Date:
15 Verification of Corrective Action: <i>See "CAR YMP-91-056 Follow-up" (2 pages) dated 2/5/92 signed by R.E. Powe, and "Verification of Corrective Action - CAR YM-91-056" dated 10/5/94 signed by Amelia I. Arceo.</i>			
16 Corrective Action Completed and Accepted: OAR <i>Amelia I. Arceo</i> Date <u>10/5/94</u>		17 Closure Approved By: OQA <i>R.E. Powe</i> <u>10/12/94</u>	

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DATE: 06/07/91

SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST
(continuation sheet)

6 Adverse Condition (continued)

SIP 6, Revision 0.6 Draft, dated 5/31/89, was issued for use without Project Office approval and quality affecting activity has begun. This deficiency was corrected during the audit by revising the QAPP via CN R 3-0-5.

2. LLNL QAPP 033-YMP-R 3, Revision 0, paragraph 1.3.1 states in part, "The LLNL-YMP conducts a technical review of the scientific investigation planning document. This review is performed by any qualified individual(s) other than those who developed the original planning document. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the LLNL-YMP QA Manager..."

No LLNL YMP procedure could be found that implements the requirement for individual advanced QA Manager approval to use the supervisor as a technical reviewer. In at least one instance, a scientific investigation planning document was technically reviewed by the supervisor with no individual advanced documented QA Manager approval. (Refer to Activity Plan DM-20-53b)

3. LLNL QAPP, 033-YMP-R 17, Revision 0, paragraph 10.2.2, Alternate Storage Facilities, states in part, "The following are acceptable alternatives to the criteria for a single storage facility:
- o Two-hour fire rated vault that meets National Fire Protection Association (NFPA) 232-1975.
 - o Two-hour fire rated Class B file containers that meet the requirements of NFPA 232-1975.
 - o Two-hour fire rated file room that meets the requirements of NFPA 232-1975..."

Contrary to the above, procedure 033-YMP-QP 17.0, Revision 2, paragraph 17.0.5.6(i), states that "Facilities in which records are stored are constructed and maintained by LLNL in accordance with LLNL policies and procedures. Records are stored in locked, one-hour fire resistant containers as deemed appropriate for fire protection by the LLNL Fire Chief."

Response withdrawn per letter dated 8/8/91

1. Corrective Action for Deficient Condition

A. Extent of Deficiency:

Three examples were furnished in which the QAPP and the implementing procedures allegedly did not agree. LLNL acknowledges two examples as deficiencies.

LLNL takes exception to the auditor's interpretation of the QAPP in the third example. The QAPP lists three alternative means for document storage. As a result of YMPO-SDR-567 (closed October 5, 1990), the implementing procedure was changed to permit the use of one-hour fire safes when deemed appropriate by the LLNL Fire Chief. This additional alternative was not precluded by the QAPP. Therefore, there was no conflict between the QAPP and the implementing procedure in this example.

Additional analysis for QAPP/Implementing Procedures compatibility is not deemed necessary at this time since the OCRWM QA requirements document is being revised and is nearly ready for issuance. Once the officially issued new requirements document is received, LLNL will review existing implementing procedures to assure compliance, and the results will be documented.

An impact analysis was conducted to determine if plans and procedures were approved without independent review. Record packages for all plans and procedures approved from May, 1990 until June 1991 were reviewed to determine if an independent technical review was documented (details below).

1) Requirement for Independent Reviewers on Plans and Procedures:

a. The QAM and YMP Leader (or their designees) signed all QPs, QAPP Requirements, QARSs, and the SQAP, indicating review and approval. In each case, one of these two individuals qualifies as an independent reviewer as required by QARD Criterion 5.

b. There were no SIPs or SPs approved.

c. The following Activity Plans were approved; the author and independent reviewer are also noted.

<u>Plan</u>	<u>Title</u>	<u>Author</u>	<u>Reviewer</u>
D-20-27	Unsaturated Degradation Tests of Glass Waste Forms	Bourcier	none
D-20-53a	Flow-Through Dissolution Tests on UO ₂	Nguyen	Bourcier
D-20-53b	Flow-Through Dissolution Tests on Spent Fuel	Leider	none
E-20-15	Establishment of Selection Criteria for Metal Barrier Mtl	Halsey	Clarke

Ltr dtd 7/22/91 - LL YMP9107096

Plan	Title	Author	Reviewer
E-20-18a	Param. Studies: Linear-Sweep Polarization to Det. Pitting Pot.	McCright	none

For Activity Plans D-20-27, D-20-53b, and E-20-18a an independent review must be completed to correct the previous oversight and deficiencies.

d. The following Technical Implementing Procedures were approved; the author and independent reviewer are also noted.

TIP	Title	Author	Reviewer
GM-11	Calibration of Nicolet Model 60SX Infrared Spectrometer	Cummins	Short
NF-16	Prepare Core Wafer Samples	Glassley	Viani
NF-17	Carbonate Analysis with the OIC Model 524D Carbon Analyzer	Glassley	Knauss
NF-18	Testing Rock-Water Interactions Using a Rocking Autoclave	Glassley	Short
NF-23	Autoclave Temp. & Pressure System Calibration	Glassley	Viani
NF-28	Solids Analysis: SEM	Stout	Clarke
NF-30	Solids Analysis: Microprobe Microanalysis	Stout	Knauss
YM-2	Collect, Store & Distr. Water from Well J-13	Stout	Clarke
YM-4	Prep. of Standards for the Det. of Trace El. in J-13 Well Water	Glassley	Shaw
YM-6	Meas. of the pH of Aqueous Solutions w/ the Glass Electr.	Stout	Glassley
YM-7	Operation of the Jarrel Ash 975 Atom Comp ICP-OES	Glassley	Goins
YM-10	Doc. & Coding Standards for Fortran Programs	Cummins	Blink
YM-11	Software Config. Mgmt Sys.	Lundeen	Blink

For TIP YM-11, L. Zucconi was S. Lundeen's supervisor at the time of the review; J. Blink became her supervisor after the review but prior to the issue date. J. Blink was independent at the time of the review.

Based on the above analyses, none of the cited deficiencies affect quality.

B. Root Cause:

The first example (Marking SIPs "Approved for Interim Use") was known to LLNL prior to the audit. The implementing procedure was changed to reflect the correct practice, as determined by the Project Leader (TPO) and the Quality Assurance Manager. However, at the time of the change, LLNL could not change its QAPP without subjecting the entire QAPP to review against the new QARD. In December, 1990, OQA determined that changes could be made without revision of the entire QAPP, and LLNL began applying the new policy. However, due to an oversight, the QAPP was not changed to be consistent with the implementing procedure for the deferred situation. This results in a deficiency.

The second example (no implementing procedure requirement for an independent reviewer for procedures and plans) was not anticipated. The original implementing procedure had no requirement for independent review. Until recently, all documentation of reviews was kept in the records package, and enough reviewers were assigned such that an independent reviewer was likely. However, the CRF declined to accept some packages because each comment on annotated drafts was not separately initialed and dated. To resolve this problem, it was recently decided to retain only minimal review documentation, and only the approvers of the document were required to furnish review documentation. As a result of the YMPO audit, LLNL realizes that independent review was in some cases, precluded by this change. The result is a deficiency.

C. Remedial Action:

For the first example, the QAPP will be changed to be consistent with the implementing procedure by August 1, 1991. For the second example, an impact analysis was conducted. In the three cases that an independent review was not documented, that review will be initiated and completed by August 30, 1991.

D. Corrective Action to Prevent Recurrence:

When the replacement for the OCRWM QARD is officially issued, LLNL will document how the requirements are met by LLNL-YMP implementing procedures. Further, the QA Manager will pay particular attention to QAPP/QP compatibility during the change notice and procedure revision process.

A change to the QAPP was submitted on June 27, 1991 (LLYMP9106156) to cite one-hour fire safe as another approved storage means if certain specified conditions exist for their facility location.

Response Approved: _____

Philip J. Jardine

**OFFICE OF CIVILIAN
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WASHINGTON, D.C.**

CAR NO. YM-91-056

DATE: _____

SHEET: _____ OF _____

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

Response Accepted: _____
QAR Date

Response Accepted: _____
OQA Date

1. Corrective Action for Deficient Condition

A. Extent of Deficiency

Three examples were furnished in which the QAPP and the implementing procedures allegedly did not agree. LLNL acknowledges two examples as deficiencies.

For the third example, Livermore considers its one-hour fire safe to be single facility storage, but the auditor considered these safes to be temporary storage. The LLNL interpretation has been documented in a change to its QAPP which is currently at the Project Office for approval (LLYMP9106156).

Additional analysis for compatibility of the QAPP and Implementing Procedures is not deemed necessary at this time since the OCRWM QA requirements document is being revised and is nearly ready for issuance. Once the officially issued new requirements document is received, LLNL will review existing implementing procedures to assure compliance, and the results will be documented.

An impact analysis was conducted to determine if plans and procedures were approved without independent review. Record packages for all plans and procedures approved from May 1990 until June 1991 were reviewed to determine if an independent technical review was documented (LLYMP9108049). As a consequence of this analysis, LLNL has determined that Activity Plans D-20-27, D-20-53b, and E-20-18a require an independent review.

B. Root Cause

The first example (Marking SIPs "Approved for Interim Use") was known to LLNL prior to the audit. The implementing procedure was changed to reflect the correct practice, as determined by the Project Leader and the Quality Assurance Manager. However, at the time of the change, LLNL could not change its QAPP without subjecting the entire QAPP to review against the new QARD. In December 1990, OQA determined that changes could be made without revision of the entire QAPP, and LLNL began applying the new policy. However, due to an oversight, the QAPP was not changed to be consistent with the implementing procedure for the deferred situation. This is a deficiency.

Str dtd 8/12/91 - LLYMP9108058

The second example (no implementing procedure requirement for an independent reviewer for procedures and plans) was not anticipated. The original implementing procedure had no requirement for independent review. Until recently, all documentation of reviews was kept in the records package, and enough reviewers were assigned such that an independent reviewer was likely. However, the CRF declined to accept some packages because each comment on annotated drafts was not separately initialed and dated. To resolve this problem, it was recently decided to retain only minimal review documentation, and only the approvers of the document were required to furnish review documentation. As a result of the YMPO audit, LLNL realizes that independent review was precluded by this change in three cases. This is a deficiency.

C. Remedial Action

For the first example, the QAPP was changed to be consistent with the implementing procedure. For the second example, an impact analysis was conducted. In the three cases that an independent review was not documented, that review will be completed by August 30, 1991.

D. Corrective Action to Prevent Recurrence

When the replacement for the OCRWM QARD is issued, LLNL will document how the requirements are met by LLNL-YMP implementing procedures. This action will be completed within 90 days of the formal issue of the OCRWM QA requirements document.

Response Approved:

John J. Jardine

1. Corrective Action for Deficient Condition

A. Extent of Deficiency

Three examples were furnished in which the QAPP and the implementing procedures allegedly did not agree. LLNL acknowledges two examples as deficiencies.

For the third example, Livermore considers its one-hour fire safe to be single facility storage, but the auditor considered these safes to be temporary storage. The LLNL interpretation was documented in a proposed change to its QAPP (LLYMP9106156) which was subsequently disapproved by the Project Office.

Additional analysis for compatibility of the QAPP and Implementing Procedures is not deemed necessary at this time since the OCRWM QA requirements document is being revised and is nearly ready for issuance. Once the officially issued new requirements document is received, LLNL will review existing implementing procedures to assure compliance, and the results will be documented.

An impact analysis was conducted to determine if plans and procedures were approved without independent review. Record packages for all plans and procedures approved from May 1990 until June 1991 were reviewed to determine if an independent technical review was documented (LLYMP9108049). As a consequence of this analysis, LLNL has determined that Activity Plans D-20-27, D-20-53b, and E-20-18a require an independent review.

B. Root Cause

The first example (Marking SIPs "Approved for Interim Use") was known to LLNL prior to the audit. The implementing procedure was changed to reflect the correct practice, as determined by the Project Leader and the Quality Assurance Manager. However, at the time of the change, LLNL could not change its QAPP without subjecting the entire QAPP to review against the new QARD. In December 1990, OQA determined that changes could be made without revision of the entire QAPP, and LLNL began applying the new policy. However, due to an oversight, the QAPP was not changed to be consistent with the implementing procedure for the deferred situation. This is a deficiency.

Str dtd 9/6/91 - LLYMP9109001

The second example (no implementing procedure requirement for an independent reviewer for procedures and plans) was not anticipated. The original implementing procedure had no requirement for independent review. Until recently, all documentation of reviews was kept in the records package, and enough reviewers were assigned such that an independent reviewer was likely. However, the CRF declined to accept some packages because each comment on annotated drafts was not separately initialed and dated. To resolve this problem, it was recently decided to retain only minimal review documentation, and only the approvers of the document were required to furnish review documentation. As a result of the YMPO audit, LLNL realizes that independent review was precluded by this change in three cases. This is a deficiency.

C. Remedial Action

For the first example, the QAPP was changed to be consistent with the implementing procedure. For the second example, an impact analysis was conducted. In the three cases that an independent review was not documented, that review will be completed by August 30, 1991.

D. Corrective Action to Prevent Recurrence

When the replacement for the OCRWM QARD is issued, LLNL will document how the requirements are met by LLNL-YMP implementing procedures. This action will be completed within 90 days of the formal issue of the OCRWM QA requirements document.

The QAPP requirement for individual advanced QA Manager approval of the use of a supervisor as a technical reviewer will be added to QP 2.1 prior to September 6, 1991.

The QAPP and implementing procedure will be changed prior to September 6, 1991 to document the QA status of the one-hour fire safes in the LLNL-YMP Local Records Center.

Response Approved: W. L. Calame

Response Accepted: A. E. Bone 9/20/91
QAR Date

Response Accepted: Catherine H. ... 9-20-91
OQA Date

CAR YMP-91-056 FOLLOW-UP

Page 1 of 2

CHRONOLOGY

6/7/91 Subject CAR was presented at Post-Audit Conference

6/24/91 CAR YMP-91-056 was issued. Respose due 7/15/91.

7/8/91 LLNL met with Don Horton to discuss CARs that were issued as a result of Audit YMP-91-01

7/16/91 LLNL requested extension to 7/19/91 for response due date.

7/18/91 LLNL requested extension to 7/22/91 for response due date.

7/22/91 LLNL responded to the CAR

7/25/91 YMOAD accepted LLNLs request for extension to 7/22/91

8/8/91 LLNL requested that 1)their 7/22/91 response be withdrawn, 2) a meeting be scheduled for 8/14/91 to discuss the CARs, and LLNL be allowed to resubmit a response by 8/23/91.

8/12/91 LLNL resubmitted a response to CARs YMP-91-055 thru -062

8/20/91 YMOAD accepted LLNL's 8/8/91 request.

9/6/91 LLNL submitted revised responses to CARs YMP-91-056, -057 and -061.

10/3/91 YMOAD notified LLNL that LLNLs responses to CARs YMP-91-056 thru -062 were acceptable.

CORRECTIVE ACTION

Committed corrective action for CAR YMP-91-056 included the following:

1. Revise the LLNL QAPP to be consistent with procedure 033-YMP-QP-2.1 by allowing the use of the "Approved for Interim Use" system.
ECD: Completed prior to 7/22/91.
2. Perform an independent review of Activity Plans D-20-27, D-20-53b, and E-20-18a.
ECD: 8/30/91
3. Revise procedure 033-YMP-QP-2.1 to reflect LLNL QAPP requirement for advanced QA Manager approval of the use a supervisor as a technical reviewer.
ECD: 9/6/91
4. Revise the LLNL QAPP and implementing procedure to reflect the use of one-hour fire rated containers in the LLNL LRC.
ECD: 9/6/91
5. Document how OCRWM QARD requirements are met by LLNL implementing procedures.
ECD: 90 days after receipt of formally issued new OCRWM QARD.

STATUS OF CORRECTIVE ACTION (Keyed to Corrective Action numbers listed above)

1. LLNL QAPP CN No. R 3-0-5 dated 6/28/91 made the committed revision and was approved by YMQAD via YMQAD:CEH-5482 on 10/10/91.
ALL ACTION COMPLETE.
2. Independent reviews of the three Activity Plans were completed by 8/30/91 (See attached FAX of information from R. Harmati to R. Powe dated 2/5/92).
ALL ACTION COMPLETE.
3. LLNL procedure 033-QP-2.1 is now at Revision 3 and paragraph 2.1.4.3.1 now reflects the LLNL QAPP requirement for advanced QA Manager approval of the use of a supervisor for technical review.
ALL ACTION COMPLETE.
4. LLNL submitted proposed changes to their QAPP to reflect how they use one-hour fire rated containers, however the proposed revision, CN-17-01 was rejected via YMQAD:CEH-5217 on 8/19/91. LLNL submitted a new proposed change, CN-17-02, however it was also rejected by YMQAD via YMQAD:CEH-965 ON 11/27/91. Also refer to ASME NQA Inquiry QA91-009 (Attached). According to telephone conversations on 2/5/92 between R. E. Powe, YMQAD and R. Monks/ R. Hamati, LLNL, a proposed revision to the LLNL QAPP to reflect use of one-hour fire rated containers for temporary storage of records is being processed now and lacks the signature of Jim Blink prior to its submittal to YMQAD for approval.
OPEN, PENDING SUBMITTAL AND YMQAD APPROVAL OF PROPOSED REVISION TO LLNL QAPP WHICH SHOULD OCCUR BEFORE 2/28/92.
5. This corrective action is awaiting OCRWM action to issue the revised QARD. The new QARD is currently scheduled to be issued for formal review by 2/28/91, therefore the ECD for action 5 is now at least 6/1/92.
OPEN, PENDING ISSUANCE OF THE NEW OCRWM QARD. NEW ECD: No earlier than 6/1/92.


R. E. Powe, QAR

2/5/92
Date

