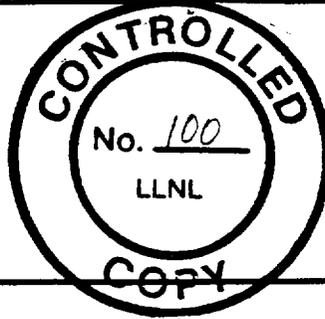


University of California

Lawrence Livermore  
National Laboratory

UCCA MOUNTAIN PROJECT  
Quality Procedures



No.: 033-YMP-QP 2.1

Revision: 4

Effective Date: 8/24/92

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Subject:

PREPARATION, APPROVAL AND REVISION OF PROCEDURES, REQUIREMENTS,  
PLANS, AND THE QUALITY ASSURANCE PROGRAM DESCRIPTION

AUTHOR:

J. Blink

Training Required: Yes  No

Comment: QA and LRC personnel only  
TALS & TLs also

Approved by: W. L. Blame 8/14/92  
Yucca Mountain Project Leader Date

Approved by: Den Wolfe 8/14/92  
YMP Quality Assurance Manager Date

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### 2.1.1 PURPOSE

This procedure describes the requirements for preparation, review, approval, and revision of procedures, plans, requirements, and the Quality Assurance Program Plan (QAPP).

### 2.1.2 SCOPE

This procedure applies to two types of quality documents; the LLNL-YMP Quality Assurance Program Plan (033-YMP-QAPP) and the Quality Procedures Manual (033-YMP-QP). The Quality Assurance Program Plan identifies those requirements of the Yucca Mountain Project Office (YMPO) Quality Assurance Plan that apply to LLNL activities. The Quality Procedures define the methods used to implement those requirements.

In addition, this procedure is applicable to the review, approval, and revision of Scientific Investigation Plans (SIP), Study Plans (SP), Activity Plans, Technical Implementing Procedures (TIP), Software QA Plans (SQAP), Individual Software Plans (ISP), internal Quality Assurance Grading Reports (QAGR), and QA Requirements Specifications (QARS).

### 2.1.3 RESPONSIBILITIES

The YMP Quality Assurance Manager is responsible for:

- Preparation of QAPP Requirements and Quality Procedures. The appropriate YMP technical group(s) may assist in the preparation of selected Quality Procedures,
- Assuring that the Quality Procedures include consideration of the technical aspects of the activities affecting quality.
- Review and/or approval of documents identified in Exhibit A.
- Assuring that all Quality Procedures implement the requirements specified in the QAPP for technical activities.

The YMP Project Leader is responsible for:

- Review and/or approval of documents identified in Exhibit A.

The YMP Technical Area Leaders are responsible for:

- Review and/or approval of documents identified in Exhibit A.
- Designating additional personnel for review of Quality Procedures, if deemed appropriate.

### 2.1.4 PROCEDURE PREPARATION AND APPROVAL

#### 2.1.4.1 Preparation

Quality Procedures and QAPP Requirements are prepared by the YMP QA Manager or others designated by the YMP QA Manager.

Personnel who prepare QAPP Requirements documents are to assure that applicable requirements of the YMPO QA Plan are included in the QAPP.

Personnel who prepare Quality Procedures are to assure that applicable requirements of the QAPP are implemented by the procedures, and that consideration is given to the technical aspects of activities in determining the methods of implementation.

#### 2.1.4.2 Format

Quality Procedures and QAPP Requirements have a title page (Exhibits B&C) and following pages (Exhibit D) and contain the following minimum information:

- Purpose
- Scope
- Responsibilities
- Procedure/Text
- Retained Documentation,

The above bullets represent procedural format that will apply to all QPs; however, individual section headings may or may not be incorporated into the body of each procedure. The term "Retained Documentation" is defined as QA Records. Additional sections may be added for clarification such as a Table of Contents and exhibits showing examples, standard forms, etc.

#### 2.1.4.3 Review

##### 2.1.4.3.1 Independent Reviewer

At least one independent reviewer is required. Independent reviewers must be qualified in the subject area. Independent reviewer(s) do not have to be employees of the organization where the work was performed.

Examples of independent reviewers (who must be qualified in the subject area) are:

- Peer in the same or another technical area who will not perform the work.
- TAL in the same technical area who will not perform the work (unless the TL will perform the work).
- The QAM or designee for quality procedures, QAPP Requirements, Internal quality assurance grading reports, and QARS documents, except for those procedures/requirements that are associated with audits by the LLNL-YMP QA organization.
- The YMP Leader or designee for QPs/QAPP requirements associated with audits by the LLNL-YMP QA organization.
- Software quality manager for individual software plans and Software Quality Assurance Plan unless involved in performing the software development.

Examples of reviewers who are not considered independent are:

- Anyone who will perform the work.
- The TL who will be responsible for the work.
- The TAL who will be responsible for the work, if the work will be done by a subordinate TL.

However, a TAL or TL who will be responsible for the work may act as an independent reviewer, if the LLNL-YMP Leader or designee concurs, and the QA manager concurs, that another qualified independent reviewer cannot be identified.

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#### **2.1.4.3.2 Documents Requiring Review**

Review copies are distributed by the originator for review as identified in Exhibit A. Quality related project documents such as Scientific Investigation Plans (SIP), Study Plans (SP), Activity Plans, Technical Implementing Procedures (TIP), Software QA Plans (SQAP), and QA Requirements Specifications (QARS) are included in Exhibit A since their review and approval process is the same. The preparation of those documents is described in Procedure 033-YMP-QP 3.0, "Scientific Investigation Control", 033-YMP-QP 3.2, "Software Quality Assurance", and 033-YMP-QP 4.1 "Preparation of Quality Assurance Requirements Specifications and Approval of Subcontractor QA Programs."

#### **2.1.4.3.3 Sequence of Reviews**

Informal reviews often precede the formal reviews identified in Exhibit A.

All formal reviews are documented. The approval signature of the QAM or YMP Leader or designee constitutes the review documentation for QPs, QAPP Requirements, QAGRs, and QARSs. For other controlled documents, review copies are accompanied by a memo identifying the comments due date, clarifying information and any special instructions. A sample memo to Reviewers is identified as Exhibit E. The QA office acts as Publication Manager for the QAPP, QP, and QARS documents. The Publications Manager tracks the document through the review process. After LLNL signatures are obtained, the Publications Manager transfers the package to the LRC (for completed documents) or stores it, pending completion, in a fire-resistant cabinet (for documents sent to YMPO for approval).

#### **2.1.4.3.4 Reviewer Responsibilities**

Reviewers are responsible for assuring:

- a. Requirements are adequately translated from the source documents and are applicable to YMP activities;
- b. Operating methods described in the procedures reflect acceptable practices and are implementable;
- c. Responsibility assignments are compatible with the organizational structure;
- d. Documentation requirements are appropriate.
- e. Study Plans, Scientific Investigation Plans, Activity Plans, and Technical Implementing Procedures address (if applicable):
  - repeatability of the activity
  - impact on the site waste isolation capability
  - interference with Site Characterization.

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A sample checklist addressing additional review criteria is identified as Exhibit F. This may be used to provide clarifying information for reviewers. The originator provides reviewers access to pertinent background data and information.

#### 2.1.4.3.5 Comments and Review Close-Out

Comments may be entered directly on the review copy and should be restricted to pertinent portions of the document. Incorporation of other comments is at the discretion of the document originator.

If there are major comments, the originator resolves them and returns the original and the reviewed draft and the Review Request to the reviewer. If comments require resolution, the preferred method is a meeting to discuss unresolved issues. If comments are resolved, the reviewer completes the bottom section of the Review Request form. If resolution cannot be achieved by the originator and reviewer, final authority rests with the LLNL-YMP Leader, who will document disposition of comments.

All review comments are retained until the review is complete. Then, actual comments and resolution notes are destroyed.

#### 2.1.4.4 LLNL Approval

The revised draft incorporating the agreed upon comments is prepared and given a final review by the originator and YMP QA Manager and routed for signature as identified in Exhibit A.

#### 2.1.4.5 Sponsor Approval

After LLNL approval, Document Control transmits the QAPP, SIPs, and SQAPs and changes thereto to YMPO for approval. Approval of Activity Plans, QPs, TIPs, QAGRs, and QARSs (both Generic and Subcontract) by YMPO is not required.

SIPs will be identified by Document Control as "Approved for Interim Use" until YMPO approval is obtained. SIPs issued as "Approved for Interim Use" may be used as though they had been approved by YMPO.

If, in the opinion of the YMP Leader, there is sufficient risk in using an "Approved For Interim Use" SIP prior to YMPO approval, the YMP Leader may elect to withhold issuance or restrict use. Details of any restrictions will be documented and distributed to custodians by Document Control.

The QAPP and SQAP and changes thereto shall be evaluated to determine if there is a reduction in committed QA requirements. If there is no reduction, they may be issued for use. The results of the evaluation shall be documented.

When sponsor approval has been obtained, Document Control will reissue with the same revision number but without the "Approved For Interim Use" restriction.

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After LLNL approval, Document Control transmits Study Plans to YMPO for approval at YMPO and OCRWM. Upon receipt of DOE-approved Study Plans, NRC will conduct a "start-work" review within three months, and inform DOE if there are any objections to starting work. The NRC has reserved the right to make detailed technical comments on selected Study Plans within six months of receipt. The State of Nevada provides comments at its discretion. Responding to NRC's detailed technical comments or to comments from the State of Nevada is not a prerequisite to starting work.

## 2.1.5 REVISIONS

### 2.1.5.1 Revision Numbering

Each revision controlled document is identified with a revision number beginning with Revision 0 for the first approved issue, with the number increasing sequentially each time the document is revised.

### 2.1.5.2 Revision Identification

Additions are usually shown in bold print. All changed areas are identified by a vertical bar in the right-hand margin, which includes areas of deletion. Only changes made from the previous issue will be identified. When the procedure is a complete or general rewrite, no vertical bar is required, but the issued document will indicate: General Rewrite or Complete Rewrite.

### 2.1.5.3 Revision Review and Approval

The review process for Preparation and Approval described in section 2.1.4 also applies to revisions.

### 2.1.5.4 Change Notices

Rather than revising and reissuing the document itself, changes may be made by issuing a Change Notice (Exhibit G).

Generally, change notices must be reviewed and approved by those authorized to approve the original document prior to issuance. Change notices of minor changes to TIPs, SIPs, Activity Plans or other controlled technical documents do not require the review or approval of the authorized technical person. Minor changes are limited to spelling and grammar corrections and editorial corrections that do not change the intent of the procedure.

Change Notices are incorporated into the next revision of the affected document. Up to five Change Notices are allowed before the document must be revised and reissued. Change Notices are issued to all custodians of the document by Document Control and are placed in front of the affected document until superseded. Change notices on the QAPP, SIPs, and SQAPs will be stamped "Approved for Interim Use" by Document Control and are to be filed at the front of the affected document until superseded.

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### 2.1.6 STATUS CONTROL

A log of controlled document revisions and Change Notices is maintained. Controlled distribution is maintained by assigning a controlled copy number. Recipients must sign and return the "Controlled Document Transmittal Record" form shown in Procedure 033-YMP-QP 6.0 for all transmittals.

### 2.1.7 EFFECTIVE DATE

The effective date of the procedure is the issue date shown in the title block and is established by Document Control.

### 2.1.8 QUALITY ASSURANCE RECORDS

Retained as QA Records:

- Current and previously issued documents.
- Record of YMPO review and approval; If applicable.
- Completed request for review form(s), Exhibit E.

EXHIBIT A

RESPONSIBILITIES FOR REVIEW AND APPROVAL  
OF CONTROLLED PROJECT DOCUMENTS

Reviewer/Approver	QAPP	QP	SIP	SP	Activity Plan	TIP	ISP	SOAP	(Gen) QARS	(Sub) QARS	(Int) QAGR
YMP QA Manager	1	1	1	1	1	1	1	1		1	2
YMP Project Leader	1	1	1	1	1	1	1	1	1	1	1
Technical Area Leader(s)			2	2	1	1	1			1	2
DOE Project Office	1		1	1				1			
<b>Software Quality Manager</b>							1	1			

1 = Review and Approval

2 = Review Only

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**YUCCA MOUNTAIN PROJECT**  
 Quality Procedures

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Subject:

AUTHOR:

Training Required: Yes  No   
 Comment: **L**

S  
 A  
 M  
 P

LL 5487 Rev. 4

<p>University of California   Lawrence Livermore  National Laboratory</p> <p><b>YUCCA MOUNTAIN PROJECT</b>  <b>QUALITY ASSURANCE PROGRAM PLAN</b></p>	No.: Revision: Effective Date: Page:                      of <b>E</b>
Subject:	APPROVED:
<p style="text-align: center; font-size: 48px; letter-spacing: 10px;">S A M P</p>	Training Required: Yes <input type="checkbox"/> No <input type="checkbox"/> Comment: <b>L</b>

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EXHIBIT D  
FOLLOWING PAGES

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b> Page _____ of _____
<b>REQUEST FOR REVIEW</b>	
TO: DISTRIBUTION <span style="float: right;">Date: _____</span> FROM RESPONSIBLE AUTHOR: _____ SUBJECT: _____	
<p>Please review and comment upon the attached document. Your review should consider the criteria listed in QP 2.1, Rev. 2, Section 2.1.4.3.4.</p> <p>Please return your markup and this memo to me by _____ (Date)</p> <p><input type="checkbox"/> Clarifying information (including additional review criteria)</p> <p><input type="checkbox"/> Special instructions</p> <p>The Independent Reviewer is _____</p> <p>Distribution:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p style="text-align: center;">-----</p> <p style="text-align: center;">Reviewer's Response</p> <p>Attached is the subject draft document that I have reviewed.</p> <p><input type="checkbox"/> No major comments, only minor (editorial) comments.</p> <p><input type="checkbox"/> I have major comments that require resolution. Major comments can be found on pages:</p> <p><input type="checkbox"/> I would like to review the next draft of the document.</p> <p><input type="checkbox"/> I have used the sample review criteria checklist (attached).</p> <p>_____          (Signature) <span style="float: right;">_____          (Date)</span></p> <p>-----</p> <p><input type="checkbox"/> All major comments have been resolved to my satisfaction.</p> <p>_____          (Signature) <span style="float: right;">_____          (Date)</span></p>	

YMP 069 REV 2

**REVIEW CRITERIA CHECKLIST**

Document Reviewed \_\_\_\_\_

	YES	NO	REMARK
1. Are source documents identified & appropriate?	---	---	---
2. Are source requirements adequately addressed?	---	---	---
3. Are the responsibilities identified & appropriate?	---	---	---
4. Are the purpose and objectives clear?	---	---	---
5. Are the methods appropriate and adequate?	---	---	---
6. Is documentation identified & appropriate?	---	---	---
7. Are interfaces (both internal & external) identified?	---	---	---
8. Have references been included?	---	---	---
9. Is the impact on waste isolation adequately addressed?	---	---	---
10. Are interferences with Site Characterization addressed?	---	---	---
11. Are technical reviews scheduled & planned?	---	---	---
12. Are hold points identified?	---	---	---
13. Are the closeout plans identified?	---	---	---
14. Is an individual software plan required?	---	---	---
15. Has a schedule been addressed?	---	---	---
16. Has equipment been identified?	---	---	---
17. Are calibration requirements identified?	---	---	---
18. Are unique materials identified?	---	---	---
19. Have adverse environmental conditions been identified?	---	---	---
20. Are special training/qualifications identified?	---	---	---
21. Are data recording/reduction techniques adequate?	---	---	---
22. Are analytical methods/techniques adequate?	---	---	---
23. Are precision and accuracy discussed?	---	---	---
24. Are sources of uncertainty identified?	---	---	---
25. Are subcontractor requirements adequate?	---	---	---

Remarks \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Reviewer's Signature \_\_\_\_\_ Date \_\_\_\_\_

Use NA (Not Applicable) in Remarks column as appropriate.

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<b>CHANGE NOTICE</b>				
CN No.: _____		Effective Date: _____		
Affected Document: _____		<b>E</b>		
Prepared by: _____		Approved by: (Technical Area Leader)		Date _____
Approved by: (YMP QA Manager)		Date _____	Approved by: (YMP Leader)	
Date _____		Date _____		Date _____
Training Required: Yes <input type="checkbox"/> No <input type="checkbox"/>		Major Changes <input type="checkbox"/>		Minor Changes <input type="checkbox"/>
Reason for Change: _____				
<b>S A M P</b>				
<b>NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT</b>				

YMP 001 Rev 5