

# YMP

## Yucca Mountain Project

# QUALITY PROCEDURES MANUAL



Lawrence Livermore National Laboratory

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(Organization)

March 21, 1989  
Transmittal Date  
102  
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SUBJECT:  
Yucca Mountain Project Quality Assurance Program Plan  
February 24, 1989

ITEM		Rev.	Date
033-YMP-QP 1.0	Organization	0	2/24/89
033-YMP-QP 2.0	Assurance	0	2/24/89
033-YMP-QP 2.1	Change Notice	0	3/15/89
033-YMP-QP 2.1	Preparation, Approval and Revision of Quality Procedures & Requirements	0	2/24/89
033-YMP-QP 2.2	Peer Review	0	2/24/89
033-YMP-QP 2.3	Change Notice	0	3/15/89
033-YMP-QP 2.3	Management Assessments	0	2/24/89
033-YMP-QP 2.4	Change Notice	0	3/15/89
033-YMP-QP 2.4	Technical Review	0	2/24/89
033-YMP-QP 2.5	Acceptance of Data Not Generated Under The Control of The YMP QAPP	0	2/24/89
033-YMP-QP 2.6	Readiness Reviews	0	2/24/89
033-YMP-QP 2.7	Stop Work Order	0	2/24/89

INSTRUCTIONS/REMARKS

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February 24, 1989

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033-YMP-QP 2.8 Assigning Levels of Quality Assurance	0	2/24/89
033-YMP-QP 2.9 Change Notice	0	3/3/89
033-YMP-QP 2.9 Indoctrination and Training	0	2/24/89
033-YMP-QP 2.10 Qualification of Personnel	0	2/24/89
033-YMP-QP 2.11 Qualification and Certification of Inspection and NDE Personnel	0	2/24/89
033-YMP-QP 3.0 Change Notice	0	3/15/89
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033-YMP-QP 3.1 Change Notice	0	3/3/89
033-YMP-QP 3.1 Design Control	0	2/24/89
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033-YMP-QP 4.0 Procurement Control and Documentation	0	2/24/89
033-YMP-QP 5.0 Technical, Implementing Procedures	0	2/24/89
033-YMP-QP 6.0 Document Control	0	2/24/89
033-YMP-QP 7.0 Control of Purchased Items and Services	0	2/24/89
033-YMP-QP 8.0 Identification and Control of Items, Samples and Data	0	2/24/89
033-YMP-QP 9.0 Control of Processes	0	2/24/89


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033-YMP-QP 13.0	Handling, Storage and Shipping	0	2/24/89
033-YMP-QP 14.0	Inspection, Test, and Operating Status	0	2/24/89
033-YMP-QP 15.0	Change Notice	0	3/3/89
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033-YMP-QP 16.0	Change Notice	0	3/3/89
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# QUALITY PROCEDURES MANUAL

## Yucca Mountain Project

CONTROLLED COPY NO. 102

ISSUED TO: J. Kennedy

ORGANIZATION: NRC

The person listed above is responsible for maintaining this manual and incorporating all subsequent revisions as they become available. This manual is subject to audit and recall by the LLNL-YMP Quality Assurance Manager and thus, should be carefully maintained and kept readily available. It is the property of LLNL and must be returned upon request or when leaving the Program.

Lawrence Livermore National Laboratory  
P.O. Box 808, Livermore, CA 94550

Quality Assurance

**NUCLEAR WASTE MANAGEMENT PROGRAM**  
CONTROLLED COPY NO. 0102

Subject:

ORGANIZATION

Approved:

Approved by *[Signature]* 2/8/89  
YMP Project Leader

### 1.0.1 INTRODUCTION

Civilian Radioactive Waste Management Program activities are assigned by the Director of the Lawrence Livermore National Laboratory (LLNL) to the Energy Program Leader. The Energy Program Leader has assigned this work to the LLNL Yucca Mountain Project (YMP) and appointed a YMP Leader.

All of the work is funded by the Department of Energy's Office of Civilian Radioactive Waste Management (OCRWM). The effort supports the Yucca Mountain Project (YMP), which is managed by DOE's Nevada Operations YMP Office (DOE Project Office).

The LLNL YMP is assigned the following responsibilities by the DOE Project Office:

Development of an integrated waste package for tuff, which includes the definition of the package environment, waste form and materials testing, package design and performance assessment; EQ3/6 geochemical modeling; testing in the exploratory shaft; and assistance to other project participants in areas of specialized expertise.

The YMP Technical Project Officer (Project Leader) is responsible to the DOE Project Office Manager to ensure that the Project activities are performed to the QAPP and that implementing procedures are consistent with the QAPP.

The YMP Leader, the Quality Assurance Manager, and the Resource Planning and Control Manager report directly to the Energy Program Leader.

The Project Leader may delegate responsibility for fulfilling technical management assignments to Technical Area Leaders.

Technical Area Leaders in turn assign Task Leaders to carry out specific responsibilities. Task Leaders are supported by Principal Investigators and technical staff.

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Integration of work performed by more than one Task Leader within a single technical area occurs at the Technical Area Leader level.

Coordination of work performed across technical area boundaries occurs at the Project Leader level.

Given the size of the YMP Project and the range of technical assignments from a particular sponsor, the YMP Project Leader may elect to assign responsibility for fulfilling technical assignments directly to Task Leaders without creating Technical Area Leaders within the Project. When Technical Area Leaders are not assigned, the YMP Project Leader fulfills the responsibilities specified in 1.0.5.3.

#### 1.0.2 PURPOSE

This procedure describes the organizational structure established by YMP to accomplish technical and administrative objectives in accordance with the quality requirements specified in the sponsors quality assurance program plans. This procedure also describes the interfaces between YMP and the DOE Project Office and other organizations.

#### 1.0.3 SCOPE

This procedure applies to all technical and administrative activities undertaken in support of DOE Project Office objectives for which the YMP Leader has responsibility.

#### 1.0.4 ORGANIZATIONAL STRUCTURE

Exhibit A illustrates the organizational LLNL relationship of the YMP Leader, the Quality Assurance Manager, and the Resource Planning and Control Manager. Exhibit B illustrates the organizational structure for the YMP Project. Exhibit C documents the current staffing for the positions represented on these two figures.

#### 1.0.5 RESPONSIBILITIES AND AUTHORITIES

The responsibilities and authorities are defined for the YMP Leader, Technical Area Leaders, Task Leaders, the QA Manager, the Resource Planning and Control Manager, and the Yucca Mountain Project Administrator.

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#### 1.0.5.1

It is the YMP philosophy that quality assurance is a line management responsibility. The YMP Leader has the overall responsibility and authority to assure that the YMP Quality Assurance Program is developed, implemented, and maintained. The QA Manager assures that independent verification of quality attainment, Quality Assurance Program implementation, and its continued effectiveness is accomplished. The YMP Leader approves all Quality Assurance Program Plan (QAPP) requirements, as well as all procedures that comprise the Quality Procedure (QP) and Administrative Procedure (AP) Manuals. The Energy Program Leader resolves any disagreements or conflicts that cannot be resolved between the YMP Leader and the QA Manager. All such resolutions are a matter of record.

#### 1.0.5.2

The YMP Leader has responsibility and authority for the overall management of the project. This includes assuring the execution of the YMP Quality Assurance Program. The YMP Leader's responsibility and authority includes:

- o Textual review of all the requirements contained in the QAPP as well as the procedures that comprise both the QP and AP Manuals.
- o Defining those procedures and requirements necessary to assure achievement of quality objectives.
- o Approval of Technical Implementing Procedures (TIP) that are written and carried out in support of YMP Quality Assurance Program.
- o Appointment of Technical Area Leaders.
- o Approval of the quality assurance levels assigned activities.
- o Fulfillment of technical review responsibilities as specified in Procedure No. 033-YMP-QP 3.3, "Review of Technical Publications."
- o Fulfillment of other responsibilities as specified in the YMP QAPP and Quality Procedures (QP), Administrative Procedures (AP) and Technical Implementing Procedures (TIP) Manuals.
- o Communicating on a regular basis with the QA Manager regarding the effectiveness and adequacy of the YMP Quality Assurance Program.

#### 1.0.5.3

Technical Area Leaders are delegated the responsibility and authority for the overall management of their technical areas. This includes implementing the YMP Quality Assurance Program as it pertains to their specific technical areas. A Technical Area Leader's responsibility and authority includes:

- o Appointment of Task Leaders.
- o Negotiating with LLNL technical support departments for staff resources.

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- o Implementation of those procedures and requirements necessary to assure achievement of quality objectives.
- o Review of the quality assurance level of activities.
- o Preparation, or delegating preparation of the Scientific Investigation Plan for the task and recommending Quality Assurance Levels for the various plan activities.
- o Reviewing the Technical Implementing Procedures (TIPs) that are written by Task Leaders to implement requirements defined by the Project Leader.
- o Identifying quality related issues and problems and reporting these to the Project Leader.
- o Fulfillment of technical review responsibilities as specified in Procedure No. 033-YMP-QP 3.3, "Review of Technical Publications."
- o Fulfillment of other responsibilities as specified in the YMP Quality Assurance Program Plan (QAPP), Quality Procedures (QP) Manual, Administrative Procedures (AP) Manual and Technical Implementing Procedures (TIP) Manual.

#### 1.0.5.4

A Task Leader is delegated the responsibility and authority to implement quality assurance at the task level. A Task Leader's principal focus is the planning, execution, quality, and reporting of the technical work. A Task Leader's responsibility and authority includes:

- o Developing functional controls in the form of administrative and technical procedures to meet the requirements established by the Project Leader.
- o Identifying and reporting quality related issues and problems.
- o Preparation of Technical Implementing Procedures (TIP) pertinent to the Task Leader's area of responsibility.
- o Fulfillment of other responsibilities as specified in the YMP Quality Assurance Program Plan (QAPP), Quality Procedures (QP) Manual, Administrative Procedures (AP) Manual and Technical Implementing Procedures (TIP) Manual.

#### 1.0.5.5

The YMP Quality Assurance Manager is delegated the responsibility, authority, and organizational freedom to assure that an appropriate quality assurance program is established, that it is effectively executed, and that it is well maintained. The QA Manager has sufficient independence from cost and schedule considerations to fulfill these responsibilities. The QA Manager has appropriate management and QA knowledge and experience and is at the same or higher organization level (see Exhibit A) as the highest line manager responsible for performing activities affecting quality.

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The management position designated "Quality Assurance Manager" is a full-time dedicated position, and additional full-time dedicated QA positions are established to assure that the QA Manager has sufficient staff to fulfill the responsibilities assigned to him. The QA Manager's responsibility and authority includes:

- o Providing assistance and support to all program personnel regarding quality assurance matters.
- o Performing independent reviews of the YMP QAPP and QP, AP and TIP Manuals to verify for the YMP Leader their appropriateness, effective execution, and maintenance.
- o Approving of (1) the QAPPs, changes thereto, and (2) QPs and all changes thereto.
- o Reviewing the TIPs and APs to assure achievement of quality objectives.
- o Providing a focal point for liaison and coordination with project offices and other participating organizations on quality assurance matters.
- o Initiating actions to stop the performance of unsatisfactory work.
- o Fulfillment of other responsibilities as specified in the YMP Quality Assurance Program Plan (QAPP), Quality Procedures (QP) Manual, Administrative Procedures (AP) Manual and Technical Implementing Procedures (TIP) Manual.

QA personnel elevate the resolution of disputes to progressively higher organization levels through established channels including the YMP DOE Project Quality Assurance Manager if the dispute cannot be resolved within the LLNL YMP organization.

#### 1.0.5.6

The Resource Planning and Control Manager is delegated the responsibility for YMP project planning and scheduling utilizing work breakdown structures and network scheduling techniques. The Resource Planning and Control Manager responsibilities also includes:

- o Preparation of budget documents and reports, maintenance of task and activity files, and preparation of work authorization documents.
- o Monitoring of program activities and reporting deviations from schedules and budgets.
- o Authorization and file maintenance of procurement documents. The Manager is responsible for reviewing all procurement documents and for assuring that QA requirements for procurement are identified and that applicable procedures are implemented.
- o Textual review of Administrative Procedures.

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#### 1.0.5.7

The Yucca Mountain Project Administrator is delegated the responsibility for the following:

- o Records management and document control.
- o Training coordination.
- o Technical procedure writing coordination and administrative procedure manual preparation.
- o YMP office operations including coordination of secretarial and clerical staff.
- o Control and transmission of reports and publications.
- o Action item tracking.

#### 1.0.6 INTERFACES

Interfaces are identified and coordinated among and within the participating organizations. Interface controls include the assignment of responsibility and establishment of procedures for review, approval, release, distribution, and revision of documents involving interfaces. Information transmitted across interfaces is documented.

Interfaces may be established between:

- o Technical Areas
- o Tasks
- o YMP and other LLNL organizations
- o YMP and its subcontractors in accordance with written procedures.
- o YMP and other YMP Participating Contractors as defined by DOE Project Office requirements.

## YUCCA MOUNTAIN PROJECT ORGANIZATION

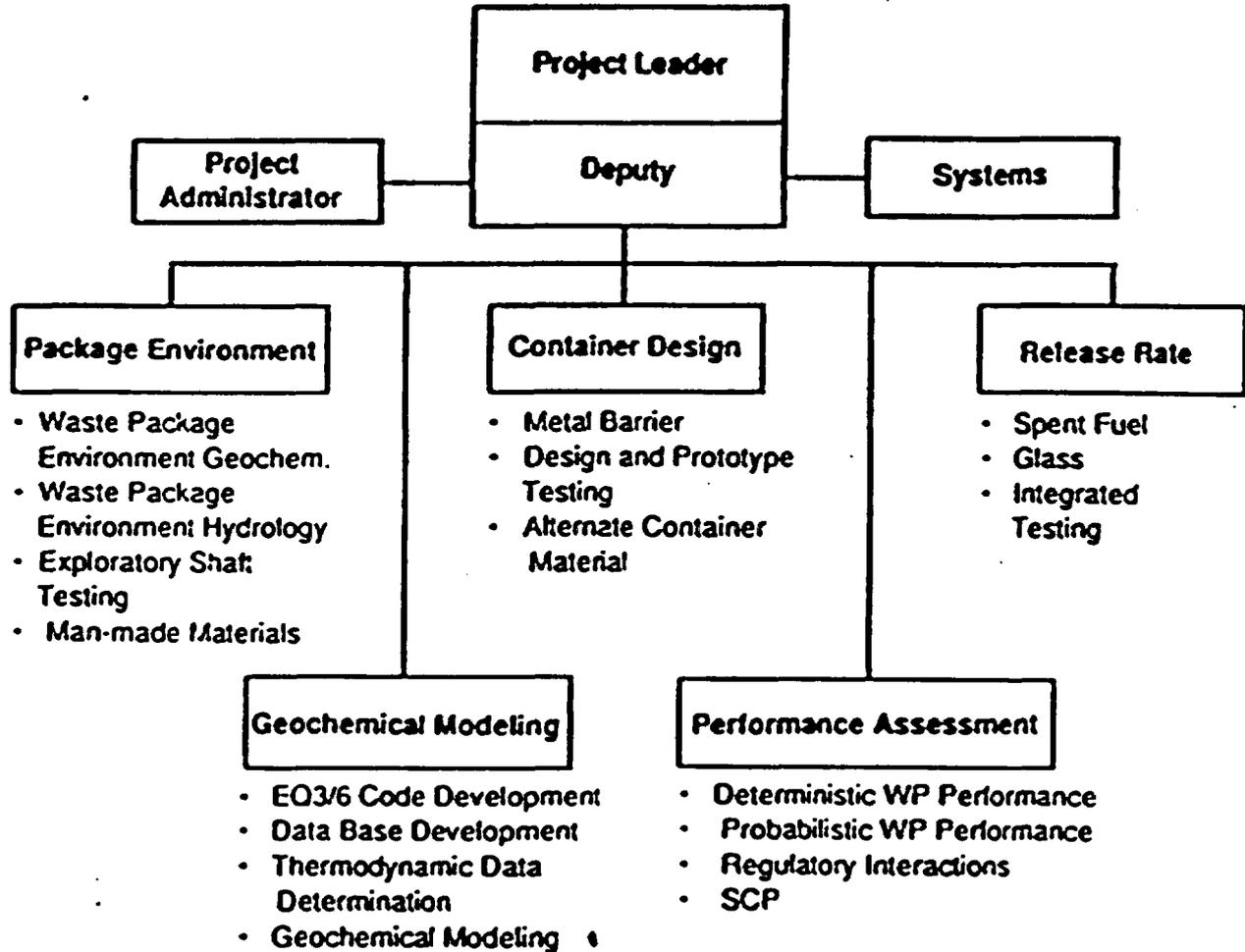


EXHIBIT A

LLNL/YMP ORGANIZATIONAL STRUCTURE

Lawrence Livermore National Laboratory

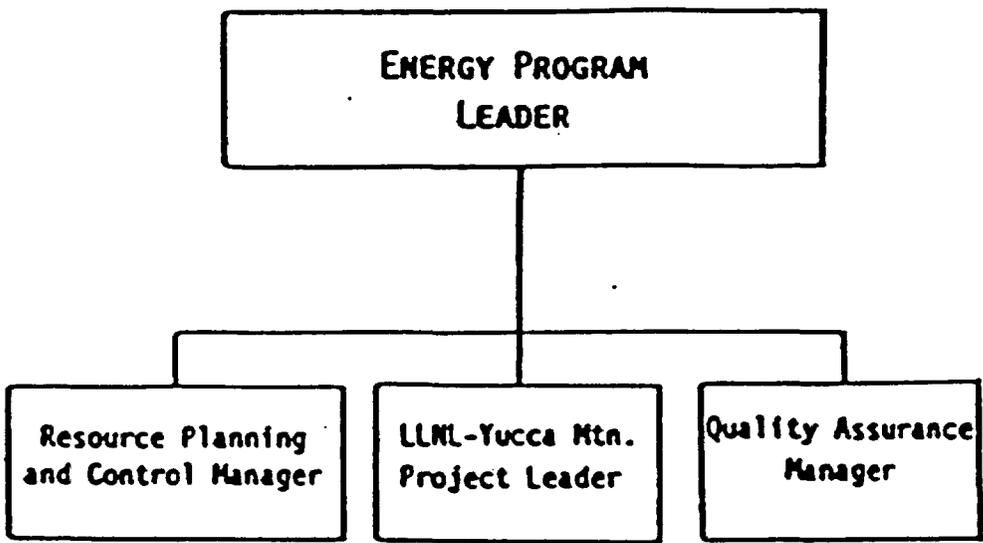


EXHIBIT B

YUCCA MOUNTAIN PROJECT ORGANIZATION

Energy Program Leader

R. Schock

YMP Leader

Deputy  
Systems  
Project Administrator

L. Ballou (acting)  
D. Short  
M. Revelli  
B. Bryan

Resource Planning & Control Manager

vacant

Package Environment

Geochemistry  
Hydrology  
Exploratory Shaft Testing  
Other Materials

D. Wilder (acting)  
W. Glassley (acting)  
A. Tompson  
A. Ramirez (acting)  
W. Bourcier (acting)

Geochemical Modeling

EQ3/6 Code Development  
Data Base Development  
Thermochemical Data  
Determination  
Geochemical Modeling

R. Aines  
K. Jackson  
D. Olness  
  
R. Silva  
C. Bruton

Container Design

Metal Barrier  
Alternate Container Material  
Design and Prototype Testing

J. Kass  
D. McCright  
E. Dalder  
T. Nelson

Performance Assessment

Deterministic WP Performance  
Regulatory Interactions  
SCP  
Probabilistic WP Performance

W. O'Connell  
D. Lappa  
W. O'Connell, (acting)  
D. Emerson  
W. O'Connell

Release Rate

Spent Fuel (Dissolution)  
Spent Fuel (Oxidation)  
Spent Fuel (Cladding)  
Glass  
Integrated Testing

H. Shaw  
H. Leider  
R. Stout  
R. Stout  
R. Ryerson, (acting)  
H. Shaw

Quality Assurance

Program Development  
Audits and Surveillances  
Quality Engineering

R. Schwartz  
R. Schwartz  
R. Oberle  
unassigned

EXHIBIT C  
CURRENT STAFFING

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

No.: 033-YMP-QP 2.0

Revision: 0

Date: **FEB 24 1989**

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Subject:

ASSURANCE

Approved:

Approved by: [Signature] 2/4/89  
YMP Project  
Leader

Approved by: [Signature] 1/12/89  
YMP Quality Assurance  
Manager

#### 2.0.1 PURPOSE

This procedure assigns specific responsibilities to the YMP Quality Assurance Manager (QA Manager). This procedure also describes the structure, preparation and application of the Yucca Mountain Project (YMP) Quality Procedures (QP) Manual.

The requirements and procedures governing YMP quality assurance program consist of a three-tier system under which work for various sponsors can be controlled and documented. In the first tier, requirements generally applicable to the work performed for the DOE Project Office are identified in the Quality Assurance Program Plan (QAPP). Procedures formulated to meet the QAPP requirements constitute the second tier and are either published as Quality Procedures (QP), or as Administrative Procedures (AP). The third tier documents are work plans in the form of Scientific Investigation Plans and Technical Implementing Procedures and are generic or specific technical procedures used to plan and direct specific work activities.

It is the philosophy of the YMP that quality assurance is a line responsibility. Each requirement and procedure is, therefore, written with the objective of being understandable and applicable at the working level.

Activities that affect quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for a given activity are satisfied.

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## 2.0.2 TERMS AND DEFINITIONS

Quality Assurance Program Plan (QAPP): Quality requirements which specify what is to be done not how. The QAPP is based on requirements specified by the Yucca Mountain Project Office.

Quality Procedure (QP): A Quality Procedure is a procedure that implements a set of requirements contained in the QAPP or a set of requirements contained in the YMP quality related Administrative Procedures. A QP is applicable to all YMP personnel.

Scientific Investigation Plans (SIP): Documents which describe the scientific investigation performed in support of the waste package design for the Yucca Mountain Project. Each SIP is subdivided into one or more subtasks or activities.

Technical Implementing Procedures (TIP): Detailed procedures which provide instructions for repetitive operations.

Administrative Procedures (AP): An Administrative Procedure is a procedure that implements a set of requirements of LLNL-YMP's Project Management Plan or a set of requirements of YMP's Administrative Procedures. An AP is applicable to all YMP personnel.

## 2.0.3 SCOPE

This procedure applies to all the requirements and procedures that collectively constitute the YMP QAPP and the QP, AP and TIP Manuals.

## 2.0.4 STRUCTURE

### a. Relationship to Other Standards

There is a one-on-one relationship of the numbers and the titles of the quality assurance elements in the Quality Assurance Program Requirements for Nuclear Facilities (NQA-1) and this three-tier set of QA requirements and procedures. There are two title differences: Element 2 is called "Assurance" in this Program rather than "Quality Assurance Program", and Element 5 is titled "Technical Implementing Procedures" instead of "Instructions, Procedures, Plans and Drawings."

### b. Issue of Requirements and Procedures

Quality Assurance requirements and procedures are issued to all holders of the YMP Quality Assurance Program Plan.

Requirements and procedures are subject to review and approval as described in Procedure No. 033-YMP-QP 2.1, "Preparation, Approval and Revision of Quality Procedures and Requirements".

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c. Issue of Technical Implementing Procedures

Technical Implementing Procedures are distributed at the discretion of the TIP's author to holders and non-holders of the YMP Quality Assurance Program Plan.

2.0.5 CONTROL OF ISSUE

The three-tier set of YMP requirements and procedures is considered to be a controlled quality assurance document. All requirements and procedures and their revisions are controlled. There is a record of issue of each copy of this document. This record contains the number assigned to each individual document holder and the contents, including revision numbers, for each copy. The record also indicates how superseded issues were handled.

2.0.6 RESPONSIBILITIES AND AUTHORITIES

The YMP Quality Assurance Manager (QA Manager) is responsible for and has the authority to:

- maintain the control system for the issuance and revision of the YMP Quality Assurance Program documents.
- verify that the YMP Quality Assurance Program remains responsive to the requirements, is implemented correctly, and continues to be effective.
- establish a program to train, qualify, and certify personnel in quality assurance methods. This program is described in Procedure No. 033-YMP-QP 2.9, "Training".
- review the implementation of the YMP Quality Assurance Program.
- perform other duties that are specifically delineated in other requirements and procedures of the YMP Quality Assurance Program documents. This includes the responsibility and authority to stop work which is not in compliance with the requirements of the QAPP.

The QA Manager is also responsible for and has the authority to conduct suitable overview of the QA activities of all organizations (including Subcontractors doing supportive work) under YMP purview. Overview includes the following as appropriate:

- Review and approval of QAPPs and QPs and review of APs.
- Surveillance of activities affecting quality to verify compliance with requirements.
- Performance of quality audits to verify the adequacy and compliance of QA Programs.

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Procedures are established by the QA Manager for the review of QA program documentation of organizations under YMP purview for adequacy, completeness and relevance. The procedures identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action. Reviews of QA program documentation are recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance. Such review and approval procedures for YMP subcontractors are consistent with the procedures found in Procedure No. 033-YMP-QP 4.0, "Procurement Control and Documentation."

#### 2.0.7 MANAGEMENT ASSESSMENTS AND READINESS REVIEWS

Management assessments are conducted at least annually to determine the effectiveness of the system and the management controls that have been established to achieve and assure quality and to assess the adequacy of resources and personnel provided to the QA program. Management verifies that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program.

Management assessments are conducted in accordance with Procedure No. 033-YMP-QP 2.3 "Management Assessments" which prescribes the planning, organizing, performing, and documenting of the management assessments. This procedure prescribes analysis and reporting of results and the tracking of recommendations that result from the management assessments. Copies of all management assessments are provided to the DOE Project Offices. Management above or outside the QA organization is responsible for the management assessment activity.

Management performs readiness reviews, as deemed appropriate in accordance with Procedures 033-YMP-QP 2.6 "Readiness Review." Readiness reviews apply to major scheduled/planned activities which could affect quality. Management above or outside the QA organization is responsible for the readiness review activity.



## CHANGE NOTICE

CN No. 2.1-0-2

Affected Document: QP 2.1, "Preparation, Approval, and  
Revision of Quality Procedures and Requirements"

Revision: 0Prepared By Ronald Schwartz

Approved By N/A  
Technical Area Leader Date

Approved By *R. E. [Signature]* 3/15/89  
YMP QA Manager Date

Approved By *A. Sallan* 3/15/89  
YMP Project Leader Date

Currently Reads as Follows:

## 1. Section 2.1.2, Second Paragraph

In addition, paragraphs describing the method for review, approval and revision may also be applied to other controlled quality related project documents such as Scientific Investigation Plans (SIP), Study Plans (SP), Activity Plans, and Technical Implementing Procedures (TIP).

## 2. Exhibit A - Review and Approval of Controlled Project Documents

Add text (see below).

Changed to Read:

## 1. Section 2.1.2, Second Paragraph:

In addition, paragraphs describing the method for review, approval and revision may also be applied to other controlled quality related project documents such as Scientific Investigation Plans (SIP), Study Plans (SP), Activity Plans, Technical Implementing Procedures (TIP), and Software QA Plans (SQAP).

## 2. Exhibit A - Review and Approval of Controlled Project Documents

Add: SQAP - Reviewer/Approver: YMP QA Manager, YMP Project Leader, Technical Area Leader(s), DOE Project Office. Each approve.

**NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT**

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0102

Subject: PREPARATION, APPROVAL AND REVISION  
OF QUALITY PROCEDURES AND REQUIREMENTS

Approved:

Approved by: *S. Shelton* 2/21/89 YMP Project Leader  
Approved by: *R. E. Smith* 2/21/89 YMP Quality Assurance Manager

2.1.1 PURPOSE

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

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, paragraphs describing the method for review, approval and revision may also be applied to other controlled quality related project documents such as Scientific Investigation Plans (SIP), Study Plans (SP), Activity Plans, and Technical Implementing Procedures (TIP).

2.1.3 RESPONSIBILITIES

The YMP Quality Assurance Manager is responsible for:

- o Preparation of QAPP Requirements and Quality Procedures. The appropriate YMP technical group(s) may assist in the preparation of selected Quality Procedures,

- o Assuring that the Quality Procedures include consideration of the technical aspects of the activities affecting quality.
- o Review and approval of documents identified in Exhibit A.
- o Assuring that all Quality Procedures implement the requirements specified in the QAPP for technical activities.

The YMP Project Leader is responsible for:

- o Review and approval of documents identified in Exhibit A.

The YMP Technical Area Leaders are responsible for:

- o Review and approval of documents identified in Exhibit A.
- o 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 YMP 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:

- o Table of Contents, if appropriate
- o Purpose
- o Scope
- o Responsibilities

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- o Procedure/Text
- o Retained Documentation,

Additional sections may be added for clarification such as exhibits showing examples, standard forms, etc.

#### 2.1.4.3 Review

Review copies are distributed by the originator for review as identified in Exhibit A. Quality related project documents such as Scientific Investigation Plans (SIPs), Study Plans (SPs), Activity Plans, and Technical Implementing Procedures (TIPs) are included in Exhibit A since their review and approval is similar. The preparation of those documents is described in Procedure 033-YMP-QP 3.0, "Scientific Investigation Control".

Review copies are accompanied by a memo identifying the comments due date, clarifying information and any special instructions.

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.

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 no comments, review copies may be discarded. Review copies with comments are returned to the originator. If comments require resolution, the preferred method is a meeting to discuss unresolved issues. If resolution cannot be achieved by the meeting participants, final authority rests with the YMP Project Leader.

A memo will be prepared by the originator to indicate the following and will be retained as a QA Record:

- o Those to whom review copies were sent;
- o Those who returned comments;
- o Disposition of comments.

Alternately, the originator may annotate and initial disposition on comment copy pages for retention as QA Records.

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#### 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 QAPPs, SPs, and SIPs to the DOE Project Office for approval. DOE Project Office approval of implementing procedures such as QPs, TIPs, etc., is not required. Until DOE Project Office approval is obtained, QAPP Requirements and SIPs are considered "Approved For Interim Use" and will be so stamped or otherwise identified by Document Control. When issued as such by Document Control YMP project members may use as though they had been approved by the DOE Project Office.

If, in the opinion of the YMP Leader, there is sufficient risk in using prior to DOE Project Office 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.

When sponsor approval has been obtained, Document Control will reissue with the same revision number but without the interim use restriction.

#### 2.1.5 REVISIONS

##### 2.1.5.1 Revision Numbering

Each revision controlled document identifies the revision number beginning with Revision 0 for the first approved issue and is revised each time the document is revised.

##### 2.1.5.2 Revision Identification

Changes will be identified by a vertical bar in the right hand margin. Only changes made from the previous issue will be identified.

##### 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 E) to rapidly implement field changes.

Change Notices are approved before issue by those who approved the original document.

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Change Notices are incorporated into the next revision of the affected document. Only three Change Notices are allowed before revision and reissue is required. Change Notices are issued to all custodians of the document by Document Control and are to be attached to the document until superseded.

#### 2.1.6 STATUS CONTROL

Document Control maintains a log of controlled document revisions and Change Notices. Controlled distribution is maintained by Document Control 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. Typically this is 5 working days after the date of the last approval signature to allow time for reproduction and distribution, unless otherwise designated by the YMP Project Leader.

#### 2.1.8 RETAINED DOCUMENTATION

##### 2.1.8.1 Retained by originator until at least the next revision:

- o Returned draft review copies,

##### 2.1.8.2 Retained by Document Control as QA Records:

- o Current and previously issued QAPP Requirements.
- o Current and previously issued QA procedures.
- o Record of YMPD review and approval.
- o Disposition of comments.

**EXHIBIT A**

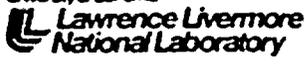
**Responsibilities for Review and Approval  
of Controlled Project Documents**

<u>Reviewer/Approver</u>	<u>QAPP</u>	<u>OP</u>	<u>SIP</u>	<u>SP</u>	<u>Act. Plan</u>	<u>IIP</u>
YMP QA Manager	1	1	1	1	1	1
YMP Project Leader	1	1	1	1	1	1
Technical Area Leader(s)	2	2	2	2	1	1
DOE Project Office QA Manager			1			
DOE Project Office	1		1			

1 = Approval

2 = Review Only

**EXHIBIT B - TITLE PAGE  
for Quality Procedures**

<p><small>University of California</small>    <b>Lawrence Livermore National Laboratory</b></p> <p><b>NUCLEAR WASTE MANAGEMENT PROGRAM</b></p> <p>CONTROLLED COPY NO. _____</p>	<p>No.:</p> <p>Revision:</p> <p>Date:</p> <p>Page: _____ of _____</p>
<p>Subject: _____</p>	<p>Approved: _____</p>
<p>Approved by: _____ Approved by: _____</p> <p>YMP Project Leader YMP Quality Assurance Manager</p> <hr/> <p align="center" style="font-size: 48px; opacity: 0.5;">S A M P L E</p>	

**EXHIBIT C - TITLE PAGE**  
For Quality Assurance Program Plan Requirements

<p>University of California    <b>Lawrence Livermore National Laboratory</b></p> <p><b>NUCLEAR WASTE MANAGEMENT PROGRAM</b></p> <p>CONTROLLED COPY NO. _____</p>	<p>No.:</p> <p>Revision:</p> <p>Date:</p> <p>Page: _____ of _____</p>
<p>Subject:</p>	<p>Approved: Reserved for DOE Project Office Approval</p>
<p>Approved by: _____ Approved by: _____</p> <p>YMP Project Leader YMP Quality Assurance Manager</p> <hr/> <p align="center" style="font-size: 48px; opacity: 0.5;">S A M P L E</p>	

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EXHIBIT D - FOLLOWING PAGES

No.	Revision.	Date	Page: of
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S  
A  
M  
P  
L  
E



NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

PEER REVIEW

Approved:

Approved by: *J. S. Pellan* 2/12/89  
YMP Project  
Leader

Approved by: *R. L. E. Adams* 1/12/89  
YMP Quality Assurance  
Manager

### 2.2.1 PURPOSE

This procedure establishes the process for planning, conducting and documenting Peer Reviews for the Yucca Mountain Project (YMP).

A Peer Review is used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.), or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation, cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

The following conditions are indicative of situations in which a Peer Review is warranted:

- a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- b. Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized.
- d. Detailed technical criteria or standard industry procedures do not exist or are being developed.
- e. Results of tests are not reproducible or repeatable.
- f. Data or interpretations are ambiguous.
- g. Data adequacy is questionable (e.g., data may not have been collected in conformance with an established QA program.)

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A Peer Review is also used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

#### 2.2.2 SCOPE

This procedure applies to Peer Reviews conducted by the LLNL-YMP and YMP subcontractors.

#### 2.2.3 DEFINITIONS

Peer - A person having technical expertise in the subject matter to be reviewed (or a critical subset of the matter to be reviewed) to a degree at least equivalent to that needed for the original work.

Peer Review - A documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being performed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria employed, or conclusions drawn in the original work.

#### 2.2.4 RESPONSIBILITIES

The YMP Project Leader is responsible for identifying Peer Review Chairmen and for concurring with the selection of Peer Reviewers. These responsibilities cannot be delegated.

YMP Technical Area Leaders are responsible for:

- a. Identifying the need to conduct a Peer Review; and
- b. Collecting and maintaining documentation required by this procedure and submitting it to the YMP Quality Assurance Manager for review and to the Records Management System.

The YMP Quality Assurance Manager is responsible for monitoring the implementation of this procedure, providing a QA Representative to serve as Secretary for each Peer Review, providing a QA Program Indoctrination for Peer Reviewers, and for reviewing the Peer Review documentation before it is submitted to the Records Management System.

The Peer Review Chairman is responsible for:

- a. Identifying Peer Review candidates who meet the requirements specified in this procedure;

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- b. Planning and conducting the Peer Review;
- c. Directing the preparation of the Peer Review Report; and
- d. Attesting to the qualifications of the Peer Reviewers.

## 2.2.5 PROCEDURE

### 2.2.5.1 Initiation of the Peer Review

The cognizant Technical Area Leader (TAL) notifies the YMP Project Leader and the YMP Quality Assurance Manager by memorandum of the need to conduct a Peer Review. After obtaining the concurrence of the YMP Project Leader for conducting the Peer Review, the TAL opens and maintains a file for the collection of all Peer Review related documents.

The YMP Quality Assurance Manager identifies a QA Representative to serve as Secretary of the Peer Review and notifies the TAL of the selection in writing.

### 2.2.5.2 Selection of Peer Reviewers

The YMP Project Leader selects the person to serve as Chairman for the Peer Review. The Chairman must meet the same selection criteria as provided in this section of the procedure for the other Peer Reviewers.

The Peer Review Chairman nominates the remaining members of the Peer Review and obtains concurrence of the nominations by the YMP Project Leader. The Peer Review Group meet the following criteria.

- a. The number of peers comprising a Peer Review group varies commensurate with the following:
  - 1. The complexity of the work to be reviewed;
  - 2. Its importance to establishing that safety or waste isolation performance goals are met;
  - 3. The number of technical disciplines involved;
  - 4. The degree to which uncertainties in the data or technical approach exist;
  - 5. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.
- b. The collective technical expertise and qualifications of Peer Review Group members spans the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. The potential for technical or organizational partiality is minimized by selecting peers to provide a balanced peer review group. Technical areas more central to the work to be reviewed receive proportionally more representation in the Peer Review Group.

- c. The technical qualification of the peer reviewers, in their review areas, is comparable to that needed for the original work under review. Each peer has recognized and verifiable technical credentials in the technical area that the peer has been selected to review.
- d. Members of the peer review group are independent of the original work to be reviewed. Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. In some cases (i.e., finding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. When the independence criteria cannot be met, a documented rationale is included in the Peer Review Report.

Contractual arrangements for obtaining the services of Peer Reviewers are processed in accordance with Procedure 033-YMP-QP 4.0, "Procurement Control and Documentation." Peer Review candidates submit a verifiable resume of educational and professional achievement, including a listing of publications, to the Peer Review Chairman prior to final selection as a Peer Reviewer.

Prior to beginning the Peer Review, the Chairman submits a memorandum to the YMP Project Leader and the TAL attesting to the qualifications of the selected peers and describing the way in which their qualifications and expertise meet the requirements of this procedure.

#### 2.2.5.3 Conducting the Peer Review

The Peer Review Chairman and the TAL develop a plan for conducting the Peer Review. The plan includes:

- a. A description of the work to be reviewed;
- b. The size of the Peer Review Group and the spectrum of Peer Reviewers' qualifications;
- c. A suggested method for accomplishing the Peer Review;
- d. A schedule for completing the review; and
- e. Copies of, or references to materials, reports and publications pertinent to the work to be reviewed.
- f. Provisions for providing the QA Program Indoctrination.

The plan is provided to the Peer Reviewers prior to the start of the review process.

Unless circumstances prohibit, the Peer Review is conducted at one or more group meetings. The TAL coordinates availability of facilities for Peer Review Meetings. When group meetings are impractical, the Peer Review Chairman assures that all Peer Reviewers are cognizant of the comments and recommendations of other Reviewers.

The Peer Review Group evaluates and reports on:

- a. Validity of assumptions;
- b. Alternate interpretations;
- c. Uncertainty of results and consequences if incorrect;
- d. Appropriateness and limitations of methodology and procedures;
- e. Adequacy of applications;
- f. Accuracy of calculations;
- g. Adequacy of requirements and criteria; and
- h. Validity of conclusions.

The QA Representative and the Peer Review Chairman prepare meeting minutes and other documents that describe the results of meetings, deliberations and other activities of the Peer Review process.

#### 2.2.5.4 Peer Review Report

The Peer Review Chairman prepares a report of the Peer Review activities. As a minimum, the report includes the following:

- a. A description of the work or issue(s) that was Peer Reviewed;
- b. The comments, conclusions and recommendations of the Peer Review group;
- c. Individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate;
- d. A listing of each Peer Reviewer and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality; and
- e. Signatures of the Peer Reviewers indicating their participation in the Peer Review.

Distribution of the Peer Review Report is determined by the TAL who initiated the review.

#### 2.2.5.5

The TAL submits the completed Peer Review documentation to the YMP Quality Assurance Manager for review. The Quality Assurance Manager assures that the document package is complete and in compliance with the requirements of this procedure.

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### 2.2.6 RETAINED DOCUMENTATION

The following documents resulting from the implementation of this procedure are Quality Assurance Records. Upon completion of the Peer Review, these records are collected, stored and maintained in accordance with Procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality Assurance Records include the following;

- a. Memoranda requesting and approving the conduct of the Peer Review;
- b. Documentation of the rationale for the technical discipline, composition, and size of the Peer Review Group;
- c. Documentation attesting to the qualifications of the individuals who participated in the Peer Review;
- d. The Peer Review plan and supporting materials;
- e. Correspondence related to the Peer Review;
- f. Minutes of all Peer Review proceedings;
- g. The Peer Review Group's report;
- h. Dispositions and replies to reviewer's comments.



## CHANGE NOTICE

CN No. 2.3-0-1Affected Document: QP 2.3, "Management Assessment"Revision: 0Prepared By Ronald SchwartzApproved By N/A

Technical Area Leader

Date

Approved By R. M. E. Schuy 3/5/89  
YMP QA Manager DateApproved By J. Salton 3/15/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 2.3.5, second paragraph, first bullet:
  - o The YMP Leader's memo designating the management assessment team...

Changed to Read:

1. Section 2.3.5, second paragraph, first bullet:
  - o The Energy Program Leader's memo designating the management assessment team members and approving the assessment scope.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

MANAGEMENT ASSESSMENTS

Approved:

Approved by: *D. A. Sellen* 2/11/89  
YMP Project Leader

Approved by: *R. E. Selby* 1/31/89  
YMP Quality Assurance  
Manager

**2.3.1 PURPOSE**

This procedure establishes controls for the conduct of management assessments of the Yucca Mountain Project (YMP) Quality Assurance Program.

**2.3.2 SCOPE**

Management Assessments are conducted at least once a year to evaluate the performance of the LLNL YMP in the following three areas:

- o training with respect to QA requirements.
- o effectiveness of the QA Program.
- o adequacy of resources provided for the QA Program.

**2.3.3 RESPONSIBILITIES**

The Energy Program Leader is responsible for assuring that management assessments of the YMP QA program are conducted at least annually in compliance with the controls specified in this procedure.

At his discretion the Energy Program Leader may designate the responsible Project Leader, another individual or a team to conduct the management assessment. When assessments are delegated, the Energy Program Leader retains responsibility for final approval of the assessment and assuring the controls of this procedure are met.

The YMP QA Manager is responsible for monitoring the implementation of this procedure and for assuring the continued effectiveness of the applicable controls, and for follow-up to close action items assigned as a result of assessments.

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#### 2.3.4 PROCEDURES

The Energy Program Leader either conducts the management assessment himself, or assigns a responsible individual to conduct the management assessment. The Energy Program Leader may, at his discretion, assemble a team to conduct the assessment.

The overall QA Program effectiveness will be assessed based upon reviews of audit reports, nonconformance reports, surveillance reports, QA reports, project reports, and interviews. Participation in and scope of assessments will be approved by the Energy Program Leader.

The Energy Program Leader's decision regarding which individual or individuals will conduct the management assessment is documented and maintained as a QA Record.

Each management assessment is designated by a unique three-digit hyphenated number (XX-Y). The first two digits designate the fiscal year in which the management assessment is conducted. The third digit indicates the number of the management assessment within that year.

Assessment areas selected for review will be identified on Management Assessment Worksheets (Exhibit A) to document the assessment and results. As appropriate, multiple worksheets are prepared for individual assessment areas.

The assessment team is responsible for evaluating the following:

- a. Status of training with respect to QA requirements.
- b. Assessment of the effectiveness of the QA program.
- c. Adequacy of resources provided to the QA program.

Exhibit B is a representative scope for which Management Assessment Worksheets would be prepared.

In performing this assessment the management assessment team utilizes, as appropriate, the following methods:

- a. Review of QA status reports.
- b. Interviews with management and staff personnel.
- c. Review of audit, surveillance, corrective action, nonconformance, and project review reports and supporting documentation.
- d. Evaluation of training documentation.
- e. Review of budget and other statistical information regarding resource use and availability.

The results of the assessment activities are documented in a report. The assessment report includes the following information:

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- a. Identification of the management assessment individual(s).
- b. A description of the assessment activities.
- c. The scope of the management assessment.
- d. Identification of personnel interviewed during the assessment.
- e. Management Assessment Worksheets.
- f. A summary of the results of the assessment.
- g. A description of any adverse conditions identified during the management assessment.

The assessment report is signed by each individual who participated in performing the assessment. Minority or dissenting comments are appended to the management assessment report.

The Energy Program Leader is responsible for reviewing and approving the management assessment report. Approval is indicated by the Energy Program Leader's signature on the cover page of the report.

The Quality Assurance Manager will track assigned action items from management assessment reports to closure, and will provide memo(s) to the Energy Program Leader and file upon closure.

Copies of the management assessment report are distributed to the DOE Project Office Director, the DOE Project Office Quality Manager, the responsible Project Leader, QA Manager, and the Technical Area Leaders.

#### 2.3.5 RETAINED DOCUMENTATION

Quality assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- o The YMP Leader's memo designating the management assessment team members and approving the assessment scope.
- o The management assessment worksheets.
- o The management assessment report.
- o The closure memo(s).

The designated assessment leader transmits the first three documents to Records Management. The YMP QA Manager or this designee submits action/closure memo's to Records Management.

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<b>MANAGEMENT ASSESSMENT WORKSHEET</b>		
<b>ASSESSMENT AREA:</b>		
<b>SOURCE OF INFORMATION:</b> Interviews -  Reports -		
<b>ASSESSMENT CRITERIA:</b>		
<b>OBSERVATIONS:</b>		
<b>RECOMMENDATIONS:</b>		

S  
A  
M  
P  
L  
E

MANAGEMENT ASSESSMENT AREAS  
(SCOPE)

- o QA PROGRAM TRAINING
- o QA PROGRAM RESOURCES AND BUDGET
- o QA PROGRAM EFFECTIVENESS
  - Nonconformance Corrective Actions
  - Procedural Compliance
  - Internal QA Audit Results/Actions
  - External QA Audit Results/Actions
  - Quality of Deliverables (based upon external tech reviews)
  - QA Program Changes/Schedules
  - Work Schedules and In Process QA Scheduling
  - Organizational Knowledge/Perspective of QA Requirements
  - Surveillance Results/Actions

EXHIBIT B

EXHIBIT B



## CHANGE NOTICE

CN No. 2.4-0-1Affected Document: QP 2.4, "Technical Review"Revision: 0Prepared By Ronald SchwartzApproved By N/A  
Technical Area Leader DateApproved By *R. L. E. Schultz* 3/15/89  
YMP QA Manager DateApproved By *J. S. Bellan* 3/15/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 2.4.5, first paragraph, second bullet:
  - o Review comment records.

Changed to Read:

1. Section 2.4.5, first paragraph, second bullet:
  - o Review comment records and comment resolution.

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0102

Subject:

TECHNICAL REVIEW

Approved:

Approved by:

  
YMP Project Leader

Approved by:

  
YMP Quality Assurance  
Manager

2.4.1 PURPOSE

This procedure describes the requirements for the technical review of Quality Level I and II activities performed under the direction of the Yucca Mountain Project (YMP). This procedure also prescribes documentation requirements associated with the review process. The intent of this procedure is to satisfy the requirements related to verification of scientific investigations/designs as specified in the YMP QAPP.

2.4.2 SCOPE

This procedure provides for the review and verification of the adequacy of specific designs/scientific investigation such that study documents (scientific notebooks, drawings, calculations, specifications, analysis, reports, etc.) are correct, satisfactory, and in compliance with requirements. The extent of the review is a function of the importance to safety or waste isolation of the system under consideration. The complexity of the investigation, the state of the art, and the similarity of the system to previous reviewed systems are also considered.

This procedure also applies to those scientific investigations that do not produce sufficient documentation to allow technical review by qualified individuals with out recourse to the originator. In these cases the review is based upon an oral presentation to a review board.

Technical reviews are scheduled as specified by the Task Leader. The review addresses objective evidence such that a technically qualified person may review, understand, and verify the work.

This procedure does not apply to those design/investigation activities that involve the use of data collection or analysis procedures and design methods that are untried, beyond the state of the art, or where detailed technical criteria and requirements do not exist or are being developed. For these cases a review conducted in accordance with the provisions of Procedure No. 033-YMP-QP 2.2, "Peer Review" applies.

### 2.4.3 RESPONSIBILITIES

It is the responsibility of YMP staff who have managerial duties at the technical area, project, and program levels to implement this procedure as appropriate to fulfill the objectives of the technical review process.

The Task Leader is responsible for initiating the technical review process, coordinating technical review meetings, documenting the review results, and maintaining documentation for QA record purposes.

The QA Manager is responsible for monitoring compliance with this procedure and for assuring adherence to quality procedure requirements.

### 2.4.4 PROCEDURE

The following represent minimum items for technical review:

#### 2.4.4.1 Schedule

Technical reviews are provided for in the work planning document of the technical area under investigation. The specific schedule for the technical review is established by the Task Leader with the concurrence of the Technical Area Leader.

#### 2.4.4.2 Review Board

The Task Leader with the concurrence of the Technical Area Leader determines the membership of the technical review board. The review is performed by qualified individuals other than those who performed the work. In exceptional cases, the originator's immediate supervisor can participate in the review if there is a limited number of technically qualified individuals, and if the need is individually documented and approved in advance with the concurrence of the QA Manager.

The review board should consist of the minimum number of members to provide representation of appropriate disciplines.

#### 2.4.4.3 Review Check List

The Task Leader or designee prepares a check list for the review board to consider during their technical review. As a minimum the check list addresses:

- a) Applicable Input - whether the selection of site characterization data, criteria letters, design basis, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards have been properly identified, approved, documented, and correctly applied to the design/scientific investigation.
- b) Input Changes - whether approved changes to the input have been identified, documented, and correctly applied to the design/scientific investigation.

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- c) Investigation/Design - whether the investigation/design has been performed and documented in sufficient detail regarding purpose, method, assumptions, design/study input, references, and units to be understandable.

#### 2.4.4.4 Review Material Distribution

The Task Leader obtains the necessary technical material and backup documentation for distribution to the review board. Documentation of investigation/design include the following: (1) objective(s), (2) method(s) used in the analysis, (3) design inputs and their sources, (4) applicable references, (5) results of literature searches, (6) assumptions [and their verifications if completed], (7) identification of computer calculations [including computer type, program name, revision, input, output, evidence of program verification] and the basis of application to the specific analysis.

Sufficient time is allowed for the review board to become familiar with the design or investigation. The material distributed should include appropriate forms to identify the activity being reviewed along with adequate space to record comments and suggested disposition of the comments. A deadline for comment submittal and the date and location of the comment resolution meeting is stated in the distribution material.

For those reviews that encompass activities that produce little or no documentation, especially in the early stages of the activity, technical documentation may consist of presentation handouts or "viewgraphs" of material used in an oral presentation.

#### 2.4.4.5 Technical Review

The technical review is a detailed critical review process intended to provide assurance that the design/investigation is correct and satisfactory. As a minimum, the following are considered by the technical review board during the review and the results of the deliberations documented:

- a) Whether the design/investigation inputs are correctly selected.
- b) Whether the assumptions necessary to perform the activity are adequately described and are reasonable. Where necessary, the assumptions are identified for subsequent reverifications when the detailed design/investigation activities are completed.
- c) Whether an appropriate method(s) has been used.
- d) Whether or not the design/investigation inputs are correctly incorporated into the activity.
- e) Whether the design outputs are reasonable when compared to the inputs.
- f) Whether the necessary design input and verification requirements for interfacing organizations have been specified in the study/design documents or in supporting procedures or instructions.

g) Whether the computer programs used for analysis are identified and verified in accordance with Procedure No. 033-YMP-QP 3.2, "Software Quality Assurance".

#### 2.4.4.6 Comment Resolution Meeting

The intent of the technical review board comment resolution meeting is to develop a concensus among the review board regarding the disposition of comments and to provide a program record of whether the design or investigation is in compliance with program requirements.

The Task Leader receives the review comments for consolidation. "No comment," is an acceptable response, but an explanation for this response must be included. The consolidated comments are distributed at the comment resolution meeting. The comment resolution meeting is chaired by the Technical Area Leader.

The Principal Investigator (or scientific staff responsible for the work) attends the comment resolution meeting and is provided an advance copy of the consolidated comments to allow preparation of appropriate responses.

With prior concurrence of the Technical Area Leader, the comment resolution meeting may be combined with an oral technical presentation, however, documentation reflecting the applicable review aspects of Section 2.4.4.5 must be prepared.

#### 2.4.4.7 Unresolved Comments

Comments that cannot be resolved during the review meeting are elevated to the next management level (Project Leader) for disposition.

#### 2.4.4.8 Technical Review Approval

Each review board member signs one technical review approval sheet attesting that the applicable aspects of Section 2.4.4.5 have been considered. The intent is to produce a single document. Interim approval (or approval with qualification) may be given subject to technical revision.

The Technical Area Leader signs the review approval sheet signifying concurrence with the conclusions of the technical review board. The conclusions of the review board may be (1) the design/investigation is acceptable, and no changes are required, (2) the work to date is acceptable with the incorporation of recommended changes, or (3) the work to date is unacceptable and a revision to the work planning document must be made.

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#### 2.4.5 RETAINED DOCUMENTATION

Quality assurance records that result from this procedure are collected, stored, and maintained in accordance with Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records." QA records include the following:

- o Technical review approval sheet(s).
- o Review comment records.
- o Recommendations for future action.

Other documents that result from this procedure are retained until the final review or report publication of the design or scientific investigation. At that point quality assurance records are produced and retained under Procedure No. 033-YMP-QP 3.3, "Review of Technical Publications". Documents retained until report publication include the following:

- o Original drafts of the review documents. In some cases this may not be possible (e.g., scientific notebooks, etc.). The document retention requirement then can be met by a statement regarding the location of the original document.

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject: ACCEPTANCE OF DATA NOT GENERATED UNDER THE CONTROL OF THE YMP QAPP

Approved:

Approved by: *J. S. Hallam* 4/13/89  
YMP Project Leader

Approved by: *R. W. E. Schmitz* 1/19/89  
YMP Quality Assurance  
Manager

**2.5.1 PURPOSE**

This procedure describes the controls necessary for the acceptance into the quality assurance records system of existing data or data interpretations not generated under the controls of the YMP Quality Assurance Program Plan (QAPP).

**2.5.2 SCOPE**

This procedure applies to existing data and data interpretations not generated under the controls of the YMP QAPP that are intended for support of licensing activities. This acceptance procedure is intended to qualify such existing data and data interpretation for use in QA Levels I and II activities by meeting the requirements of NUREG-1298, "Qualifications of Existing Data for High-Level Nuclear Waste Repositories" (February 1988). Once accepted, the existing data are classified as "primary data" for licensing purposes.

This procedure may not be used to qualify data collected in a QA Level III activity.

**2.5.3 RESPONSIBILITIES**

The Project Leader is responsible for the overall implementation of this procedure.

The Technical Area Leader is responsible for approval of the reviewers selected to perform the technical review process. The Task Leader is responsible for initiating the controls specified in this procedure. The Task Leader is also responsible for coordinating the acceptance action and for collecting any available supporting documentation that is used during the acceptance process.

The Quality Assurance Manager is responsible for assuring implementation of the requirements of this procedure.

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#### 2.5.4 TERMS AND DEFINITIONS

Existing Data: Data developed prior to the implementation of a 10 CFR Part 60, Subpart G quality assurance program by DOE and its contractors; or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities; or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.).

#### 2.5.5 PROCEDURE

There are four methods or combination of methods that are acceptable to qualify existing data or data interpretations for use in QA Levels I and II activities. These methods are:

- [1] The implementation of the peer review process in accordance with provisions of Procedure No. 033-YMP-QP 2.2, "Peer Review."
- [2] The use of corroborating data to support or substantiate other existing data. Inferences drawn to corroborate the existing data must be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. The amount of corroborating data needed is dealt with on a case-by-case basis in the documented review for qualification.
- [3] The use of a confirmatory testing program conducted in accordance with the provisions of Procedure No. 033-YMP-QP 3.0, "Scientific Investigation Control," which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing data base. The amount of confirmatory testing required is dealt with on a case-by-case basis in the documented review for qualification.
- [4] The demonstration that a QA program meeting the requirements of the YMP QAPP was utilized for the collection of the data being reviewed.

Methods [2] through [4] require a technical review process conducted in accordance with the provisions of this procedure. Two sets of review forms are utilized, one for acceptance of existing data or data interpretations from a technical journal, and the other set for acceptance of existing data or data interpretations from other sources.

##### 2.5.5.1 Initiating Acceptance Activities

The need for qualification of existing data is identified by the cognizant Task Leader directing the activity for which it is to be used. The Task Leader begins the acceptance process by completing Part I of the Data/Data Interpretation Acceptance Review Form (Exhibit A) and any Continuation Sheets as needed (Exhibit B). If the existing data to be qualified is from a technical journal, the Task Leader follows the procedure sequence of Section 2.5.5.5.

The Task Leader provides the following information as part of the Review Form:

1. Detailed description of the data and the activity for which its use is being considered.
2. Justification why the data should be used and why the data acquisition process need not be repeated under controlled conditions. Also included is a recommendation of which of the four acceptance methods (or combination of methods) is preferred for accepting this existing data. If confirmatory testing is recommended, then the amount of testing is addressed. Cost and schedule considerations are included in the justification.
3. Description of the procedures and resources used during the data acquisition process.

The Task Leader collects any available supporting documentation for use during the acceptance process. Supporting documentation may include: statements of work, logs or notebooks, technical procedures, documented reviews, and calibration records.

#### 2.5.5.2 Peer Review

If a peer review is the recommended and approved acceptance method, then the review proceeds according to the requirements of Procedure No. 033-YMP-QP 2.2, "Peer Review."

#### 2.5.5.3 Technical Review

If a selection other than a peer review is the recommended and approved acceptance method, the Task Leader selects a review team comprised of three individuals to conduct separate and independent reviews of the data. Two of the reviewers have the appropriate technical background and were not involved in data collection or interpretation. The third reviewer, also not involved in the data collection or interpretation, has expertise in quality assurance. The selections are noted in Part II of the Review Form (Exhibit A), and statements of their qualifications are attached. The Task Leader forwards the package to the Project Leader for concurrence in the selection of the review team. The Project Leader indicates concurrence by initial and date in Part II of the Review Form.

When the Task Leader has received Project Leader concurrence, copies of the Review Form (Exhibit A, and B if required) and the supporting documentation are submitted to each of the reviewers with a Data/Data Interpretation Acceptance Review - Appendix Sheet (Exhibit C). The Task Leader retains the original of the review package. Each reviewer performs his review separately and independently from the other reviewers.

#### 2.5.5.4 Conduct of Technical Review

The reviewer responds to the questions on the Appendix Sheet, documenting these responses on the Appendix or Continuation Sheets. As appropriate to the category of data being reviewed, the reviewer considers the following attributes during the review process:

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1. Qualifications of personnel or organizations generating the data compared to qualification requirements of personnel generating similar data under the YMP QAPP.
2. The technical adequacy of equipment and procedures used to collect and analyze the data.
3. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).
4. The environmental conditions under which the data were obtained if germane to the quality of the data.
5. The quality and reliability of the measurement control program under which the data were generated.
6. The extent to which conditions under which the data were generated may partially meet requirements of 10 CFR Part 60, Subpart G, "Quality Assurance."
7. Prior uses of the data and associated verification processes.
8. Prior peer or other professional reviews of the data and their results.
9. Extent and reliability of the documentation associated with the data.
10. Extent and quality of corroborating data or confirmatory test results.
11. The degree to which independent audits of the process that generated the data were conducted.
12. The importance of the data to showing that the proposed repository design meets the performance objectives of the YMP.
13. Replication of test results.

When the review is complete, the reviewer signs and dates the Appendix Sheet (Exhibit C) and returns the package to the Task Leader.

The Task Leader reviews the package and is responsible for resolving any issues raised by the reviewers. All resolutions are made part of the review package. The Task Leader signs and dates Part III of the Review Form and forwards the original package with the reviewers comments to the Project Leader. The acceptance process continues per the requirements of Section 2.5.5.6.

#### 2.5.5.5 Data or Data Interpretation from a Technical Journal

The Task Leader is responsible for initiating acceptance actions for data from a technical journal that will be essential to support the end result of QA Levels I and II activities. The Task Leader begins the review process by completing Part I of the Technical Journal Data/Data Interpretation Acceptance Form (Exhibit D). The Task Leader provides the following information as part of the Review Form:

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1. Complete reference of the technical journal, including other relevant references if the article is part of a series.
2. Description of the data in the journal article and its relationship to the current activity in which the data is to be used.
3. Justification why the data should be used and why the process cannot or need not be repeated under controlled conditions. Cost and schedule considerations are included in the justification. Also included is a recommendation of which of the four acceptance methods (or combination of methods) is preferred for accepting this existing data. If confirmatory testing is recommended, then the amount of testing is addressed.
4. An attached list of published supporting articles and a list of published rebuttal articles, if appropriate.
5. A complete reference of known independent verification of the data, if available, including how the verification was performed.

The Task Leader selects one individual to review the information independently. The reviewer has the appropriate technical background, and was not involved in data collection or interpretation. A statement of the reviewer's qualifications is included with the review package. If the reviewer selected by the Task Leader is acceptable to the Technical Area Leader, he indicates approval by initiating and dating Part II of the Review Form.

After concurrence is received, the Task Leader forwards a copy of the review package to the reviewer along with a Technical Journal Data/Data Interpretation Acceptance Review - Appendix Sheet (Exhibit E). The reviewer responds to the questions on the Appendix Sheet, documenting these responses on the Appendix (and/or Continuation Sheet). As appropriate to the category of data being reviewed, the reviewer considers the attributes of Section 2.5.5.4 in his review. When the review is complete, the reviewer signs and dates the Appendix Sheet and returns the package to the Task Leader."

The Task Leader reviews the package and responds to any issues raised by the reviewer. All resolutions are made part of the review package. If the reviewer and Task Leader have a difference of opinion that cannot be resolved, the Technical Area Leader appoints another individual to review the article independently. The second review is done in accordance with this section (2.5.5.5). Upon resolution of the difference of opinion, the Task Leader signs and dates Part II of the Review Form and forwards both packages to the Project Leader.

#### 2.5.5.6 Review Approvals

The Project Leader reviews the package to assure that the subject information had adequate controls for its intended use in the Project. The Project Leader indicates concurrence by signature and date in Part IV of the Review Form. If the Project Leader does not concur, a meeting is held with the Task Leader to resolve any comments. These resolutions are also made part of the review package. After the Project Leader concurs, the package is reviewed and approved by the QA Manager and submitted to the Yucca Mountain Project Office for approval.

If the Yucca Mountain Project Office does not concur in the review, a meeting is held with the Task Leader, Project Leader, and the appropriate Yucca Mountain Project Office personnel to resolve any comments and obtain approval.

After Yucca Mountain Project Office approval, the review package is returned to the Project Leader who forwards it to Document Control for distribution and incorporation into the quality assurance records system.

#### 2.5.6 RETAINED DOCUMENTATION

Quality assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records resulting from this procedure includes:

- o Technical Journal Data/Data Interpretation Acceptance Reviews, and
- o Data/Data Interpretation Acceptance Reviews.

#### 2.5.7 EXHIBITS

Exhibit A Data/Data Interpretation Acceptance Review Form

Exhibit B Data/Data Interpretation Acceptance Review Continuation Sheet

Exhibit C Data/Data Interpretation Acceptance Review - Appendix Sheet

Exhibit D Technical Journal Data/Data Interpretation Acceptance Review Form

Exhibit E Technical Journal Data/Data Interpretation Acceptance Review - Appendix Sheet

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**DATA/DATA INTERPRETATION ACCEPTANCE REVIEW FORM**

Use continuation sheets when necessary. Activity Number \_\_\_\_\_

**PART I - BACKGROUND INFORMATION**

Task Leader (TL) \_\_\_\_\_ Organization \_\_\_\_\_  
 Original Investigator \_\_\_\_\_ Organization \_\_\_\_\_  
 Subject Data Description \_\_\_\_\_

Activity in which data will be used: \_\_\_\_\_

Technical Justification (why data should be used and need not be repeated under YMP QAPP Plan controlled requirements)

Cost and Schedule Justification \_\_\_\_\_

Procedure/Resources used during Data Collection \_\_\_\_\_

**PART II - REVIEW INFORMATION (Comments documented on Appendix Sheets)**

Technical Reviewer 1 \_\_\_\_\_ Affiliation \_\_\_\_\_ Date \_\_\_\_\_  
 Technical Reviewer 2 \_\_\_\_\_ Affiliation \_\_\_\_\_ Date \_\_\_\_\_  
 QA Reviewer \_\_\_\_\_ Affiliation \_\_\_\_\_ Date \_\_\_\_\_  
 Technical Area Leader Concurrence \_\_\_\_\_ (Initial and Date)

**PART III - TL COMMENTS ON REVIEW**

TL \_\_\_\_\_ Date \_\_\_\_\_

**PART IV - MANAGEMENT CONCURRENCE** Approval Disapproval

Project Leader _____	( )	( )	Date _____
DOE PO Branch Chief _____	( )	( )	Date _____
DOE PO POM _____	( )	( )	Date _____

YMP 002 REV 0

**EXHIBIT A  
 DATA/DATA INTERPRETATION  
 ACCEPTANCE REVIEW FORM**



**DATA/DATA INTERPRETATION ACCEPTANCE REVIEW - APPENDIX SHEET**

Activity Number \_\_\_\_\_

**REVIEWER'S COMMENTS:** Evaluate the subject information using the following questions as guides; you may use others that you feel are relevant to the review. Use continuation sheets, if necessary.

**T = Technical Reviewer** **Q = QA Reviewer**

1. Are experiments and tests associated with the data conducted in accordance with documented plans, procedures, etc., and is the documentation of the experiments and tests sufficient to support use of the data? T,Q
2. How do you know that the methods, practices, techniques, and experiments used to obtain and treat the data are technically sound, and objective? T
3. Are data calculations (including statistical analyses) correct, i.e., were they verified? T
4. How do you know whether measuring and testing equipment were calibrated to known standards before and after the experiment or test was conducted? T, Q
5. Are the data sufficiently well measured to support the conclusions? T
6. Are samples, specimens, and data adequately identified and controlled for use within the experiment or test? T,Q
7. Are original samples or specimens available for further experiments or tests, and where are they located? T,Q
8. Is the operating procedure stated in sufficient detail so that the experiment or test can be reconstructed? T,Q
9. Where are the raw data recorded? Are they retrievable? Q
10. Is the input data sufficient to make a reasonable interpretation, and is the interpretation supported by documented analysis? T
11. Are assumptions used in the interpretation adequately identified and reasonable and are all possible assumptions considered? T
12. Based on your review, do you concur that the data or data interpretations are logical and valid? (Explain) T
13. Based on your review, do you concur with the use of the data or data interpretations for the YMP Project? (Explain) T,Q

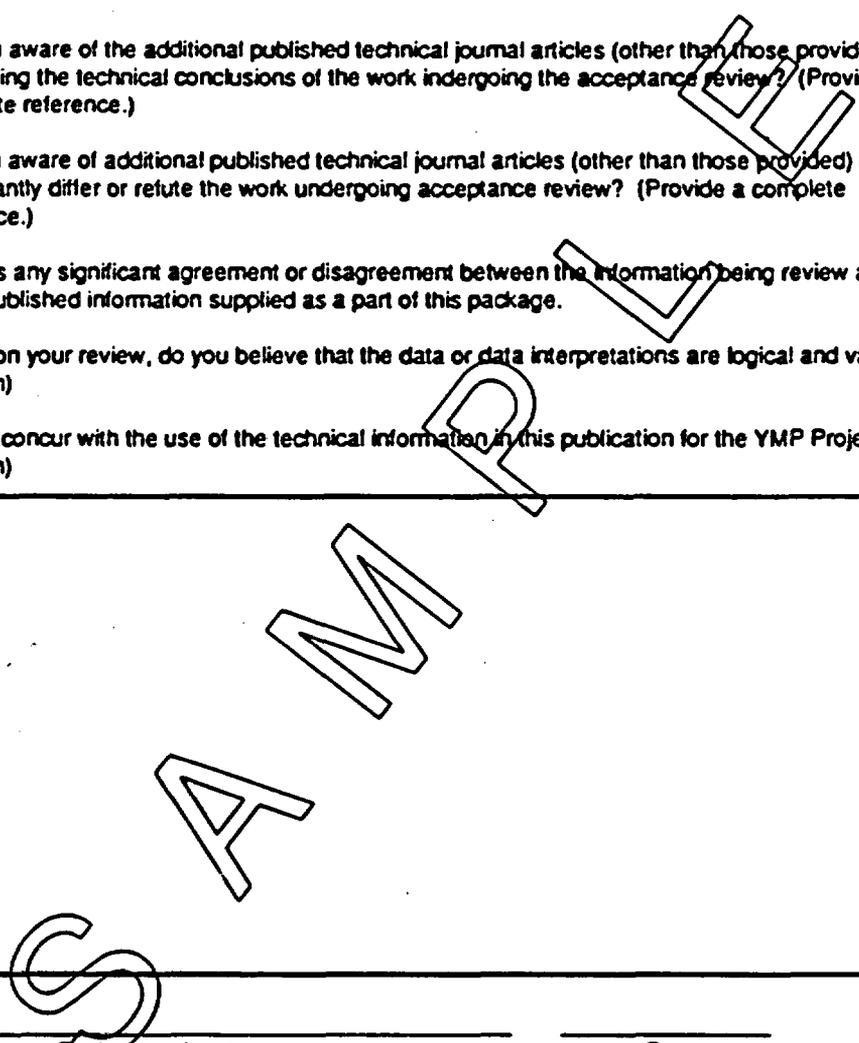
(Reviewer's signature)	(Date)
(Organization)	(Phone Number)

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UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	YUCCA MOUNTAIN PROJECT Page _____ or _____
<b>TECHNICAL JOURNAL DATA/DATA INTERPRETATION ACCEPTANCE REVIEW FORM</b>	
Use continuation sheets when necessary. Activity Number _____	
<b>PART I - BACKGROUND INFORMATION</b>	
Task Leader (TL) _____ Organization _____	
Subject Technical Journal _____	
Date _____ Issue _____ Author(s) _____	
Article Title _____	
Relevant Reference _____	
Description of Subject Data/Interpretation _____	
Activity in which data will be used: _____	
Technical Justification (why the data interpretation should be used) _____	
Cost and Schedule Justification _____	
List of Supporting Articles Attached ( ) (Provide a complete reference.) List of Rebutting Articles Attached ( ) (Provide a complete reference.) Documentation of Independent Verification Attached ( ) No. of Pages _____	
<b>PART II - REVIEW INFORMATION (Comments documented on Appendix Sheets)</b>	
Technical Reviewer _____ Affiliation _____ (Date) _____	
Technical Area Leader Concurrence _____ Date _____	
<b>PART III - TL COMMENTS ON REVIEW</b>	
TL _____ DATE _____	
<b>PART IV - MANAGEMENT CONCURRENCE</b>	
Project Leader _____	Approval ( ) Disapproval ( ) Date _____
DOE PO Branch Chief _____	Approval ( ) Disapproval ( ) Date _____
DOE PO POM _____	Approval ( ) Disapproval ( ) Date _____

YMP 005 REV 0

**EXHIBIT D  
TECHNICAL JOURNAL DATA/DATA INTERPRETATION  
ACCEPTANCE REVIEW FORM**

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<b>TECHNICAL JOURNAL DATA/DATA INTERPRETATION ACCEPTANCE REVIEW - APPENDIX SHEET</b>			
Activity Number _____			
<p><b>REVIEWER'S COMMENTS:</b> Evaluate the subject information using the following questions as guides; you may use others that you feel are relevant to the review. Use continuation sheets as necessary.</p>			
<ol style="list-style-type: none"> <li>1. Are you aware of the additional published technical journal articles (other than those provided) supporting the technical conclusions of the work undergoing the acceptance review? (Provide a complete reference.)</li> <li>2. Are you aware of additional published technical journal articles (other than those provided) that significantly differ or refute the work undergoing acceptance review? (Provide a complete reference.)</li> <li>3. Address any significant agreement or disagreement between the information being review and other published information supplied as a part of this package.</li> <li>4. Based on your review, do you believe that the data or data interpretations are logical and valid? (Explain)</li> <li>5. Do you concur with the use of the technical information in this publication for the YMP Project? (Explain)</li> </ol>			
			
_____ Reviewers signature		_____ Date	
_____ Organization		_____ Phone Number	

YMP 006 REV 0

**EXHIBIT E  
TECHNICAL JOURNAL DATA/DATA INTERPRETATION  
ACCEPTANCE REVIEW - APPENDIX SHEET**

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

No.: 033-YMP-QP 2.6  
Revision: 0  
Date: **FEB 24 1989**  
Page: 1 of 4

Subject: READINESS REVIEWS

Approved:

Approved by: *D. S. Bellan* 7/1/89  
YMP Project  
Leader

Approved by: *R. E. Johnson* 1/12/89  
YMP Quality Assurance  
Manager

### 2.6.1 PURPOSE

The purpose of this procedure is to provide instructions for conducting readiness reviews prior to the start of major, QA Level I & II activities.

### 2.6.2 SCOPE

This procedure applies to major scheduled/planned activities which could affect QA Level I & II quality. Readiness reviews are performed when deemed appropriate by responsible management. Readiness reviews are to verify that specified prerequisites and programmatic requirements have been identified prior to starting a major activity. Readiness reviews may also be appropriate for the restart of work activities following extended interruption, major program change, or extensive corrective actions.

### 2.6.3 RESPONSIBILITIES

The YMP Deputy Project Leader is responsible for determining the appropriateness and assigning responsibility for performance of individual readiness reviews.

The YMP QA Manager advises the Deputy Project Leader on the appropriateness of readiness reviews, and may establish holdpoints for performance of QA surveillance or audit independent of readiness reviews.

Technical Area Leaders are generally responsible for performance of readiness reviews, unless otherwise designated.

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Task Leaders are responsible for demonstrating that all readiness prerequisites have been met and for precluding start of work until assigned readiness reviews are completed. Task Leaders may elect to use a copy of the readiness review checklists in their preparation for the start of new activities.

Document Control is responsible for assigning unique identifiers to each readiness review document, for maintaining a master log, and for retaining readiness review documents in Record files.

#### 2.6.4 PROCEDURE

The Deputy Project Leader identifies the need, assigns and schedules completion of the readiness review, and advises the QA Manager and affected TAL's/TL's. Consultation with the QA Manager may be appropriate but is not required.

The readiness reviewer(s) obtains a copy of the readiness review checklist form from document control (see Exhibit A), identifies items applicable and adds any special prerequisite not on the checklist.

Exceptions will be noted and the actions required to clear exceptions will be identified by the reviewer(s). The reviewer(s) will not sign off until all prerequisites are completed. Completion of the review for purpose of start of work will normally require coordination with the responsible Task Leader or individual to clear exceptions found.

When the readiness review is completed and acceptable, the readiness reviewer(s) will document completion by signature on the readiness review checklists. When exceptions cannot be readily resolved, readiness review checklists will be forwarded to the Deputy Project Leader for resolution. When satisfied, the Deputy Project Leader may elect to approve himself or to submit checklists to the original readiness reviewer(s) for signature.

#### 2.6.5 RETAINED DOCUMENTATION:

The readiness reviewer(s) or Deputy Project Leader will submit the completed checklist to document control for logging, distribution, and record retention.

Completed checklists required by this procedure for QA Level I & II activities are Quality Assurance Records collected, handled, stored, and maintained in accordance with Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."

**EXHIBIT A**

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b> Page _____ of _____																																																			
<b>READINESS REVIEW CHECKLIST</b>																																																				
<div style="text-align: right;">Document No. _____</div> <div style="text-align: right;">Page _____ of _____</div> <div style="text-align: center; margin-top: 20px;"><b>READINESS REVIEW CHECKLIST</b></div> <p><u>Activity:</u> _____</p> <p><u>Readiness Reviewer(s):</u> _____</p> <table style="width:100%; border-collapse: collapse; margin-top: 20px;"> <thead> <tr> <th style="text-align: left; width: 15%;"><u>Applicable</u></th> <th style="text-align: center; width: 60%;"><u>Item</u></th> <th style="text-align: right; width: 25%;"><u>Acceptable</u></th> </tr> </thead> <tbody> <tr><td>_____</td><td>Study Plans Approved</td><td>_____</td></tr> <tr><td>_____</td><td>SIP Approved</td><td>_____</td></tr> <tr><td>_____</td><td>Test Plans Complete</td><td>_____</td></tr> <tr><td>_____</td><td>Calibrations Scheduled</td><td>_____</td></tr> <tr><td>_____</td><td>Personnel Assigned</td><td>_____</td></tr> <tr><td>_____</td><td>Personnel Trained</td><td>_____</td></tr> <tr><td>_____</td><td>QA Orientations Complete</td><td>_____</td></tr> <tr><td>_____</td><td>Long Lead Procurements Scheduled</td><td>_____</td></tr> <tr><td>_____</td><td>Budget Allocation Approved</td><td>_____</td></tr> <tr><td>_____</td><td>Procedures Identified/Approved</td><td>_____</td></tr> <tr><td>_____</td><td>Controlled Documents Available at the Work Location</td><td>_____</td></tr> <tr><td>_____</td><td>Traceable Test Samples Available</td><td>_____</td></tr> <tr><td>_____</td><td>Quality Level Assigned</td><td>_____</td></tr> <tr><td>_____</td><td>QA Notified</td><td>_____</td></tr> <tr><td>_____</td><td>QA Surveillance Scheduled</td><td>_____</td></tr> <tr><td>_____</td><td>QA Holdpoints Identified</td><td>_____</td></tr> </tbody> </table>		<u>Applicable</u>	<u>Item</u>	<u>Acceptable</u>	_____	Study Plans Approved	_____	_____	SIP Approved	_____	_____	Test Plans Complete	_____	_____	Calibrations Scheduled	_____	_____	Personnel Assigned	_____	_____	Personnel Trained	_____	_____	QA Orientations Complete	_____	_____	Long Lead Procurements Scheduled	_____	_____	Budget Allocation Approved	_____	_____	Procedures Identified/Approved	_____	_____	Controlled Documents Available at the Work Location	_____	_____	Traceable Test Samples Available	_____	_____	Quality Level Assigned	_____	_____	QA Notified	_____	_____	QA Surveillance Scheduled	_____	_____	QA Holdpoints Identified	_____
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_____	QA Holdpoints Identified	_____																																																		
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EXHIBIT A (cont)

	UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b> Page _____ of _____
<b>READINESS REVIEW CHECKLIST (CONTINUED)</b>		
<u>Applicable</u>	<u>Other Items</u>	<u>Acceptable</u>
_____	_____	✓
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	✓
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
<b>NOTES / EXPLANATIONS:</b>		
S A M P L E		
<b>APPROVALS:</b>		
Readiness Reviewer (s):	_____ / _____	(Date)
	_____ / _____	(Date)
	_____ / _____	(Date)
Deputy Project Leader:	_____ / _____	(Date)

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

STOP WORK ORDER

Approved:

Approved by: *R. S. Sellen* 7/11/89  
YMP Project Leader

Approved by: *R. E. S. Sellen* 1/19/89  
YMP Quality Assurance  
Manager

### 2.7.1 PURPOSE

This procedure establishes the responsibility and method for issuing and processing a Stop Work Order. A Stop Work Order is used to stop specified work when continued work efforts could result in conditions adverse to quality or adverse to safety that could not be readily corrected.

### 2.7.2 SCOPE

This procedure applies to all quality-affecting activities of the LLNL Yucca Mountain Project (YMP). It encompasses the procedure initiated by the Quality Assurance Manager (QA Manager) to halt work that is producing a condition not meeting the requirements of the YMP Quality Assurance Program Plan (QAPP). Authorization to resume work is issued only after implementation and verification of appropriate corrective action.

### 2.7.3 RESPONSIBILITIES

The Project Leader/Deputy Project Leader is responsible for acknowledging and implementing the Stop Work Order and for preparing the Request for Release once the condition noted in the Stop Work Order has been corrected. The Project Leader/Deputy Project Leader may delegate these tasks as appropriate down to the Task Leader level.

The QA Manager is responsible for evaluating activities being conducted under the control of the YMP QAPP to determine if a Stop Work Order is required. The QA Manager may issue a Stop Work Order when it is determined that conditions adverse to quality exist. The QA Manager is then responsible for monitoring the provisions of this procedure to verify that the Stop Work Order and the appropriate corrective action are correctly implemented.

All personnel performing quality-affecting work are responsible for identifying and reporting conditions adverse to quality which could require the issuance of a Stop Work Order.

#### 2.7.4 PROCEDURE

A Stop Work Order is used to stop work activities that, if continued, could result in significant conditions adverse to quality. When a condition is identified which may require the issuance of a Stop Work Order, it is reported to the Project Leader/Deputy Project Leader, and the QA Manager, through the YMP organizational structure.

The QA Manager evaluates the reported condition to determine if a Stop Work Order is required. The Stop Work Order is issued using the form shown in Exhibit A. Each Stop Work Order is uniquely numbered.

The Stop Work Order specifies:

1. The responsible Technical Area Leader, and Principal Investigator (if applicable),
2. A description of the work to be stopped,
3. The deficiency observed,
4. The criteria for resuming work.

The Project Leader/Deputy Project Leader acknowledges the Stop Work Order, returns a signed copy to the QA Manager, and proceeds to stop work as directed by the order by notifying personnel performing the activity. Work is stopped in a manner that ensures a safe stopped condition and proper retention of data.

During the period of stop work, the following conditions are observed:

1. Appropriately described work in the subject activity is suspended.
2. Work previously completed on the subject activity and still within control of the LLNL YMP is not issued or released.

The Request for Release portion of the Stop Work Order is completed by the Project Leader/Deputy Project Leader, or his designee, and forwarded to the QA Manager. The Request for Release identifies the actions taken to correct the adverse condition as well as the corrective action implemented or planned (including implementation dates) to prevent recurrence.

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The QA Manager directs verification of the corrective action to ensure that it has been properly implemented and is adequate to preclude recurrence of the adverse condition. When verification of the corrective action is completed, the QA Manager approves the Request for Release portion of the Stop Work Order. This rescinds the Stop Work Order. The QA Manager issues the rescinded Stop Work Order to the Project Leader/Deputy Project Leader.

#### 2.7.5 RETAINED DOCUMENTATION

A copy of each Stop Work Order, including applicable documentation such as Nonconformance Reports, Corrective Action Reports, and Standard Deficiency Reports, and any additional information necessary to document the action taken to identify, evaluate, and resolve each stop work deficiency, is forwarded to Document Control for retention. Where the applicable documentation is retained in Document Control in accordance with provisions of its own procedure only a reference to the document need be included with this document package.

The completed Stop Work Order package, when the order is rescinded, is a QA record. Quality assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."





CURRENTLY READS AS FOLLOWS:

4. Section 2.8.6, second paragraph, third line.  
...Specification Records (Exhibits A, B, and C), and ...
5. 2.8 Exhibits, new Exhibit E added (see below).

CHANGED TO READ:

4. Section 2.8.6, second paragraph, third line.  
...Specification Records, Summary Sheet (Exhibits A, B, C, and D), and ...
5. 2.8 Exhibits, new Exhibit E added (see attached).



**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

ASSIGNING LEVELS OF QUALITY ASSURANCE

Approved:

Approved by: *D. Sellan* 2/23/89 YMP Project Leader  
 Approved by: *R. M. E. Johnson* 2/23/89 YMP Quality Assurance Manager

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### 2.8.1 PURPOSE

This procedure assigns responsibilities and describes the process whereby Levels of Quality Assurance are assigned to work performed in support of the LLNL Yucca Mountain Project (YMP). It also describes the process for grading the QA Levels for applicability of the requirements of the LLNL QAPP.

### 2.8.2 SCOPE

This procedure applies to all scientific investigations and design work performed in support of the YMP. It applies to YMP-related work performed by LLNL project personnel. It also applies to YMP-related work by subcontractors to LLNL.

### 2.8.3 DEFINITIONS

Activity: Any work including, but not limited to, procurements, scientific investigations, or designs that is directed toward the achievement of the objectives stated in the WBS Dictionary.

Item: An all-inclusive term that is used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, and prototype hardware. This term includes magnetic media, and other materials that retain or support data.

Quality Assurance Level I: Activities conducted and items used with the intent to provide direct support for the Department of Energy to submit a license application for a potential repository; activities and items that are radiological health and safety related, are important to either safety or waste isolation, and are associated with the ability of a nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public.

Quality Assurance Level II: Activities and items related to systems, structures, and components that require a level of quality assurance sufficient to provide for reliability, maintainability, public nonradiological health and safety, repository worker health and safety, both radiological and nonradiological, and other operational factors that would have an impact on the DOE Project Office concerns and on the environment.

Quality Assurance Level III: Activities and items that are not assigned Level of Quality Assurance I or II.

QA Grading: A process that defines the specific QA requirements judged necessary to assure the quality of an item or an activity.

Work Breakdown Structure (WBS) Dictionary: A product-oriented document framework for organizing and defining work to be accomplished.

#### 2.8.4 RESPONSIBILITIES

This section describes the responsibilities for assigning levels of quality assurance, and for assigning the applicable sections of the QAPP to assure the quality of an item or activity.

##### 2.8.4.1 General

The assignment of Levels of Quality Assurance to activities is an interactive effort. Such assignments are made formally and are agreed to by the Task Leader responsible for the activity, the appropriate Technical Area Leader, the Project Leader, and the YMP Quality Assurance Manager (QA Manager). Final review and approval of Level of Quality Assurance assignments and the graded application of the Quality Assurance Program Plan (QAPP) is the responsibility of the DOE Project Office.

Certain aspects of this interactive effort require the delegation of specific responsibilities among the participants. These responsibilities are fully described in Section 2.8.5, but an outline is given here for ease of reference.

##### 2.8.4.2 Task Leader

The Task Leader is responsible for:

- defining the activity and the initial grading (initial definition).
- initiating the meeting to assign the Level of Quality Assurance.
- participating in the meeting to assign the Level of Quality Assurance.
- assuring that all activities that fall within the scope of this procedure and for which the Task Leader has responsibility have a Level of Quality Assurance assigned to them.

##### 2.8.4.3 Technical Area Leader

The Technical Area Leader is responsible for:

- participating in the meeting to assign and grade the Level of Quality Assurance.

##### 2.8.4.4 Project Leader

The Project Leader is responsible for:

- assuring that this procedure is implemented and remains effective.
- participating in the meeting to assign and grade the Level of Quality Assurance.
- assuring that justification for, exceptions to, and documentation of the assignments and grading of Levels of Quality Assurance are consistent.

- assuring that all the required documentation is submitted to the QA Manager.
- approving the required documentation.

#### 2.8.4.5 QA Manager

The QA Manager is responsible for:

- chairing the meeting to assign and grade the Level of Quality Assurance.
- assuring that all necessary references are available to the meeting participants.
- assuring that all the necessary Quality Assurance criteria are included in the Level of Quality Assurance assignment and that they are correctly applied.
- assuring that the DOE Project Office receive the assignment of Levels of Quality Assurance for review and approval.
- preparation of QA level meeting minutes.

#### 2.8.5 PROCEDURE

This section describes the requirements for assigning levels of quality assurance.

##### 2.8.5.1 Identification of Activities

Level of Quality Assurance assignments are made and graded for items and activities that are identified in a Scientific Investigation Plan (SIP). Level of Quality Assurance assignments for items and activities are made after the internal (internal to YMP) approval of the SIP that identifies the items and activities. Information about SIPs is specified in Procedure No. 033-YMP-QP 3.0, "Scientific Investigation Control."

If an activity is assigned a Level of Quality Assurance without further division, then all of its subactivities have the same Level of Quality Assurance. If an activity is subdivided further and some of its subactivities are assigned a Level of Quality Assurance different from the activity itself, then these assignments and gradings are justified and documented.

It is the responsibility of Task Leaders to assure that all the activities in their areas of responsibility are subjected to this procedure. No actual work on any activity may be started until this procedure has been used to assign and grade a Level of Quality Assurance to the activity.

It is the responsibility of the QA Manager to follow-up on all activities that were assigned Level of Quality Assurance III. Level III activities are reviewed annually as part of the internal audit process (see Procedure No. 033-YMP-QP 18.0, "Audits") to determine whether the Level of Quality Assurance is still appropriate. These reviews are documented. If, as a result of the audit, the Level III designation is deemed inappropriate, the QA Manager initiates proceedings to assign an appropriate Level of Quality Assurance.

#### 2.8.5.2 QA Level Panel

The actual assignment and grading of the Level of Quality Assurance is accomplished by a panel that consists of the Task Leader whose activity is under consideration, the appropriate Technical Area Leader, the Project Leader, and the QA Manager. Any of these parties may have an alternate represent them on the panel. Any party sending an alternate documents this action and provides a copy of this documentation to the QA Manager.

The panel meeting fulfills the requirement for an independent review of the level assignments. The intent is to achieve a consensus among the panel members as to the appropriate QA level and to resolve any comments developed during the review process.

##### 2.8.5.2.1 Task Leader

The Task Leader initiates the proceeding for assigning and grading Levels of Quality Assurance by notifying the Project Leader, Technical Area Leader, and QA Manager that an activity has been identified that requires the assignment of a Level of Quality Assurance.

The activity must be part of, or refer to, an approved SIP. There can be no Level of Quality Assurance assignment to an activity without an internally approved SIP. After the Project Leader, Technical Area Leader, and QA Manager have been notified, the Task Leader prepares for the panel meeting.

Preparation consists of a predetermination of the Level of Quality Assurance by the Task Leader using the criteria and the checklist (see Appendix A and B). This predetermination, which does not have to be documented, serves as a point of reference for the actual determination.

As appropriate, the Task Leader divides an activity into subactivities. Each subactivity is defined so that it constitutes a coherent unit. Although there is no specified format, this division is documented and the documentation is made available to the panel members at the time of the meeting.

##### 2.8.5.2.2 QA Manager

The QA Manager prepares for the panel meeting when notified that an activity has been identified that requires the assignment of a Level of Quality Assurance. A mutually acceptable time and place for the meeting is scheduled, generally no later than two weeks after notification.

The QA Manager assembles all the necessary references in sufficient quantities to accommodate all participants during the meeting.

The QA Manager chairs all meetings. The QA Manager relates all activities and subactivities to the appropriate quality assurance elements contained in the Quality Assurance Program Plan and assures that the correct control and grading documentation requirements are applied. The QA Manager also assures that review comments are resolved and provides minutes of the meeting. These minutes summarize the meeting's content and are distributed to all participants after the meeting. The minutes become part of the meeting documentation.

#### 2.8.5.2.3 Project Leader

When the Project Leader is notified that an activity has been identified that requires the assignment and grading of a Level of Quality Assurance, he prepares for the meeting and determines which people from which technical area are to attend the meeting.

The Project Leader is responsible for assuring that, over a period of time, the deliberations and decisions are consistent.

#### 2.8.5.3 Assignment of QA Levels

Information about the upper tier QA level assignments is developed and provided by the DOE Project Office (YMP). If information is not available the form entries are left blank.

The assignment of Levels of Quality Assurance is a function of the definitions of the three levels and the decision criteria (see the Appendix A and B) applied to each activity. Specifically, the following sequence is used:

- divide each activity into subactivities, if appropriate.
- process each subactivity (or activity) sequentially through the Decision Criteria (see Appendix B) until a Level of Quality Assurance is apparent.
- record justifications for each Decision Criteria evaluated on the Decision Criteria Record (Exhibit A).
- record the QA level assignment for each subactivity (or activity) on Exhibit A.
- record which of the quality assurance elements apply to each subactivity (or activity) on the Graded QA Control Specification Record (Exhibit B).

#### 2.8.5.4 QA Level Meeting Documentation

After the assignment and grading has been completed, all necessary documentation is collected in a documentation package. The Task Leader is responsible for preparing the meeting documentation, except the meeting minutes, in final form. Once all documentation is in final form, the Technical Area Leader and the QA Manager sign and date the QA Level Assignment and Grading Approval Sheet (Exhibit C), and then the documentation is forwarded to the YMP Leader for review and approval.

The YMP Leader reviews the document package to determine the acceptability of the assignment and grading of the Level of Quality Assurance. If he approves, then he signs and dates Exhibit C and forwards the documentation package to the QA Manager. If the YMP Leader does not approve, then a meeting is convened to resolve the issues. This meeting is chaired by the YMP Leader. Both the issues and their eventual resolution are documented, and the documentation is made part of the documentation package.

The QA Manager is responsible for obtaining approval from the DOE Project Office. A controlled copy of the entire package is submitted to the DOE Project Office and one copy to the YMP Program Administrator.

Obtaining approval from the DOE entails sending the document package to the DOE Project Office. When a copy of the document package is forwarded to the DOE, the following simultaneous distribution is made:

- copy to Quality Assurance for monitoring.
- copy to the Project Leader.
- copy to Technical Area Leader.
- copy to Task Leader.

After the DOE Project Office approves the determination, a copy of the approval is provided to the Task Leader.

#### 2.8.5.5 QA Level Changes

Any changes to the Level of Quality Assurance are handled through the same process used to assign the original level.

#### 2.8.6 RETAINED DOCUMENTATION

Quality records created by this procedure are collected, stored, and maintained in accordance with Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."

Quality records include the approved QA Level Assignment and Grading Approval Sheets, Decision Criteria Records, Graded QA Control Specification Records (Exhibits A, B, and C), and meeting minutes of the QA Level Meeting.

UNIVERSITY OF CALIFORNIA



Lawrence Livermore National Laboratory

YUCCA MOUNTAIN PROJECT

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DECISION CRITERIA RECORD

Upper Tier QALA Record No. Rev: Dated:

Lower Tier

WBS No. Activity No.

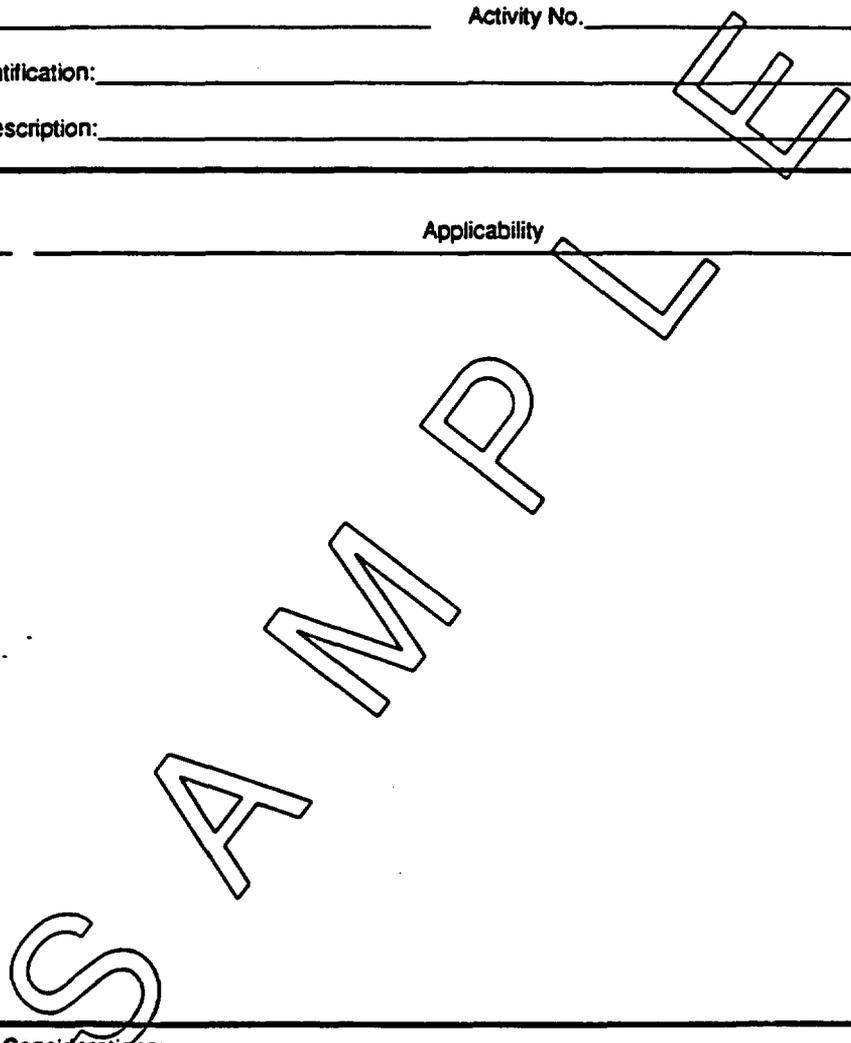
S.I.P. Identification:

Activity Description:

Decision Criteria Applicability

Additional Considerations:

Quality Assurance Level:



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EXHIBIT A Decision Criteria Record

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<b>GRADED QA CONTROL SPECIFICATION RECORD</b>		
<b>Upper Tier</b> QALA Record No. _____ Rev: _____ Dated: _____		
<b>Lower Tier</b> WBS No. _____ Activity No. _____ S.I.P. Identification: _____ Activity Description: _____		
<b>LLNL QUALITY ASSURANCE PROGRAM PLAN (QAPP) STRUCTURE</b>		
<b>APPLICABLE (YES/NO)</b>	<b>DESCRIPTION</b>	<b>JUSTIFICATION OR CONTROL PROCEDURE(S)</b>
YES	Section I - ORGANIZATION	033-YMP-QP 1.0 033-YMP-QP 2.series
YES	Section II - QA PROGRAM	
_____	Section III - SCIENTIFIC INVESTIGATION & DESIGN CONTROL	
_____	1.0 Scientific Investigation Control	
_____	1.1 Preparation of Plans	
_____	1.2 Assignment of QA Levels	
_____	1.3 Review & Approval Process	
_____	1.4 Scientific Investigation Data Interpretation and Analysis	
_____	1.5 Use of Computer Programs	
_____	1.6 The Use of Scientific Notebooks Versus the Use of Technical Implementing Procedures	
_____	1.7 Change Control	
_____	1.8 Interface Control	
_____	1.9 Verification of Scientific Investigations	
_____	1.10 Surveillance of Scientific Investigations and Experiments	
_____	1.11 Reports, Conclusions and Recommendations	
_____	1.12 Close-Out Verification	
_____	2.0 Design Control	
_____	2.1 General	
_____	2.2 Design Input	
_____	2.3 Design Analysis	
_____	2.4 Design Verification	
_____	2.5 Design Change Control	
_____	2.6 Design Interface Control	
_____	2.7 Design Output Requirements	
_____	2.8 Design Documents as QA Records	
_____	3.0 Software Quality Assurance and Control	
_____	3.1 Computer Software Documentation and Control	
_____	3.2 Documentation of Computer Software	
_____	3.3 Software Configuration Management	
_____	4.0 Peer Reviews	
_____	5.0 Technical Reviews	

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**EXHIBIT B  
Graded QA Control Specification Record**

UNIVERSITY OF CALIFORNIA



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National Laboratory

YUCCA MOUNTAIN PROJECT

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of \_\_\_\_\_

GRADED QA CONTROL SPECIFICATION RECORD (CONTINUED)

APPLICABLE (YES/NO)	DESCRIPTION	JUSTIFICATION OR CONTROL PROCEDURE(S)
	<b>Section IV - PROCUREMENT DOCUMENT CONTROL</b>	
	1.0 Requirements	
	1.1 Measures to Assure Adequate Quality	
	2.0 Additional Requirements for Level I Activities	
	2.1 Content of Procurement Documents	
	2.2 Procurement Document Review	
	2.3 Procurement Document Changes	
	2.4 Distribution of Procurement Documents	
YES	<b>Section V - INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS</b>	033-YMP-QP 5.0
YES	<b>Section VI - DOCUMENT CONTROL</b>	033-YMP-QP 6.0
	<b>Section VII - CONTROL OF PURCHASED ITEMS AND SERVICES</b>	
	1.0 General Requirements	
	1.1 Procurement Planning	
	1.2 Source Evaluation and Selection	
	1.3 Bid Evaluation	
	1.4 Supplier Performance Evaluation	
	1.5 Control of Documents Generated by Suppliers	
	1.6 Acceptance of Item or Service	
	1.7 Acceptance of Services Only	
	1.8 Control of Supplier Non-Conformances	
	2.0 Commercial-Grade Items	
	2.1 Alternatives	
	<b>Section VIII - IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA</b>	
	<b>Part A - Identification and Control of Items</b>	
	1.0 Identification	
	1.1 General	
	2.0 Control	
	<b>Part B - Identification and Control of Samples</b>	
	1.0 Identification	
	1.1 General	
	<b>Part C - Identification and Control of Data</b>	
	1.0 Identification	
	1.1 General	
	<b>Section IX - CONTROL OF PROCESSES</b>	
	1.0 General Requirements	
	2.0 Process Control	
	2.1 Method	
	2.2 Identification of Special Processes	
	2.3 Qualification of Special Process Procedures	
	2.4 Qualification of Personnel Performing Special Processes	
	2.5 Special Process Equipment	
	2.6 Special Process Records	

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EXHIBIT B (Continued)  
Graded QA Control Specification Record

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b>	Page _____ of _____
<b>GRADED QA CONTROL SPECIFICATION RECORD (CONTINUED)</b>		
APPLICABLE (YES/NO)	DESCRIPTION	JUSTIFICATION OR CONTROL PROCEDURE(S)
_____	<b>Section X - INSPECTION</b>	
_____	1.0 General Requirements	
_____	2.0 Personnel	
_____	2.1 Reporting Independence of Personnel	
_____	2.2 Qualification	
_____	3.0 Inspection Hold Points	
_____	4.0 Inspection Planning	
_____	4.1 Sampling	
_____	5.0 In-Process Inspection	
_____	5.1 Combined Inspection and Monitoring	
_____	5.2 Controls	
_____	6.0 Final Inspection	
_____	6.1 Inspection Requirements	
_____	6.2 Acceptance	
_____	6.3 Modifications, Repairs or Replacements	
_____	7.0 In-Service Inspection	
_____	7.1 Methods	
_____	8.0 Qualifications Requirements	
_____	9.0 Records	
_____	9.1 Inspection Records	
_____	9.2 Personnel Qualification Records	
_____	<b>Section XI - TEST CONTROL</b>	
_____	1.0 General Discussion	
_____	2.0 Test Requirements	
_____	3.0 Test Procedures	
_____	3.1 Test Instructions, Procedures and Drawings	
_____	3.2 Test Prerequisites	
_____	3.3 Review of Procedures	
_____	3.4 Potential Sources of Error	
_____	3.5 Alternatives	
_____	4.0 Test Results	
_____	5.0 Records	
_____	<b>Section XII - CONTROL OF MEASURING AND TEST EQUIPMENT</b>	
_____	1.0 General	
_____	1.1 Maintaining Accuracy of Equipment	
_____	1.2 Scope of Control Program	
_____	1.3 Description of Responsibilities	
_____	2.0 Purpose of Equipment	
_____	2.1 Selection	
_____	2.2 Calibration	
_____	2.3 Control	
_____	2.4 Commercial Devices	
_____	2.5 Handling and Storage	
_____	2.6 Records	

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**EXHIBIT B (Continued)  
Graded QA Control Specification Record**

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**GRADED QA CONTROL SPECIFICATION RECORD (CONTINUED)**

APPLICABLE (YES/NO)	DESCRIPTION	JUSTIFICATION OR CONTROL PROCEDURE(S)
_____	<b>Section XIII - HANDLING, SHIPPING AND STORAGE</b>	
_____	1.0 General	
_____	1.1 Special Equipment and Protective Environments	
_____	1.2 Specific Procedures	
_____	1.3 Inspection and Testing of Special Tools	
_____	1.4 Operators of Special Equipment	
_____	1.5 Marking and Labeling	
_____	<b>Section XIV - INSPECTION, TEST AND OPERATION STATUS</b>	
_____	1.0 Indication of Status	
_____	2.0 Methods of Indicating Status	
_____	3.0 Application and Removal of Status Indicators	
<u>YES</u>	<b>Section XV - CONTROL OF NONCONFORMING ITEMS</b>	033-YMP-QP 15.0
<u>YES</u>	<b>Section XVI - CORRECTIVE ACTION</b>	033-YMP-QP 16.00
<u>YES</u>	<b>Section XVII - QUALITY ASSURANCE RECORDS</b>	033-YMP-QP 17.00
<u>YES</u>	<b>Section XVIII - AUDITS</b>	033-YMP-QP 18.00

**Supplemental Controls Required:**

**Justification:**

**Remarks:**

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**EXHIBIT B (Continued)**  
**Graded QA Control Specification Record**

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b>
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**QA LEVEL ASSIGNMENT & GRADING APPROVAL SHEET**

Upper Tier  
 QALA Record No. \_\_\_\_\_ Rev: \_\_\_\_\_ Dated: \_\_\_\_\_

Lower Tier

WBS No. \_\_\_\_\_ Activity No. \_\_\_\_\_

S.I.P. Identification: \_\_\_\_\_

Activity Description: \_\_\_\_\_

Quality Assurance Level: \_\_\_\_\_ QALA Meeting Date: \_\_\_\_\_

Additional Comments: \_\_\_\_\_

Meeting Attendees: \_\_\_\_\_

SIGNATURES INDICATE APPROVAL OF LEVEL OF QUALITY ASSURANCE & GRADED  
 SELECTION OF APPLICABLE REQUIREMENTS

\_\_\_\_\_  
 Technical Area Leader                      Date                      YMP QA Manager                      Date

\_\_\_\_\_  
 YMP Project Leader                      Date

AFTER PROJ LEADER APPROVAL, RETURN TO QA MGR W/COPY TO TASK LEADER

\_\_\_\_\_  
 DOE (YMP) Proj Office                      Date                      DOE Proj Office QA Mgr                      Date

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**EXHIBIT C:  
 QA Level Assignment and Grading Approval Sheet**

## APPENDIX A

### CRITERIA FOR DETERMINATION OF LEVELS OF QUALITY ASSURANCE

#### A2.8.1 General

The YMP uses an approach to quality assurance that allows selective application of the 18 quality assurance elements described in the YMP Quality Assurance Program Plan. The approach is used to allow application of the requirements contained in each of the 18 elements to the extent necessary to provide assurances that the work is done correctly and those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses are identified and covered by a commensurate QA program.

#### A2.8.2 Criteria for Quality Assurance Level I

QA Level I is the most stringent level of quality assurance. It is to be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. QA Level I activities which are on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and by-product material (waste) at the geologic repository.

QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment, procurement and construction, facility operation, performance confirmation, procurement closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard. To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety as well as long-term isolation as per the following:

- o Where items and activities that could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.
- o Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. This data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package as well as the assessment of repository performance.

- o Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.
- o Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.
- o Where items and activities that, having failed, could cause a failure of a QA Level I item, or irretrievable loss of QA Level I data.
- o The design phase involves the preparation of detailed design documents (such as drawings, specifications, and analyses) that are assigned a QA Level I. One of the purposes of this design phase is to define items that are to be procured and/or contracted as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds and the QA Level for items is identified and approved, design, procurement, and construction activities associated with the items are governed by the QA level assigned to the items.

#### A2.8.3 Criteria for Quality Assurance Level II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation are applied to the YMP Project activities, and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker.

The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled. Therefore, Quality Assurance Level II must be applied to activities and items as follows:

- o Where items and activities are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.
- o Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.
- o Where items and activities could affect the retrievability of waste up to the time of repository closure.
- o Where items and activities involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components..

- o The design phases which involve the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, are assigned a QA level of II prior to execution. Where a particular item can be identified during this phase and warrants a different QA level assignment (other than II), then a separate QA level assignment may be made for that item. Once the QA level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.
- o Where items and activities that, having failed, could result in a major cost overrun.
- o Where items and activities that, if failed, could result in a major schedule slippage.

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with Procedure No. 033-YMP-QP 2.5, "Acceptance of Data Not Generated Under the Control of the YMP QAPP." Deviations within applicable criteria are permissible for Level II items and activities provided that adequate justification has been documented and approved by the DOE Project Office.

#### A2.8.4 Criteria for Quality Assurance Level III

The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by the organizations participating in the YMP Project. QA Level III is the least stringent level of Quality Assurance. Level III Quality Assurance items and activities are such that they have no major function in the characterization of the site and design of the repository, but they require good practices for the intended use. Design phases which are purely preliminary and are conducted to define the range of alternatives/methods/equipment which are felt to be worthy of more detailed study are assigned a QA Level of III prior to execution. Those activities controlled in accordance with the Quality Assurance Level III program cannot subsequently be used to directly support Quality Assurance Level I activities.

In some cases, data or data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the YMP Quality Assurance Program Plan may be used in the licensing process as background or corroborative information.

**APPENDIX B**

**INSTRUCTIONS FOR COMPLETION OF DECISION CRITERIA RECORDS (EXHIBIT B)**

**B2.8.1 General**

The decision criteria for determining QA levels have been broken down into a number of categories. An outline of this breakdown follows.

**I. HARDWARE**

**II. ACTIVITIES**

- A. General
- B. Computer Software/Modeling
- C. Laboratory Experiment, Field Testing, Data Acquisition, Data Analysis, and Reports
- D. Storage of Records/Samples
- E. Historical or Background Studies and Reports
- F. Environmental/Socioeconomic Studies and Reports
- G. Laboratory Experimental (Scoping) or Testing/Analysis and Reports
- H. Construction/Manufacturing/Operations/Maintenance Activities

**B2.8.2 Procedure**

Determine the category that applies to the item or activity/subactivity under consideration. Answer the questions in the applicable category, noting the question identity (e.g., II.C.3) and the justification for inclusion or not on the Decision Criteria Record (Exhibit A).

If information to answer the decision criteria is provided by the upper tier QALA Record but is not available, note the criteria identification and record the justification as indeterminate.

**DECISION CRITERIA FOR DETERMINING QA LEVELS**

Categories of Items or Activities:	QA Level if YES
------------------------------------	--------------------

**I. HARDWARE**

- |  |    |
|--|----|
| 1. Is the item a structure, system, or component important to safety?            | I  |
| 2. Is the item an engineered barrier important to waste isolation?               | I  |
| 3. Could failure of the item cause failure of a QA Level I item?                 | I  |
| 4. Does the item relate to the non-radiological health and safety of the public? | II |
| 5. Is construction of the item on the Quality Activities List?                   | I  |

Categories of Items or Activities: QA Level  
if YES

---

- |  |     |
|--|-----|
| 6. Would failure or malfunction of the item cause a cost or schedule impact on DOE Mission objectives of:                        | II  |
| a. Greater than \$ 500,000.?   | III |
| b. Less than \$ 500,000.?  |     |
| 7. Does the item relate to the program to implement the requirement of 10 CFR Part 20 or OSHA/MSHA?                              | II  |
| 8. Does procurement of the item involve long-lead time and/or cost in excess of \$ 500,000.?                                     | II  |
| 9. Do the following sections of the American Society of Mechanical Engineers - Boiler and Pressure Vessel Code apply:            |     |
| a. Section III?  | I   |
| b. Section VIII?   | II  |
| 10. Will the item provide data for use in site characterization, design, and/or licensing activities?                            | I   |
| <br><b>II. ACTIVITIES</b>  |     |
| <b>A. GENERAL</b>  |     |
| 1. Is the activity on the Quality Activities List?   | I   |
| <br><b>B. COMPUTER SOFTWARE</b>  |     |
| 1. Are the computer software/models used to support items on the Q-List?   | I   |
| 2. Are the computer software/models used to support activities on the Quality Activities List?                                   | I   |
| 3. Do the computer software/models and codes supply data to support a licensing decision such as performance assessment?         | I   |
| 4. Are the computer software/models complex, requiring peer or technical review?   | II  |
| 5. Do the computer software/models support critical DOE Mission documents?   | II  |
| 6. If the computer software/model, data, or records were lost/destroyed, or of indeterminate quality, would the following occur? |     |
| a. The quality of an item on the Q-List or an activity would be indeterminate.   | I   |
| b. Repetition resulting in cost and/or schedule impact greater than \$ 500,000.  | II  |
| c. Repetition resulting in cost and/or schedule impact less than \$ 500,000.   | III |
| 7. Is the computer software only used for such tasks as data sorting and collection?   | III |

Categories of Items or Activities: QA Level  
if YES

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- C. LABORATORY EXPERIMENTS, FIELD TESTING, DATA ACQUISITION, DATA ANALYSIS, AND REPORTS
1. Are the data used to support an engineering design criterion for an item on the Q-List or other QA Level I item? I
  2. Will the data provide input to performance assessment and/or design models required to support licensing documents? I
  3. Does the work provide input to critical DOE Mission documents? II
  4. Could the failure of the test affect items on the Q-List? I
  5. Could the failure of the test affect the natural barrier? I
  6. If the collected data or records were lost/discarded, would the following occur?
    - a. The quality of a Q-List item or an activity on the Quality Activities List would be indeterminate. I
    - b. Repetition resulting in cost and/or schedule impact greater than \$ 500,000. II
    - c. Repetition resulting in cost and/or schedule impact less than \$ 500,000. III
- D. STORAGE OF RECORDS/SAMPLES
1. Do records/samples support licensing activities? I
  2. Do records/samples support items on the Q-List or activities on the Quality Activities List? I
  3. Do records/samples support critical DOE Mission documents? II
  4. If the collected data or records were lost/discarded or of indeterminate quality, would the following occur?
    - a. The quality of an item on the Q-List or an activity on the Quality Activities List would be indeterminate. I
    - b. Repetition resulting in cost and/or schedule impact greater than \$ 500,000. II
    - c. Repetition resulting in cost and/or schedule impact less than \$ 500,000. III

Categories of Items or Activities: QA Level  
if YES

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E. HISTORICAL OR BACKGROUND STUDIES AND REPORTS

- 1. Will the information be used in a licensing document? I
- 2. Do the studies support a computer model or design criterion for a QA Level I item or activity? I
- 3. Does the work support critical DOE Mission objectives? II
- 4. If the collected data or records were lost/discarded or of indeterminate quality, would the following occur?
  - a. The quality of a Q-List item or an activity on the Quality Activities List would be indeterminate. I
  - b. Repetition resulting in cost and/or schedule impact greater than \$ 500,000. II
  - c. Repetition resulting in cost and/or schedule impact less than \$ 500,000. III

F. ENVIRONMENTAL/SOCIOECONOMIC STUDIES AND REPORTS

- 1. Do the reports or studies provide critical information to support requirements of the Nuclear Waste Policy Act of 1982, as amended? II
- 2. Will the reports or studies be used for portions of a licensing document? II
- 3. Does the work support critical DOE Mission objectives? II
- 4. If the collect data or records were lost/discarded or of indeterminate quality, would the following occur?
  - a. The quality of a Q-List item or an activity on the Quality Activities List would be indeterminate. I
  - b. Repetition resulting in cost and/or schedule impact greater than \$ 500,000. II
  - c. Repetition resulting in cost and/or schedule impact less than \$ 500,000. III

Categories of Items or Activities: QA Level  
if YES

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- G. LABORATORY EXPERIMENTAL (SCOPING) OR TESTING/ANALYSIS AND REPORTS
1. Will the data results be used to support performance assessment and/or design models? I
  2. Does the experimental testing provide analytical data to support functional design bases? I
  3. If the collected data or records were lost/discarded or of indeterminate quality, would the following occur?
    - a. The quality of a Q-List item or an activity on the Quality Activities List would be indeterminate. I
    - b. Repetition resulting in cost and/or schedule impact greater than \$ 500,000. II
    - c. Repetition resulting in cost and/or schedule impact less than \$ 500,000. III
- H. CONSTRUCTION/MANUFACTURING/OPERATIONS/MAINTENANCE ACTIVITIES
1. Is the activity supporting a Q-List structure, system, or component? I
  2. Is the activity intended to control radiation exposure or release and/or effluent radioactivity within the limits prescribed in 10 CFR Part 20? II
  3. Is the activity supporting a highly critical item with a high cost of repair or replacement? II
  4. Is the system important for reliability? II



## CHANGE NOTICE

CN No. 2.9-0-1Affected Document: QP 2.9 "Indoctrination and Training"Revision: 0Prepared By Fran DooleyApproved By N/A  
Technical Area Leader DateApproved By *R. M. E. Smith* 3/3/89  
YMP QA Manager DateApproved By *A. S. Sallou* 3/3/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 2.9.3.3  
The YMP Quality Assurance Manager is responsible for preparing and documenting training materials to accomplish Quality Assurance indoctrination and training and for assuring...
2. Section 2.9.3.4, third paragraph  
The TC or other certified instructor, is responsible for documented direction/supervision of non-certified instructors...
3. Section 2.9.3.4, fourth paragraph, second sentence  
If retraining is required, the Technical Area Leader,...

Changed to Read:

1. Section 2.9.3.3  
The YMP Quality Assurance Manager is responsible for preparing and documenting training materials to accomplish Quality Assurance indoctrination and training for all project personnel and for assuring...
2. Section 2.9.3.4  
The TC or designee is responsible for documented direction/supervision of instructors...
3. Section 2.9.3.4, fourth paragraph, second sentence  
If retraining is required, the responsible manager,...

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

CURRENTLY READS AS FOLLOWS:

4. Section 2.9.9  
Training materials include as appropriate a lesson plan (Exhibit B) identifying the subjects/topics to be covered, training setting, performance objectives, handouts, visual aids, Instructor Notes (Exhibit C), proficiency evaluation records...
5. Section 2.9.11, first paragraph, second sentence  
This includes objective and content, dates, name of instructor, attendees (see Exhibit E), proficiency evaluation records, training materials, instructor certifications and other applicable information.
6. Section 2.9.11, second paragraph, second sentence  
Subsequent to data entry, the Training Coordinator will forward records...
7. Exhibit D, title "Proficiency Evaluation Record"
8. Section 2.9.11, add third paragraph (see below)

CHANGED TO READ:

4. Section 2.9.9  
Training materials include as appropriate a lesson plan (Exhibit B) identifying the subjects/topics to be covered, training setting, performance objectives, handouts, visual aids, Instructor Notes (Exhibit C), training evaluation records...
5. Section 2.9.11, first paragraph, second sentence has been deleted.
6. Section 2.9.11, second paragraph, second sentence  
Subsequent to data entry, the Training Coordinator will forward QA records...
7. Exhibit D, title "Training Evaluation Record"
8. Section 2.9.11, add third paragraph

Quality Assurance Records include the following as a minimum:

- o Training Record (Exhibit A)
- o Trainer Preparation Sheet (Exhibit B)
- o Training Evaluation Record (Exhibit D)
- o Class Attendance Sheet (Exhibit E)

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

INDOCTRINATION AND TRAINING

Approved:

Approved by: *J.S. Sullivan* 2/23/89 YMP Project Leader  
Approved by: *R. E. Smith* 2/23/89 YMP Quality Assurance Manager

### 2.9.1 PURPOSE

To identify the requirements, establish responsibilities and describe the program for the proficiency, indoctrination, training and retraining of Project personnel assigned to perform and/or verify activities that affect the quality of LLNL produced deliverables for the Yucca Mountain Project (YMP) in conformance with LLNL-YMP QAPP Plan and the YMP Training Management Plan (TMP).

This procedure is implemented through training materials prepared by the LLNL functional organizations assigned responsibility for specific project task and activity work scope or by the Training Coordinator.

### 2.9.2 SCOPE

This procedure applies to personnel employed by LLNL and LLNL-YMP contractor personnel who plan, direct, manage, perform and/or verify activities that affect the quality of YMP deliverables. This procedure applies to work performed in support of YMP by subcontractors to LLNL when invoked by procurement documents.

### 2.9.3 RESPONSIBILITIES

#### 2.9.3.1 Functional Managers/Supervisors

Each LLNL functional manager/supervisor is responsible for assuring that YMP personnel they assign are indoctrinated and trained, as required.

### 2.9.3.2 Technical Area Leaders

Technical Area Leaders are responsible for assuring that required indoctrination and training is accomplished. The subject matter or topics of training are identified, documented and approved by the Technical Area Leader in conjunction with the Training Coordinator (see Exhibit A).

Technical Area Leaders are responsible for notifying the Training Coordinator and Quality Assurance Manager whenever new personnel are assigned so that indoctrination and training can be scheduled.

### 2.9.3.3 YMP Quality Assurance Manager

The YMP Quality Assurance Manager is responsible for preparing and documenting training materials to accomplish Quality Assurance indoctrination and training and for assuring that all Quality Assurance personnel receive Quality Assurance indoctrination and training, as required.

### 2.9.3.4 Training Coordinator

The Training Coordinator (TC) is responsible for reviewing and approving indoctrination and training materials for effectiveness. Associated with this activity is the responsibility for approval of training settings (e.g., self-study, reading lists, on-the-job-training, classroom, etc.)

The TC is responsible for collecting and collating training records. Subsequent to data entry into the training data base, the TC is responsible for submitting these records to the Local Records Center for retention and storage.

The TC or other certified instructor, is responsible for documented direction/supervision of non-certified instructors performing on-the-job-training (e.g., subject matter experts or job incumbents)

The TC is responsible for determining whether retraining is required. If retraining is required, the Technical Area Leader, in conjunction with the Training Coordinator will determine the appropriate method of retraining.

### 2.9.4 INDOCTRINATION

Personnel assigned to the YMP receive indoctrination prior to performing activities that affect quality as to the purpose, scope, methods of implementation and applicability of the following documents, as a minimum, as they relate to the work to be accomplished:

- o Quality Assurance Program Plan
- o Applicable implementing procedures and work instructions
- o Regulations (10 CFR 60, 10 CFR 960 and 40 CFR 191)
- o Project level documents

Indoctrination may be accomplished by the use of group classroom presentations, video presentations, a mandatory reading list or other instructional methods.

#### 2.9.5 QUALITY ASSURANCE TRAINING

Personnel assigned to the YMP project receive training on specific Quality Assurance procedures prior to performing activities that affect quality, as determined by the Technical Area Leader and the Training Coordinator. Subsequent to general training resulting from major program revisions, the extent of training is determined through a job and task analysis performed by the Training Coordinator.

Personnel performing surveillances, audits, inspections and non destructive examinations receive training as required to meet the qualification and certification requirements prescribed in Procedure 033-YMP-QP 2.11, "Qualification and Certification of Inspection and NDE Personnel" and Procedure 033-YMP-QP 18.2, "Qualification of Quality Assurance Audit Personnel".

#### 2.9.6 TECHNICAL TRAINING

If needed to gain required proficiency, personnel receive technical training prior to performing activities that affect quality.

The extent of training is determined through job and task analysis performed by the Training Coordinator in conjunction with the Technical Area Leader or Task Leader.

#### 2.9.7 RETRAINING

Refresher training necessary to maintain or regain proficiency is provided to project personnel at the discretion of the Technical Area Leader when necessary to preclude recurrence of nonconformances or as part of corrective action when required.

Quality Assurance retraining is required for project personnel who perform work affected by revised Quality Procedures prior to the implementation of those procedures. Retraining may be performed by classroom sessions or mandatory reading lists.

Technical retraining is required whenever applicable TIPs or planning documents are revised. Retraining may be performed by classroom sessions or mandatory reading lists.

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#### 2.9.8 SHORT TERM PARTICIPANTS

Short term or temporary employees (casual participants) who are assigned to the project for less than 90 days will receive, as a minimum, Quality Assurance Indoctrination.

#### 2.9.9 TRAINING MATERIALS

Training materials include as appropriate a lesson plan (Exhibit B) identifying the subjects/topics to be covered, training setting, performance objectives, handouts, visual aids, Instructor Notes (Exhibit C), proficiency evaluation records (e.g., a comprehension questionnaire, exam, etc., see Exhibit D) and other instructional information. Training materials are prepared by the Instructor and/or Training Coordinator and approved by the Training Coordinator prior to use.

#### 2.9.10 TRAINING PROGRAM ASSESSMENT

The effectiveness of the implementation of the training program is assessed periodically via the Annual Management Assessment Procedure (QP 2.3), the Trend Analysis Procedure (QP 16.2), the Audit Procedure (QP 18.0), and the Surveillance Procedure (QP 18.1).

#### 2.9.11 RETAINED DOCUMENTATION

All records pertaining to indoctrination and training are forwarded to the Training Coordinator for entry into the training data base. This includes objective and content, dates, name of instructor, attendees (see Exhibit E), proficiency evaluation records, training materials, instructor certifications and other applicable information.

Functional managers/supervisors are responsible for forwarding records to the Training Coordinator. Subsequent to data entry, the Training Coordinator will forward records to Document Control for retention and storage as Lifetime QA Records.



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<b>TRAINER PREPARATION SHEET</b>			
Trainers Name:		Date:	
Course Title:			
Lesson Title:			
Time Period:			
References:			
Objectives:			
Instructional Aids:			
Trainee Preparation:			
Presentation Method:			
Evaluation:			

SAMPLE

YMP 040 REV 0

GC69012

**EXHIBIT B - Trainer Preparation Sheet**

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University of California



Lawrence Livermore National Laboratory

YUCCA MOUNTAIN PROJECT

Page \_\_\_\_\_  
Of \_\_\_\_\_

INSTRUCTOR NOTE PAGE

Instructor's Name:

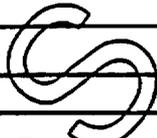
Subject/Procedure:

Discussion Points:

Instructor/Student Activity:

S  
A  
M  
P  
L  
E

EXHIBIT C - Instructor Note Page

University of California  Lawrence Livermore National Laboratory	Page _____ Of _____
<b>YUCCA MOUNTAIN PROJECT</b>	
<b>PROFICIENCY EVALUATION RECORD</b>	
Name: _____	
Subject/Procedure: _____	
Please Answer the Following:	
<div style="text-align: right; font-size: 2em; margin-right: 10%;">           LE            L            P            M            A            S         </div>	
<b>Approvals:</b> <div style="text-align: center; margin-top: 10px;">  </div>	
The above named employee has satisfactorily demonstrated comprehension of the subject material.	
Trainer: _____	Date: _____
Training Coordinator: _____	Date: _____

YMP 042 REV 0

GD89010

**EXHIBIT D - Proficiency Evaluation Record**



NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject: QUALIFICATION OF PERSONNEL

Approved:

Approved by: *[Signature]* 2/23/89  
YMP Project Leader

Approved by: *[Signature]* 2/23/89  
YMP Quality Assurance  
Manager

### 2.10.1 PURPOSE

This procedure identifies the requirements and establishes the responsibilities and methods for the qualification and certification of personnel assigned to perform or verify activities that affect the quality of deliverables for the Yucca Mountain Project (YMP).

### 2.10.2 SCOPE

This procedure applies to personnel employed by LLNL and its contractors, both full and part time, who do work for the YMP. This procedure applies to work done in support of YMP by subcontractors to LLNL, depending on the subcontract specified QA interface requirements, and the Level of Quality Assurance assigned to the scope of subcontract work.

This procedure applies only to the implementation of Project Quality Assurance Program requirements. LLNL personnel policies and procedures not relevant to Project deliverable quality is outside the scope of this procedure.

### 2.10.3 RESPONSIBILITIES

Each LLNL functional manager/supervisor is responsible for the implementation of the requirements and instructions of this procedure.

The YMP Project Leader has the overall authority and is responsible for establishing and specifying the qualification requirements for Project personnel assigned to perform YMP work. Except for the Project positions of Technical Area Leaders and YMP Quality Assurance Manager, the YMP Project Leader may delegate authority and responsibility for implementation of this procedure's requirements.

The Technical Area Leader(s) has been delegated authority and responsibility for establishing and approving the technical qualification requirements of personnel who are assigned to perform technical activities/tasks within the scope of the Technical Area(s). Except for the Project positions of Task Leader, the Technical Area Leader(s) may delegate their authority and responsibility for implementation of this procedure's requirements.

The YMP Quality Assurance Manager or designee has been delegated the authority and responsibility for establishing and approving the qualification requirements of personnel who are assigned to perform quality verification functions. In addition, the YMP Quality Assurance Manager has been delegated authority and responsibility for:

- a) Review and approval of subtier implementing procedures and instructions for compliance to the Project QA Program requirements prior to issue for use.
- b) Review and approval of Personnel Qualification Records for compliance to Project QA Program requirements prior to acceptance as a Quality Assurance Record.

The Project Training Coordinator, in conjunction with the YMP Records Manager, is responsible for maintaining the Personnel Qualification Records (PQRs) and associated files.

#### 2.10.4 PROCEDURE

Upon receipt of a YMP activity or task assignment, and prior to performing any quality affecting work, the responsible Project functional manager/supervisor will identify personnel skills, qualifications, and resources required based on a review of the work planning documents that identify assigned activity/task attributes, characteristics and required deliverables. Project functional managers/supervisor prepare, review, approve and issue PQR documentation packages for personnel assigned to perform work within their area of responsibility using the following general procedural steps.

##### 2.10.4.1 Position Description

A written Position Description, prescribing minimum qualification requirements that include education, experience, and skills is prepared by the responsible project functional manager/supervisor and approved by the YMP QA Manager for each Project functional position. The Position Description requirements are to correlate with and be commensurate with the technical and/or functional scope of activity and/or task to which personnel are assigned.

Standard educational, industrial, government and professional Position Description requirements may be used, where applicable, in the preparation of Position Descriptions.

Exhibit "A" illustrates an example of an acceptable format for a Position Description. Instructions for completing the form are contained on the form and are self-explanatory.

#### 2.10.4.2 Personnel Resume

A Personnel Resume for each Project position incumbent/candidate is prepared by the candidate and the relevant education and experience history is verified by YMP Management. Verification will consist of confirmatory documentation obtained from LLNL Human Resources Division for LLNL employees. Contractor/subcontractor personnel and independent consultants will sign a release enabling YMP Management to obtain such confirmatory documentation for verification purposes. The Personnel Resume includes as a minimum the following information relative to the position assigned or sought:

- a) Identity of individual.
- b) Formal education history.
- c) Work experience history.
- d) Training history (as applicable).
- e) Special skills (if any).
- f) Past and current certification held (if any).

Exhibit "B" illustrates an example of an acceptable format for the Personnel Resume.

#### 2.10.4.3 Management Certification

Incumbent/candidate personnel are evaluated through a Management Certification as follows.

- 1) Incumbent/candidate is interviewed by the responsible supervisor/manager.
- 2) The individual's education, experience and training are evaluated against Position Description requirements and documented by the responsible Project supervisor.
- 3) Relevant education and experience is verified and documented by the responsible Project supervisor.

The responsible Project supervisor evaluates and verifies the resume content with the Position Description requirements, and if they correspond with each other, signs and dates the Management Certification form signifying the satisfactory completion of the evaluation process. Exhibit "C" illustrates an example of an acceptable format for the Management Certification.

#### 2.10.4.4 Proficiency Appraisal

Prior to each individual's annual anniversary date or change in position assignment, whichever comes first, Project management performs and documents a Proficiency Appraisal of each person assigned to perform YMP activity.

The Proficiency Appraisal includes, as a minimum, the name of the evaluated employee, the evaluator, the evaluation results, date of evaluation, and the activities covered by the evaluation. This appraisal is the sole project record with respect to proficiency of participants.

Exhibit "D" illustrates an example of an acceptable format for the Proficiency Appraisal record.

#### 2.10.5 RETAINED DOCUMENTATION

Personnel Qualification Records required to be prepared, processed and retained as Quality Assurance Records for each person assigned to participate in the YMP include:

- a) Position Description
- b) Personnel Resume
- c) Management Certification
- d) Proficiency Appraisal (as applicable)

Quality Assurance records that result from the implementation of this procedure are collected, stored, and maintained as lifetime Quality Assurance Records in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

University of California Lawrence Livermore National Laboratory		<b>YUCCA MOUNTAIN PROJECT</b>		Page _____
<b>POSITION DESCRIPTION</b> <small>See back of page for instructions</small>				
1. Position Title:		2. Organization (functional):		
3. Reports To (functional):		4. Rev.:	5. Effective Date:	
6. Duties:				
7. Responsibilities:				
8. Minimum Education and/or Experience Requirements:				
<b>Approvals:</b>				
9. Resp. Manager/Supervisor:		Date:	10. Resp. Functional Organization Mgr.:	
			Date:	

S A M P L E

YMP 028 (1) REV 0

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**EXHIBIT A  
Position Description Form**

**FORM INSTRUCTIONS**

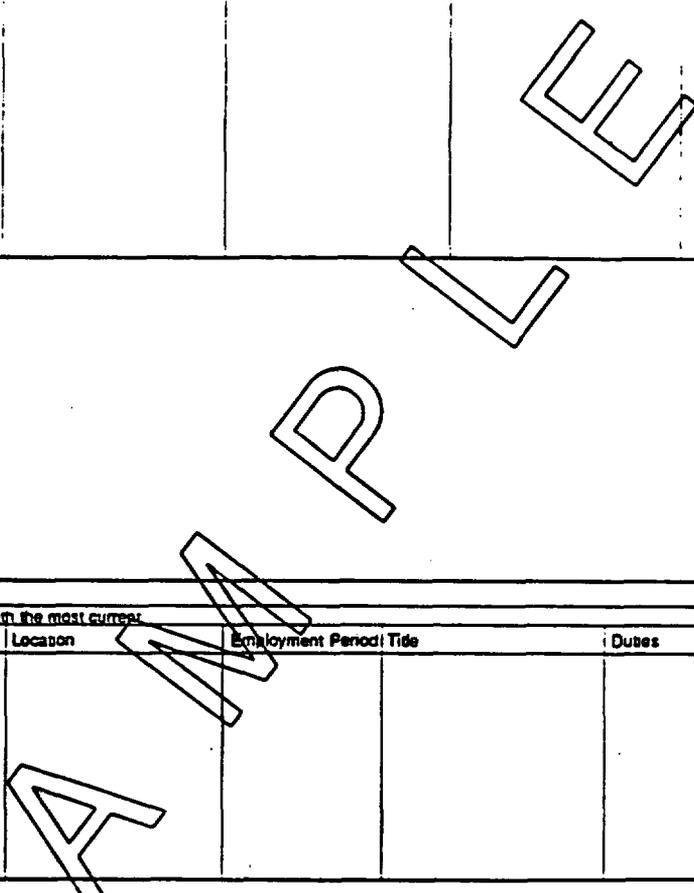
Position Description

**PURPOSE**

This "Position Description" is intended to describe a position in the terms of duties, responsibilities, qualifications and measurable performance criteria relative to project assignments. Since this document will provide the basis for performance evaluation, it should be completed as carefully as possible. The facts and criteria presented should be pertinent and concise, written in such a manner that someone unfamiliar with the position would be able to understand the functions performed. The completed document is reviewed, signed, and forwarded to QA Records for retention.

1. **Position Title:**  
Position title should correlate with the functional organization structure described in the project organization chart.
2. **Organization (functional):**  
Identify the functional organization to which the position is assigned, as described in the project procedures.
3. **Reports To:**  
Identify the functional manager/supervisor to whom the position reports.
4. **Revision:**  
Indicate the current revision being processed and approved.
5. **Effective Date:**  
Indicate the effective date.
6. **Duties:**  
Describe the principal activities, duties, functions and tasks to be performed by this position relative to the project.
7. **Responsibilities:**  
Describe the primary responsibilities and accountabilities of this position relative to the project.
8. **Minimum Education and/or Experience Requirements:**  
Describe or specify the minimum required level of formal education and/or experience required for the position. Where possible, relevant education and experience should be identified as an alternative. Specific training, qualifications and certifications required by governing codes and standards are identified in this section.
9. **Responsible Manager/Supervisor:**  
The immediate manager or supervisor responsible for directing or supervising the position indicates approval by signing and dating.
10. **Responsible Functional Organization Manager:**  
The next higher manager or leader of this position indicates approval by signing and dating.

**EXHIBIT A (cont.)  
Position Description Form Instructions**

University of California  Lawrence Livermore National Laboratory		<b>YUCCA MOUNTAIN PROJECT</b>		Page _____ Of _____
<b>PERSONNEL RESUME</b> <small>See back of page for instructions</small>				
1 Name		2. Position Title:		3. Rev
<b>4. Educational Summary:</b> <small>List schools attended beyond high school, including technical, military, professional, college or university.</small>				
<small>School Name</small>	<small>Location</small>	<small>Dates Attended</small>	<small>Major/Minor</small>	<small>Degree Type/Year</small>
				
<b>5. Experience Summary:</b>				
<b>6. Employment History:</b> <small>List relevant employment beginning with the most current.</small>				
<small>Company Name</small>	<small>Location</small>	<small>Employment Period</small>	<small>Title</small>	<small>Duties</small>
<b>7. Attachments:</b>				
<input type="checkbox"/> Resume <input type="checkbox"/> Certificates <input type="checkbox"/> Indocriation Records		<input type="checkbox"/> Training Records <input type="checkbox"/> Professional Society List <input type="checkbox"/> Publications List		<input type="checkbox"/> References <input type="checkbox"/> Other: _____
<b>Concurrence:</b> 8. Employee: _____ Date: _____		<b>Approvals:</b> 9. Resp. Manager/Supervisor: _____ Date: _____		
		10. Resp. Functional Organization Mgr.: _____		Date: _____

YMP 023 (1) REV 6

GC6903

**FORM INSTRUCTIONS**  
Personnel Resumes

**PURPOSE**

This "Personnel Resume" is intended to document and verify an individual's qualifications for a specified project position description.

1. **Name:**  
Indicate individual's full name.
2. **Position Title:**  
Indicate position title assigned.
3. **Revision:**  
Indicate revision number of the resume.
4. **Educational Summary:**  
Indicate the name of the educational institutions attended, dates of attendance, major course of study or training, and degree or certificate obtained. List additional formalized education, training, seminars, etc. that are relevant to the performance of the position assigned. Include additional pages if necessary.
5. **Experience Summary:**  
Prepare a brief summary of work experience relevant to the assigned position.
6. **Employment History:**  
List relevant employment history beginning with the current or most recent employment. Identify employers, locations, duties and periods of employment. A properly formatted resume may be referenced and attached as an alternative.
7. **Attachments:**  
Indicate by marking the corresponding box all supporting documents attached to this Personnel Resume form. Paginate and annotate all attachments as part of this Personnel Resume form.
8. **Employee:**  
The employee indicates concurrence of the validity and accuracy of the information contained in the resume by signing and dating.
9. **Responsible Manager/Supervisor:**  
The immediate manager or supervisor responsible for directing or supervising the position indicates approval by signing and dating.
10. **Responsible Functional Organizational Manager:**  
The next higher manager or leader of this position indicates approval by signing and dating.

University of California  Lawrence Livermore National Laboratory	<b>YUCCA MOUNTAIN PROJECT</b>	Page _____ Of _____
<b>MANAGEMENT CERTIFICATION OF PERSONNEL QUALIFICATION</b>		
<p>I have evaluated the qualifications of _____  <small>(Full Name)</small></p> <p>and certify that this individual's education and experience are commensurate with the requirements specified in the _____  <small>(Position Title)</small></p> <p>position description.</p> <p>_____ <small>(Responsible Manager/Supervisor)</small>      _____ <small>(Date)</small></p>		
<p>➤ Note: Attach completed position description and personnel resume forms and forward to the Quality Assurance Manager for review and forwarding to the project Training Coordinator.</p>		

**EXHIBIT C**  
**Management Certification of Personnel Qualification**

University of California Lawrence Livermore National Laboratory		<b>YUCCA MOUNTAIN PROJECT</b>		Page _____ Of _____
<b>PROFICIENCY APPRAISAL</b> <small>(See back of page for instructions)</small>				
1 Name	2. Position Title:	3 Evaluation Period From: To:		
4. Position Change: <input type="checkbox"/> Yes <input type="checkbox"/> No <small>If yes, attach new "management certification of personnel qualification form" and new "position description form"</small>				
5. Knowledge of Work: <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory <input type="checkbox"/> N/A <small>If unsatisfactory or N/A, explain:</small>				
6. Quality of Work: <input type="checkbox"/> Satisfactory <input checked="" type="checkbox"/> Unsatisfactory <input type="checkbox"/> N/A <small>If unsatisfactory or N/A, explain:</small>				
7. Compliance to Procedures: <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory <input type="checkbox"/> N/A <small>If unsatisfactory or N/A, explain:</small>				
8. Action Plan (for position change, unsatisfactory and/or N/A evaluation results only):				
Approvals:			Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	
9. Resp. Manager/Supervisor:	Date:	10. Employee:	Date:	

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**EXHIBIT D**  
**Proficiency Appraisal.**

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

No.: 033-YMP-QP 2.11

Revision: 0

Date: FEB 24 1989

Page: 1 of 5

Subject: QUALIFICATION AND CERTIFICATION OF  
INSPECTION AND NDE PERSONNEL

Approved:

Approved by:

*A. S. Bellan* 2/4/89  
YMP Project Leader

Approved by:

*R. M. E. Smith* 2/1/89  
YMP Quality Assurance  
Manager

### 2.11.1 PURPOSE

The purpose of this procedure is to identify the requirements and establish the responsibilities and methods for the qualification and certification of personnel assigned to perform inspection and nondestructive examination of components, items, services and activities that affect the quality of LLNL produced deliverables for the Yucca Mountain Project (YMP). This procedure provides specific supplemental qualification requirements to 033-YMP-QP 2.10, "Qualification of Personnel".

### 2.11.2 SCOPE

This procedure applies to personnel employed by LLNL and its contractors, both full and part time who plan, direct, manage, perform and/or verify inspection and nondestructive examination activities and results. This procedure may apply to work done in support of YMP by subcontractors to LLNL depending on the subcontract specified QA interface requirements and scope of subcontract work.

### 2.11.3 DEFINITIONS

Listed below are key terms and phrases used in this procedure.

**Authorized Examiner:** As used in this procedure, is an Inspection/NDE discipline Level III delegated authority by LLNL-YMP Quality Assurance Manager to conduct qualification examinations and to certify LLNL inspection and NDE personnel.

**Inspection:** Examination or measurements to verify whether an item or activity conforms to specified requirements.

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033-YMP-QP 2.11	0	FEB 24 1989	2 of 5

**Nondestructive Examination (NDE):** Is a specialized technological discipline that develops, qualifies and uses methods of material examination without destroying the material under examination. The American Society of Nondestructive Testing (ASNT) has promulgated a nationally recognized reference standard SNT-TC-1A June 1980 edition as required by NNWSI/88-9 & 88-16 that establishes requirements for the qualification and certification of NDE personnel.

**Written Practice:** As used in this procedure, it is an implementing procedure manual and/or plan that prescribes the detailed qualification/certification requirements for specific disciplines of NDE and inspection activities and their Level of Proficiency in accordance with the SNT TC.1A, NQA-1, Supplement 2S-1 and other related standards.

#### 2.11.4 RESPONSIBILITIES

The Task Leader is responsible for assuring that personnel assigned to perform NDE or inspection activities within their area of responsibility holds and has on record, appropriate and current qualification certifications in accordance with this procedure and applicable project specified codes and standards.

The LLNL-YMP Quality Assurance Manager or his designee is responsible for preparing a Qualification Plan (Written Practice) for preparing implementing procedures to accomplish the qualification and certification of personnel within the scope of this procedure, and has the authority for Project certification of Level III inspection and NDE disciplines.

The Project Level III (NDE/inspection discipline) designated by the LLNL-YMP Quality Assurance Manager is responsible for the technical review, approval and compliance to recognized standards of discipline qualification requirements. The Level III has approval authority for NDE position descriptions described in Procedure 033-YMP-QP 2.10, "Qualification of Personnel."

Assigned inspection/NDE personnel are responsible for performing and documenting inspection and NDE activities in accordance with project approved procedures, instructions and specifications.

The Project Training Coordinator is responsible for receiving, reviewing, processing and maintaining a copy of the Qualification/Certification records of Project assigned inspection and NDE personnel.

#### 2.11.5 REQUIREMENTS

##### 2.11.5.1

Inspection personnel are certified in accordance with a Qualification Plan (Written Practice) incorporating the requirements of NQA-1, Supplement 2S-1, and establishing minimum requirements appropriate to designated capability level as identified below:

**Level I Inspector** - capable of following prepared inspection plan and recording inspection data;

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Level II Inspector - Level I capability plus capable of preparing inspection plans, evaluating results and supervising Level I inspectors and other same level inspectors;

Level III Inspector - Level II capability plus capable of approving inspection plans, and training, qualifying, and certifying lower level inspectors.

#### 2.11.5.2

NDE personnel are certified in accordance with a Qualification Plan incorporating the requirements of ASNT-SNT-TC-1A June 1980 edition and LLNL applicable Position Description for the capability level as follows:

NDE Level I - qualified to perform specific calibrations, specific tests, and specific evaluations according to written instructions and to record the results.

NDE Level II - qualified to set up and calibrate equipment and to interpret and evaluate results with respect to applicable codes, standards, and specifications; thoroughly familiar with the scope and limitation of the method; able to prepare written instructions, and to organize and report nondestructive testing investigations.

NDE Level III - capable of and responsible for establishing techniques; interpreting code standards and specifications; and designating the particular test method and technique to be used. A Level III is responsible for the complete NDE operation disciplines qualified for and assigned to, and is capable of evaluating results in terms of existing codes, standards, and specifications; has sufficient practical background in applicable materials, fabrication, and/or product technology to establish techniques and to assist the scientist/design engineer in establishing acceptance criteria where none are otherwise available; has general familiarity with other commonly used NDE methods; and responsible for the training and certification of NDE Level I and Level II personnel, including personnel described below.

#### 2.11.5.3

NDE personnel who witness, monitor and evaluate nondestructive examinations performed by others on behalf of Project are designated "ADM" (Administration) for the discipline capability level as follows:

NDE Level I (ADM) - demonstrates knowledge of and ability to perform specific calibrations, specific tests, and specific evaluations according to written instructions and to record results. In work practice, witnesses and evaluates the performance of NDE by a qualified Level I Examiner.

NDE Level II (ADM) - demonstrates knowledge of and ability to perform NDE method for which qualified: set up and calibrate equipment; interpret and evaluate results with applicable codes, standards, and specifications; prepare written instructions and report NDE results, In work practice, witnesses and evaluates the performance of NDE methods by qualified Level II or Level I Examiner; exercises supervision and direction of other Level II (ADM) personnel; reviews NDE instructions and procedures, test results and reports for completeness, accuracy, and acceptability.

#### 2.11.5.4

Inspectors meet appropriate qualification plan criteria for the capability level consistent with the requirements of the Project Quality Assurance Plan requirements, and work planning document requirements for the Activity. In lieu of other specified requirements, inspectors meet qualification plan criteria of ANSI N45.2.6 - 1978 as applied to the specific identified inspection discipline.

#### 2.11.5.5

Inspectors are physically able to perform the inspection activity to which assigned; they have corrected near vision acuity and color perception capability consistent with the inspection activity to which assigned; and as measured by annual examination.

#### 2.11.5.6

Inspectors successfully complete prescribed training through the implementation of 033-YMP-QP 2.9, "Indoctrination and Training", including:

- o Orientation to the Project Quality Assurance Program;
- o Indoctrination to quality requirements, quality assurance program manuals, inspection plans and procedures, applicable codes, industry standards, regulations and quality criteria.
- o Basic inspector training, as necessary, in the inspection principles, methods and techniques, and accepted practice for the inspection discipline to which assigned.
- o Inspectors exhibit competence for the discipline inspection activity by passing examination(s) and/or demonstration(s) prepared and administered by the Authorized Examiner.

#### 2.11.6 INSPECTOR CERTIFICATION

Level I and Level II discipline inspectors are certified by a designated discipline Level III inspector; Level III inspectors are certified by the LLNL-YMP Quality Assurance Manager or designee.

Certifications are valid for a period of three years and renewable based on continued, satisfactory annually evaluated and documented performance.

#### 2.11.7 NDE QUALIFICATION REQUIREMENTS

NDE personnel have the physical ability to perform NDE activity to which assigned and have the necessary corrected near sight and color perception established by ASNT, SNT-TC-1A which is verified by an annual medical examination.

NDE personnel successfully complete training appropriate to the level and discipline method to which assigned including:

- o Orientation to the Quality Assurance Program;
- o Indoctrination to quality requirements, quality assurance program manuals and procedures, NDE application for appropriate code requirements, industry standards and accepted practice;
- o Basic NDE training in the methods, techniques, and practice for the test method for which certified; applicable minimum training hours for level and NDE method established by SNT-TC-1A shall apply.
- o NDE personnel shall exhibit competence for the activity by successful completion of an examination(s) and/or demonstrations prepared and administered by the Authorized Examiner.

#### 2.11.8 CERTIFICATION OF NDE PERSONNEL

Level I and Level II personnel are certified by a designated Level III in the appropriate examination technique.

All Level III NDE personnel are certified by a Project Level III under cognizance of the LLNL-YMP Quality Assurance Manager.

Certifications are for a period of three years and renewable based on continued, annually evaluated satisfactory performance.

#### 2.11.9 PROCEDURE

Procedural details for the qualification and certification of Inspection and NDE personnel are covered in the Qualification Plan or Written Practice prepared for each identified inspection or NDE discipline position description as specifies by the Project work planning documents and this procedure.

#### 2.11.10 RETAINED DOCUMENTATION

Quality Assurance records that result from the implementation and execution of this procedure are collected, stored and maintained in accordance with Procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records required to be prepared, processed and retained for each include, but are not limited to, those identified in Procedure 033-YMP-QP 2.9, "Indoctrination and Training", Procedure 033-YMP-QP 2.10, "Qualification of Personnel" and records required by approved Qualification Plan or Written Practice for the applicable inspection/NDE discipline.

Qualification and Certification records are submitted to and maintained by the "Training Coordinator" and LLNL-YMP Records Manager.



## CHANGE NOTICE

CN No. 3.0-0-1Affected Document: QP 3.0, "Scientific Investigation Control"Revision: 0Prepared By Ronald SchwartzApproved By N/A  
Technical Area Leader DateApproved By Ronald E. Schwartz 3/15/89  
YMP QA Manager DateApproved By [Signature] 3/15/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 3.0.4.1, add new second paragraph (see below).
2. Section 3.0.7, delete entire text of this section and replace with new text (see below).
3. Section 3.0.10, delete last paragraph and replace with new text.  
"Consent to waive any specified hold point shall be documented..."

Changed to Read:

1. Section 3.0.4.1, new second paragraph:  
"The intent to use scientific notebooks and the purpose for their use is identified in the SIP."
2. (See page 2 of change notice)

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

CURRENTLY READS AS FOLLOWS:

4. Section 3.0.12, add new second paragraph (See below).
5. Section 3.0.13, second paragraph, add new first bullet (see below).
6. Section 3.0.14, add new fourth paragraph prior to list of QA records (see below).

CHANGED TO READ:(continued)

2. Section 3.0.7, new text:

Verification of a scientific investigation is accomplished through technical review as described in 033-YMP-QP 2.4, "Technical Review," the use of QA checklists (see Section 3.0.9), and/or surveillances conducted in accordance with 033-YMP-QP 18.1, "Surveillance."

As appropriate, peer reviews performed in accordance with 033-YMP-QP 2.2, "Peer Review," can be used as a supplemental means of verification.

Means for verification and the individuals or groups responsible for performing the verification are prescribed in the Activity Plan.

Close-out verification is handled in accordance with the applicable provisions of 033-YMP-QP 3.3, "Review of Technical Publications."

3. Section 3.0.10, new last paragraph:

Waiver of a specified hold point is approved by the QA Manager and documented before work can proceed beyond the designated hold point.

4. Section 3.0.12, add new second paragraph:

Impact of changes on the associated Quality Level Assignments are assessed and handled in accordance with 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance."

5. Section 3.0.13, second paragraph, add new first bullet:

- o Summary of results.

6. Section 3.0.14, add new fourth paragraph prior to list of QA records:

Quality Assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of 033-YMP-QP 17.0, "Quality Assurance Records."

Quality Assurance records include the following:

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0102

Subject:

SCIENTIFIC INVESTIGATION CONTROL

Approved:

Approved by: *A. Seltman* 2/23/89 YMP Project Leader  
 Approved by: *R. E. Selman* 2/23/89 YMP Quality Assurance Manager

**3.0.1 PURPOSE**

The purpose of this Quality Procedure is to describe the control of scientific investigations for the LLNL Yucca Mountain Project (YMP).

**3.0.2 SCOPE**

This procedure applies to all scientific investigation activities which are designated QA Level I and II as determined in accordance with Procedure 033-YMP-QP 2.8 "Assigning Levels of Quality Assurance." Control of these activities is maintained throughout the course of the project. This procedure does not apply to QA Level III activities.

Scientific investigation activities involving the development or use of computer software are described in Procedure 033-YMP-QP 3.2 "Software QA."

**3.0.3 RESPONSIBILITIES**

**3.0.3.1** The Principal Investigator (PI), Task Leader (TL) or designee is responsible for:

- o Preparation and revisions of work planning documents.
- o Overall conduct of work and reporting of experiments, analysis and conclusions.
- o Specifying personnel qualifications and selections of qualified personnel.
- o Preparation of Scientific Investigation Plans (SIP) and Study Plans (SP).

- o Coordination of verification as described in paragraph 3.0.9, if specified by the next level of project management.
- o Transmittal of QA records as described in Procedure 033-YMP-QP 17.0, "Quality Assurance Records".
- o Identification of interfaces which transcend technical area boundaries.

3.0.3.2 The next level of project management above the individual performing the work is responsible for assuring that:

- o The work is proceeding according to the work planning document(s).
- o Modification or changes to the work are within the limitations stated in paragraph 3.0.9.
- o Revisions which may be required to the work planning documents are identified and implemented in a timely manner to allow the work to continue according to an approved plan.
- o The data collected and/or analysis performed meet the objectives of the work planning documents and will lead to a supportable conclusion.
- o Any required verifications have been performed.

3.0.3.3 The Technical Area Leader or designee is responsible for:

- o Assuring that activities described in the work planning documents meet the objectives of the programmatic requirements for which he/she is responsible.
- o Approval of work planning documents identified in Exhibit A.
- o Identifying any interfacing Technical Area Leaders whose activities may be effected. Interfacing Technical Area Leaders will be added to the planning document approval list.

3.0.3.4 The YMP Quality Assurance Manager or designee is responsible for:

- o Concurring with the quality levels of activities identified in the Scientific Investigation Plans in accordance with Procedure 033-YMP-QP 2.8 "Assigning Levels of Quality Assurance".
- o Assuring that the applicable Quality Procedures are addressed in the work planning documents.
- o Approval of work planning documents identified in Exhibit A.
- o Performing audits and surveillances to verify compliance with quality assurance requirements.
- o Transmittal of SIPs and SPs to the DOE Project Office for reviews and approval.

3.0.3.5 The YMP Project Leader or designee is responsible for:

- o Approval of work planning documents identified in Exhibit A.
- o Concurring with the quality levels of activities identified in the Scientific Investigation Plans in accordance with Procedure 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance".

#### 3.0.4 WORK PLANNING DOCUMENTS

Before work begins, i.e., before data is generated, analysis is performed or conclusions are reached, the work is planned, reviewed and approved by preparation of one or more of the following work planning documents:

Scientific Investigation Plans  
Study Plans (for Site Characterization activities)  
Activity Plans

Contents of work planning documents are described as follows and in paragraph 3.0.5.

##### 3.0.4.1 Scientific Investigation Plans (SIPs)

Scientific Investigation Plans are high level planning documents prepared by the Task Leader or Principal Investigator that contain a description of the activities to be performed and include a discussion of the overall purpose and objectives, applicable regulations, requirements, performance criteria, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items. The discussion identifies, at an appropriate level, all of the factors and concerns that are important for the planning or the performance of the scientific investigation. All quality affecting activities subject to the quality level assignment process are identified in the SIP.

If applicable, the SIP contains a description of any previous work which will be used in support of the scientific investigation, including the identification of the Quality Assurance Levels, or Quality Assurance controls, under which that previous work was performed.

Each SIP contains one or more activities that may be further subdivided. Activities are identified by an activity number.

Each SIP is reviewed in accordance with Procedure 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance" to establish the quality level of each activity. The SIP's contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to each activity.

The SIPs and the Quality Assurance Level assignment sheet(s) are submitted to the DOE Project Office for approval.

#### 3.0.4.2 Study Plans (SPs)

Study Plans are higher level planning documents comparable to SIPs. They are prepared for Site Characterization investigations in accordance with the requirements of Appendix K of the QAPP. They are approved by YMP, the DOE Project Office, and by the Office of Civilian Radioactive Waste Management (OCRWM) prior to use as identified in Exhibit A.

#### 3.0.4.3 Activity Plans

Activity Plans describe the specifics of how an activity is to be performed and typically provide more detail than an SIP or SP. In addition to technical details, Activity Plans may include schedules, relationship to other activities and programs, use of supplementing TIPs, expected results, etc. Activity Plans are reviewed and approved by the Technical Area Leader.

Prior to initiating Quality Level I or II work, the individual(s) responsible for preparing the work planning document(s) identify and/or address the following, as applicable, in one or more of the previously described work planning documents.

The level of detail will vary on a case by case basis but must be appropriate for the work to be performed and be in sufficient detail that a reviewer with comparable qualifications could review and understand the plan.

#### 3.0.5 TECHNICAL IMPLEMENTING PROCEDURES (TIPs)

TIPs are documented, approved procedures that provide detailed direction for the performance of work. They include instructions, procedures, plans, sketches, drawings or other information to define and control operations which do not require technical judgement and may be performed by qualified personnel.

TIPs are generally used when qualified personnel are performing repetitive work that does not include the use of professional judgement or trial and error methods. TIPs are used when it is not possible to deviate from a prescribed sequence of actions, without compromising quality of the results that will be obtained from the work.

TIPs are described in Procedure 033-YMP-QP 5.0, "Technical Implementing Procedures."

### 3.0.6 SCIENTIFIC NOTEBOOKS

The scientific notebook will be used to record data, information, analysis and work progress on a daily or as appropriate basis. It is the principal recording document from which work related to an activity can be traced.

The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgement or trial and error methods, or both, in their work. The extent of documentation in the scientific notebook is such that another qualified scientist can use the notebook to retrace the investigation and confirm the results or repeat the experiment without recourse to the original investigator. Control of scientific notebooks is in accordance with Procedure No. 033-YMP-QP 3.4, "Scientific Notebooks".

### 3.0.7 VERIFICATION

Verification of the planning document may be appropriate:

- a) To assure the investigation plan is correct and satisfactory,
- b) To assure that all necessary assumptions, methods and prerequisites have been met.

The decision of whether verification is required is the responsibility of the next level of project management above the document preparer. Verification may be by peer review as described in Procedure 033-YMP-QP 2.2, "Peer Review" or by technical review as described in Procedure 033-YMP-QP 2.4, "Technical Review."

Verification of the scientific investigation is also accomplished through the use of QA checklists (see Section 3.0.9) and surveillances (see Section 3.0.10)

### 3.0.8 REVIEW AND APPROVAL

SIPs, SPs, Activity Plans, and TIPs are revision controlled documents. Their review, approval and revision is performed in accordance with Procedure 033-YMP-QP 2.1, "Preparation, Approval, and Review of Quality Procedures and Requirements." Review is for in-depth technical and programmatic content. cursory supervisory reviews will not satisfy the intent of this review. The QA Manager transmits the SIP or SP to the DOE Project Office for review and approval.

### 3.0.9 QUALITY ASSURANCE CHECKLIST

Following approval of the planning document(s) Quality Assurance prepares a checklist to identify quality related functions which will be monitored before, during, and after the course of work. The checklist will be used to schedule surveillances and/or audits to verify that work is performed in accordance with the planning documents.

The checklist will be updated by Quality Assurance as required to reflect progress of the work.

### 3.0.10 HOLD POINTS

The Principal Investigator/Task Leader will identify the hold points in the Activity Plan to assure that during the progress of work:

- o The activity is proceeding according to the plan.
- o Data and other Quality Assurance Records are properly recorded and maintained.
- o Verifications have been accomplished, if required.
- o Experiments, data and analysis are traceable through information contained in the scientific notebooks.

A hold point is established when it is appropriate that work not continue until after review has been completed.

Consent to waive any specified hold point shall be documented before work can be continued beyond the designated hold point.

### 3.0.11 INTERFACE CONTROLS

- o The Principal Investigator/Task Leader identifies in the planning document(s) any interfaces and interface controls which transcend boundaries between LLNL technical areas. During review of the planning document(s), the originating Technical Area Leader identifies any additional interfaces of which the Principal Investigator/Task Leader may not be aware and adds other Technical Area Leaders to the approval list for the planning document.
- o Interface controls may also be in the form of TIPs or in accordance with Procedure 033-YMP-QP 8.0, "Identification and Control of Items, Samples, and Data."
- o Interface controls between LLNL YMP and Subcontractors/Suppliers are in accordance with Procedure 033-YMP-QP 4.0, "Procurement Control and Documentation."
- o Interface controls between LLNL YMP and other Participating Organizations are in accordance with requirements defined by the DOE Project Office.

### 3.0.12 REVISIONS TO WORK PLANNING DOCUMENTS

When interim results necessitate a change in work plans, the work planning documents are updated and approved by revision or change notice as described in Procedure 033-YMP-QP 2.1, "Preparation, Approval and Revision of Quality Procedures and Requirements."

### 3.0.13 DOCUMENTATION OF RESULTS

Results of activities are documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.

Documentation of interpretation/analysis includes the following:

- o Definition of the objective of the interpretation/analysis.
- o Discussion of whether the work's objectives as outlined in the planning document(s) were achieved.
- o Definition of input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data.
- o Statement of assumptions.
- o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the basis of application to the specific problem.
- o Signatures and dates of review and approval by appropriate personnel.

### 3.0.14 RETAINED DOCUMENTATION

- o Retained by the Principal Investigator/Task Leader until at least the next revision:
  - Returned planning document review copies.
- o Transmitted by the Principal Investigator/Task Leader to Document Control as QA Records.
  - Planning documents, revisions and Change Notices.
  - Data sheets or other data records.
  - Analyses, conclusions and reports.
  - Comment resolution meeting minutes.
  - Verification records.
  - Interface control records.
  - Personnel qualification and requirement records.

EXHIBIT A

Responsibilities for Review and Approval  
of YMP Work Planning Documents

<u>Reviewer/Approver</u>	<u>SIP</u>	<u>SP</u>	<u>Activity Plan</u>	<u>TIP</u>
YMP QA Manager	1	1	1	1
YMP Project Leader	1	1	1	1
TAL(s)	2	2	1	1
DOE Project Office QA Manager	1	1	—	—
DOE Project Office	1	1	—	—
OCRWM	—	1	—	—

1 = Approval

2 = Review



## CHANGE NOTICE

CN No. 3.1-0-1Affected Document: QP 3.1 "Design Control"Revision: 0Prepared By Ronald SchwartzApproved By N/A

Technical Area Leader

Date

Approved By R. E. Schwartz 3/3/89  
YMP QA Manager DateApproved By J. Sallan 3/3/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 3.1.5.2, first paragraph, first sentence  
Applicable design inputs...are identified and documented, and their selections reviewed and approved by the responsible Task Leader.
2. Section 3.1.5.5, fifth paragraph, last sentence  
The Deputy for QA reviews and approves this rationale.

Changed to Read:

1. Section 3.1.5.2, first paragraph, first sentence  
Applicable design inputs...are identified and documented, and their selections reviewed and approved by the responsible Task Leader and the QA Manager.
2. Section 3.1.5.5, fifth paragraph, last sentence  
The QA Manager reviews and approves this rationale.

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

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**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

DESIGN CONTROL

Approved:

Approved by: [Signature] 2/4/89 YMP Project Leader  
Approved by: [Signature] 1/12/89 YMP Quality Assurance Manager

**3.1.1 PURPOSE**

This procedure establishes controls for designs prepared in support of Yucca Mountain Project (YMP) activities. These controls are established to assure that design activities occur in a controlled and timely manner and that documentation is initiated early in the design process to facilitate subsequent evaluation, review, or verification.

**3.1.2 SCOPE**

This procedure applies to hardware related and structural design activity in support of the LLNL YMP program, including preparation of specifications, drawings, and calculations; incorporation of design criteria; and formulation of component performance requirements.

Design of equipment used in conducting scientific investigations is addressed in Procedure No. 033-YMP-QP 12.0, "Control of Measuring and Test Equipment," and is not included in this procedure. Computer programs used as part of the design effort are subject to the controls of Procedure No. 033-YMP-QP 3.2, "Software Quality Assurance" and are not within the scope of this procedure.

**3.1.3 TERMS AND DEFINITIONS**

**Design Process:** Technical and administrative managerial processes that commence with the identification of design inputs and that lead to and conclude with the issuance of design output documents.

**3.1.4 RESPONSIBILITIES AND AUTHORITIES**

The Task Leader whose activities warrant the use of this procedure is responsible for implementing the controls.

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The YMP Quality Assurance Manager is responsible for monitoring the design process, analysis, documentation, and verification; for assuring the effectiveness of the applicable controls; and for maintaining this procedure.

### 3.1.5 CONTROLS

Design procedures for repetitive activities are prescribed in individual Technical Implementing Procedures (TIP's) in accordance with Procedure No. 033-YMP-QP 5.0, "Technical Implementing Procedures." These TIP's provide sufficient detail to correctly perform the design process and to permit verification that the design meets specified requirements, and include:

#### 3.1.5.1 Level of Quality Assurance Assignment

Prior to the initiation of design activities associated with LLNL's YMP program, Levels of Quality Assurance (QA) are assigned to each activity. In the case of an activity for which YMP has primary responsibility, the Level of QA is assigned and a Level of QA Assignment Approval Sheet is prepared in accordance with the requirements of Procedure No. 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance." In the case of an activity for which an external YMP Program organization has primary responsibility, the Level of QA assigned by that organization is applied to work performed by YMP.

#### 3.1.5.2 Design Input

Applicable design inputs (such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards) are identified and documented, and their selections reviewed and approved by the responsible Task Leader. Data resulting from scientific investigations is collected and used as design input. All design inputs are specified, approved, documented, and controlled on a timely basis. Design inputs are defined to the level of detail necessary to permit the basis for making decisions, accomplishing design verification measures, and evaluating design changes.

Changes to approved design inputs, including the reasons for the changes, are identified, approved, controlled and documented as revision controlled documents.

#### 3.1.5.3 Design Process

The Task Leader prescribes and documents the design activities on a timely basis and to the level of detail necessary to assure that the design process is performed correctly, and that the design meets requirements. Although the completed or final design of a facility or item may evolve from a sequential order of design activities (or phases), with the design becoming progressively more detailed as the final design phase is approached, the Level of QA assigned to the activity normally is maintained throughout the design phase.

Satisfactory design control requires adequate interface control, both internal to the YMP and between the YMP and external organizations. Interface information exchanged between organizations is identified, approved, documented, and controlled.

#### 3.1.5.4 Design Analyses

Design analysis is documented in sufficient detail to describe the purpose, method, assumptions, and design inputs utilized, such that a technically qualified person can verify the analysis without recourse to the originator. These documents are legible and in a form suitable for reproduction, filing, and retrieval. Calculations are identifiable by subject (including structure, system, or component), originator, reviewer, date, and other appropriate data.

Computer programs may be utilized for design analysis without individual verification of the program for each application, provided: (1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within the defined limits for each parameter employed, and (2) the encoded mathematical model has been shown to produce a valid solution to the physical problems associated with the particular application.

Computer programs are controlled in accordance with provisions of Procedure No. 033-YMP-QP 3.2, "Software Quality Assurance."

Documentation of design analysis includes the following:

- (a) definition of the objective of the analysis;
- (b) listing of the qualified YMP or subcontractor personnel performing the analysis together with a reference to documentation of personnel qualifications;
- (c) definition of design inputs and their sources;
- (d) listing of applicable references, including the source of the analytical method or technique;
- (e) results of literature searches or other applicable background data;
- (f) identification of assumptions and indication of those that require verification as the design proceeds;
- (g) identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem; and
- (h) evidence of review and approval.

### 3.1.5.5 Design Verification Requirements for QA Levels I and II Design Activities

Design verification is the documented process of reviewing, confirming, or substantiating the design by one or more methods to provide assurance that the design meets the specified design requirements. Design verification methods include, but are not limited to, any one or combination of the following: (A) technical reviews, (B) alternate calculation or analysis, (C) suitable qualification testing, (D) similarity of design, and (E) peer review.

The Task Leader is responsible for implementing the design verification process. The QA Manager is responsible for reviewing the verification process to assure compliance with requirements. Design verifications are performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities. In those cases where verification cannot be performed prior to release, the portion or portions of design which have not been verified are identified and controlled. In all cases, the verification is completed prior to relying on the component, system, or structure to perform its function.

The extent of design verification required is a function of the importance to safety or waste isolation of the item or system under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity of the new design to perviously proven designs. Known problems affecting standardized, or perviously proven designs, and effects on other features are considered. The original design and associated verification measures are referenced in the files of subsequent applications of the design.

Where changes to perviously verified designs have been made, design verification is required for the changes, including evaluation of the effects of those changes on the overall design.

Design verifications are performed by qualified personnel other than the originator. Personnel performing the verification can be from the same organization; from an organization contracted for the purpose; or the originator's supervisor, if the supervisor is the only individual competent to perform the verification and did not designate the design inputs or design approach. The rational for using the originator's supervisor is documented and approved by the Project Leader. The Deputy for QA also reviews and approves this rational.

Specific information for design verification methods include the following:

(A) **Technical Reviews** - A technical review is conducted according to the provisions of Procedure No. 033-YMP-QP 2.4, "Technical Review." The results of the technical reievew are documented and made part of the design's output documentation.

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(B) **Alternative Calculations** - Alternative calculations are analyses that are made with alternate methods to verify the correctness of the original calculations or analyses. Included is a review of assumptions, inputs, and software used in the original calculations or analysis, if applicable. If the alternate agrees (within accepted engineering standards) with the original results, no further verification is required. If, however, there is insufficient agreement between the original calculation and the check calculation, the check calculation is completely verified as though it were the principal calculation. Conflicts resulting from significant differences between verified alternate approaches are subjected to design verification according to the provisions of Procedure No. 033-YMP-QP 2.4, "Technical Review."

(C) **Qualification Tests** - Where design adequacy is to be verified by qualification tests, the tests are identified, including the scope of testing, in accordance with requirements of Procedure No. 033-YMP-QP 11.0, "Test Control of Engineered Items." Test configurations are clearly defined and documented. Tests are designed to demonstrate the adequacy of performance under the most adverse design conditions, if appropriate. Operating modes and environmental conditions in which the item must perform satisfactorily are considered in determining the most adverse design conditions. Where the test is intended to verify only specific design features, the other features of the design are verified by other means.

Test results are documented and evaluated by the responsible Task Leader to assure that requirements have been met. If qualification testing indicates that modifications to the item or system are necessary to obtain acceptable performance, the needed modification is documented and the item or system modified and retested or otherwise verified to assure satisfactory performance. If models or mockups are tested, then scaling laws are established and verified. The results of model tests are subject to error analysis, if appropriate, prior to use in the design.

(D) **Similarity of Design** - Design verification can be accomplished by developing a design similar to a previously tested or operated item or system. Where all or portions of a design are verified by similarity to prior designs, verification establishes that: (1) conditions under which the prior design operated were the same as, or more severe than, relevant conditions in which the present design will operate; (2) the prior design operated, or was tested under the most adverse combination of design conditions applicable to the present design; and (3) the designer has determined and appropriately accounted for any deficiencies discovered during operation of the prior design.

(E) **Peer Review** - Peer review is an acceptable method of design verification when the design is beyond the state of the art and other methods of design verification are not feasible. Peer reviews of design activities are conducted when deemed necessary by the Technical Area Leader, or the Project Leader to provide adequate confidence in the design being produced. Peer reviews are conducted in accordance with the provisions of Procedure No. 033-YMP-QP 2.2, "Peer Review."

### 3.1.5.6 Design Change Control for QA Levels I and II Design Activities

Changes to approved design inputs and design processes are justified and subjected to design control measures commensurate with those applied to the original design. The same organization that reviewed and approved the original design reviews and approves any changes.

### 3.1.5.7 Design Interface Control for QA Levels I and II Design Activities

Design interfaces are identified and design efforts are coordinated among and within the participating organizations. Interface controls include the assignment of responsibility and establishment of procedures for review, approval, release, distribution, and revision of documents involving design interfaces. Design information transmitted across interfaces is documented and controlled. Transmittals include identification of the status of the design information or document provided and, where necessary, identification of incomplete items which require further evaluation, review, or approval.

### 3.1.5.8 Design Output Documentation for QA Levels I and II Design Activities

Design output documents are sufficiently detailed to provide adequate information for verification or evaluation of the design. Assemblies or components used as part of a design are completely identified and traceable to documents that might specify any modifications to the assembly or component. When assemblies or component parts are commercial grade items that, prior to their installation, are modified or selected by special inspection or testing, or both, to requirements that are more restrictive than the Supplier's published product description, the component parts are represented as different from the commercial grade items in a manner traceable to a documented definition of the difference.

Design output documents are reviewed and approved in accordance with Procedure No. 033-YMP-QP 3.3, "Review of Technical Publications" prior to release.

### 3.1.6 RETAINED DOCUMENTATION

Quality assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- Level of Quality Assurance Assignment Approval Sheets,
- Drawings,
- Specifications,
- Calculations,
- Information transmitted across interfaces,
- Identification of design inputs/outputs,
- Description of the design process/analysis,
- Description and results of design verification,
- Description and results of qualification tests,
- Documentation of design changes, and
- Documentation of peer reviews.



## CHANGE NOTICE

CN No. 3.2-0-1Affected Document: QP 3.2, "Software Quality Assurance"Revision: 0Prepared By Ronald SchwartzApproved By N/A  
Technical Area Leader DateApproved By *R. E. Johnson* 3/15/89  
YMP QA Manager DateApproved By *A. Mellan* 3/15/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 3.2.3.1, third bullet:
  - o Assuring that the Software QA Plans or Technical Implementing Procedures contain the procedures and methods which describe how the requirements of Appendix H of the LLNL QAPP are implemented.
2. Section 3.2.7, add new first paragraph  
(see below)

Changed to Read:

1. Section 3.2.3.1, third bullet:
  - o Assuring that the Software QA Plans or Technical Implementing Procedures contain the procedures and methods which describe how the requirements of Appendix H of the LLNL QAPP and 033-YMP-R 3 Section 3.0 are implemented.
2. Section 3.2.7, add new first paragraph

Quality Assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of 033-YMP-QP 17.0, "Quality Assurance Records."

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

SOFTWARE QUALITY ASSURANCE

Approved:

Approved by: *D. S. Sellen* 2/23/89  
YMP Project Leader

Approved by: *R. E. Schuy* 2/23/89  
YMP Quality Assurance  
Manager

### 3.2.1 PURPOSE

The purpose of this procedure is to describe the control of software for the LLNL Yucca Mountain Project.

### 3.2.2 SCOPE

This procedure applies to all computer software used to produce or manipulate data in support of Quality Level I or II activities and to the planning documents which describe control of that software, such as Software QA Plans and Technical Implementing Procedures which supplement those plans. Software QA Plans may be prepared for individual activities or a single, generic Software QA Plan may be prepared for LLNL-YMP work.

### 3.2.3 RESPONSIBILITIES

#### 3.2.3.1

The responsible Technical Area Leader is responsible for:

- o Preparation and revision of the Software QA Plan, if a separate plan is used.
- o Preparation and revision of Technical Implementing Procedures which supplement the Software QA Plan, if required.
- o Assuring that the Software QA Plans or Technical Implementing Procedures contain the procedures and methods which describe how the requirements of Appendix H of the LLNL QAPP are implemented.

- o Assuring that the software planning documents are consistent with other Project Quality Procedures such as those related to:
  - 1) Documentation of work progress.
  - 2) Document identification and control.
  - 3) Revision of controlled documents.
  - 4) Peer and technical reviews.
  - 5) Control of purchased items and services.
  - 6) Corrective Action.
  - 7) Records Management.
- o Assuring that work is performed according to and within the scope of the software planning documents.

#### 3.2.3.2

The Task Leaders are responsible for:

- o Assuring that work is performed according to and within the scope of the software planning documents. This is accomplished by periodically reviewing and approving the documentation required by the software planning documents during the progress of work.
- o Assuring that information contained in the documentation specified in the software planning documents represents a traceable path throughout the course of the work.

#### 3.2.3.3

The YMP Quality Assurance Manager is responsible for:

- o Assuring that the applicable Project Quality Procedures are addressed in the software planning documents.
- o Approval of software planning documents.
- o Performing audits and surveillances to verify compliance with QA requirements.

#### 3.2.3.4

The YMP Project Leader is responsible for:

- o Approval of software planning documents.

### 3.2.4 PREPARATION OF SOFTWARE QA PLANS

Before development, acquisition or application of software for Quality Level I or II activities, Software QA Plans are prepared which address how software will be controlled during YMP project activities. The Software QA Plans may cover a generic class of software or specific software products.

Software QA Plans are revision controlled planning documents that address the requirements specified in Appendix H of the LLNL QAPP and include:

- o Organizational responsibilities
- o Software products to which the software QA plans apply
- o Criteria for meeting requirements of Appendix H
- o Software lifecycle model used and lifecycle controls
- o Documentation required
- o Reviews required
- o Configuration management system
- o Verification and validation
- o Discrepancy reporting and corrective actions
- o Software change control
- o Control of software applications
- o Control of commercial and acquired software

The planning documents contain the procedures or methods that describe how the requirements of Appendix H are implemented.

### 3.2.5 REVIEW, APPROVAL AND REVISION OF SOFTWARE PLANNING DOCUMENTS

Software QA Plans are reviewed, approved and revised in accordance with paragraphs 2.1.4.3 through 2.1.7 of Quality Procedure 033-YMP-QP 2.1, "Preparation, Approval and Revision of Quality Procedures and Requirements". In addition to approvals by the responsible Technical Area Leader, QA Manager, Project Leader and DOE Project Office, additional Technical Area Leaders may be added to the approval list if activities interface with other technical areas.

Technical Implementing Procedures may be prepared to supplement the Software QA Plans and are reviewed and approved as described above but do not require DOE Project Office approval.

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### 3.2.6 DOCUMENTATION

If the progress of work is recorded in a scientific notebook, the documentation procedure described in the planning documents must be consistent with the applicable requirements of Quality Procedure 033-YMP-QP 3.4, "Scientific Notebooks".

### 3.2.7 RETAINED DOCUMENTATION

QA records and any other retained documentation is defined in the Software QA Plans.

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

REVIEW OF TECHNICAL PUBLICATIONS

Approved:

Approved by: *R. S. Sellow* 4/10/89 YMP Project Leader  
 Approved by: *R. L. E. Smith* 2/19/89 YMP Quality Assurance Manager

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### 3.3.1 PURPOSE

The purpose of this procedure is to describe the review process for technical documents, written under the auspices of the LLNL Yucca Mountain Project (YMP), prior to publication. This procedure also prescribes documentation requirements associated with the review process.

### 3.3.2 SCOPE

This procedure applies to all technical reports, abstracts, or summaries that result from work conducted within the scope of the YMP Quality Assurance Program Plan, either on- or off-site, and that are intended for publication.

This procedure may be invoked by the YMP Project Leader to apply to administrative reports at his or her discretion.

This procedure does not apply to:

- o weekly, monthly, or quarterly reports;
- o abstracts and summaries not intended for outside publication;
- o letter reports from subcontractors;
- o YMP letter reports to DOE Project Office.

### 3.3.3 RESPONSIBILITIES

The YMP Project Leader and Technical Area Leaders are responsible for the effective implementation of this procedure. Specific responsibilities for this procedure are described in Section 3.3.5, "Procedure."

### 3.3.4 SUMMARY OF THE REVIEW PROCESS

Informal technical reviews of draft reports are encouraged. These reviews can be as often and as informal as desired and do not have to become part of any record. There comes a juncture, however, when draft reports, if they are to be published, must be submitted to a formal, controlled, and thoroughly traceable review process.

Draft reports that fall within the scope of this procedure undergo six reviews before they can be submitted to the Laboratory's Technical Information Department for release or publication, (see Section 3.3.6.2 for technical reports from YMP subcontractors).

The six review steps are:

1. For technical content,
2. For technical approval,
3. For project approval,
4. For DOE Project Office approval,
5. For YMP administrative approval, and,
6. For Quality Assurance procedure approval.

These reviews are described in detail in Section 3.3.5, "Procedure," and are shown in Exhibit A. The coordination of the first review, the one for technical content, is the responsibility of the Review Coordinator. The coordination of all the other reviews is the responsibility of the YMP Publications Manager.

### 3.3.5 PROCEDURE

The review sequence is described in this section and shown in tabular form in Exhibit A.

#### 3.3.5.1 First Review: Technical Content

The purpose of this review is to assure that qualified people review the draft report for technical content and to establish a record of such a review. The reviewers are qualified in the report's subject area. They do not have to be employees of the organization where the work was performed.

##### Senior Author

This procedure never removes the Senior Author's responsibility for the content of the report, either in draft or final form. Therefore, throughout the review process, comments, questions, and requests are to be mutually resolved, answered, and accommodated by the Senior Author and the reviewer. Personal contact for resolution is encouraged, but records of such contact are made part of the review process documentation.

When the Senior Author intends to submit the data documented in the report to the YMP Technical Data Base (TDB), an appendix to the report is prepared specifically to contain that data. The appendix title indicates that the contents are intended for the YMP Site and Engineering Properties Data Base.

The first page of that appendix contains the following information:

- o A brief description of the type of data,
- o Published references that contain the data,
- o The QA level of the activity producing the data,
- o The WBS number of the activity, and
- o The length of the appendix (number of pages).

The formal review process begins with the Senior Author's submittal of three copies of the draft report to an individual at the first level of management who has the primary technical responsibility for the content of the draft. This procedure titles such an individual the Review Coordinator.

##### Review Coordinator

The Review Coordinator oversees the first review. At least two technical reviewers are selected. The Review Coordinator may be one of these, provided that he or she is technically qualified and independent of all efforts that resulted in the draft, requirements which apply to all technical reviewers.

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The technical review is similar to a review as would be conducted for a refereed technical journal. Such a review includes an examination of the report's technical accuracy, a determination whether the data support the conclusions, and whether the description of the work is sufficient to allow replication by an independent peer.

The Review Coordinator provides each reviewer with a copy of the draft accompanied by a "Technical Reviewer's Comment Form", see Exhibit B, and any special instructions which may be appropriate. When they have completed their reviews, the reviewers return their comments to the Review Coordinator.

The Review Coordinator monitors this review by initiating a "Technical Report Review Record for YMP Reports" (Review Record, Exhibit C). The Review Record is retained by the Review Coordinator while the drafts are out for review.

The Review Coordinator receives the comments from the reviewers. He or she is responsible for resolving the comments before the draft advances to the next review step. Comments are resolved in a manner suitable to their nature. Regardless of method, both the comments and their resolutions are made part of the review record. Resolved comments usually result in a revised draft. When the Review Coordinator receives an acceptable revision from the Senior Author, the next review can commence.

The Review Coordinator sends the following to the YMP Publications Manager:

- three copies of the revised draft;
- all Comment Forms;
- original of the Review Record;
- any other documentation that has become part of the record; this includes a copy of the original draft and copies of pages of the draft containing the reviewer's margin comments.

### 3.3.5.2 Second Review: Technical Approval

The purpose of this review is for YMP management's assurance that the technical content of the draft report is coordinated with similar technical work, and that the work's original technical specifications are met.

#### Publications Manager

The Publications Manager oversees the remaining reviews. He or she sends for technical approval a copy of the revision, appended with a Comment Form and the original Review Record, to a technically qualified individual typically one management level above the Review Coordinator. This is usually a Technical Area or Task Leader.

If the second review results in comments, then these are resolved in much the same manner as described in the first review, with the Publications Manager acting as the formal interface between reviewer and Senior Author. Approval of the draft is signified by the reviewer's signature in the "Technical Approval" signature block of the Review Record. The second review is now complete, and the third review can begin.

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The Technical Reviewer returns the following to the Publications Manager:

- o Revised draft;
- o Comment Form;
- o Review Record with signature;
- o any other documentation that has become part of the record.

The Publications Manager adds the material received from the Technical Reviewer to the existing documentation and annotates the copy of the Review Record.

If changes pertaining to the technical content of the draft report are made during any review after the second review, the Senior Author or the Publications Manager returns the draft report to the individual who signed off for Technical Approval. The latter will determine whether the changes are significant enough to warrant another review for technical content.

#### 3.3.5.3 Third Review: Project Approval

The purpose of this review is to assure that the draft report is ready for transmittal to the DOE Project Office. This review focuses on programmatic relevance, policy, and cross-discipline and project interface concerns.

##### Deputy Project Leader

The third review is conducted by the Deputy Project Leader. If this review results in comments, then these are resolved in much the same manner as was described in the previous two reviews, with the Publications Manager acting as the formal interface between reviewer and Senior Author. Comments are made and resolved, another revision is prepared if necessary, records are kept and added to the existing ones, status is maintained and approval is signified by signature in the appropriate signature block of the Review Record.

#### 3.3.5.4 Fourth Review: DOE Approval

The purpose of this review is to obtain the approval of the DOE (YMP) Project Office before documents within the scope of this procedure are published.

Note: The Laboratory requires completion of the LLNL Publication Release form (LL-2956) prior to document transmittal offsite.

If changes have been made to the publication during the review process up to the point of submittal for DOE Approval, then the Review coordinator is responsible for providing a corrected original and five copies to the Publications Manager.

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The Publications Manager submits the current approved report to the DOE Project Office with an appropriate cover letter. Again, the DOE review may require another sequence of comments, followed by resolutions and revisions. These comments will be sent with a formal letter from the DOE. The letter and comments will be sent to the author by the Publications Manager. The author responds directly on the DOE Document Review Sheets and returns these sheets plus any pages of the report that have been changed to the Publications Manager. The Publications Manager drafts a letter for the YMP Leader's signature transmitting these responses back to the DOE. When approval is obtained, the date of the DOE approval is written in the appropriate space on the Technical Report Review Record. The DOE approval letter, as well as any DOE letter that contained DOE Document Review Sheets, the completed DOE Document Review Sheets, and the transmittal letter for these comments, all become part of the document's package. This closes the fourth review.

#### 3.3.5.5 Fifth Review: YMP Administrative Approval

The purpose of this review is to provide the YMP Leader with an important method of reviewing the program's end-product. It also serves as a technically oriented quality assurance review.

YMP Leader

The Publications Manager submits the entire report package with the current approved version to the YMP Leader. Similar comment and comment resolution procedures as were described previously also pertain here. Administrative approval is signified by the YMP Leader's signature in the appropriate signature block on the Review Record.

#### 3.3.5.6 Sixth Review: Quality Assurance Procedure Approval

The purpose of this review is to assure that proper quality assurance records exist for each YMP sponsored publication. Additionally, this review assures that the previous five reviews took place and are documented. The Publications Manager submits all documentation thus far accumulated to the Quality Assurance Manager (QA Manager).

QA Manager

The QA Manager reviews the documentation to determine whether the review process was properly followed and adequately documented. The QA Manager also determines whether the documents and data supporting the content of the draft's current revision have been submitted or are identified for archiving to the records system. If the draft is part of a series and is not a final report, then the QA Manager verifies the existence of supporting documentation and determines whether the documentation is properly stored. The documentation required to be submitted with the report will be mutually agreed upon by the QA Manager, or a person designated by the QA Manager, and the Senior Author.

The QA Manager also determines if the work that supports the publication has any open action items, e.g., Nonconformance Reports (NCR's), Corrective Action Reports (CAR's), or audit findings pending. If such action items exist, then the QA Manager notifies the Senior Author and the Publications Manager that the draft is not to be released for publication until all open items have been resolved.

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If the supporting documentation has not been submitted for archiving or has not been identified, the QA Manager notifies the Senior Author and the Publications Manager that the draft is not to be released for publication until its supporting documentation is collected or identified. It is the responsibility of the Senior Author to resolve this issue with the QA Manager. Once the QA Manager has given approval, signified by a signature on the appropriate block on the Review Record, the latest revision and the Review Record are returned to the Publications Manager for record tracking and submittal to Document Control. The requirement for the submittal or identification of documentation does not apply to published abstracts.

### 3.3.5.7 Publishing the Manuscript

After QA approval, the Publications Manager sends a copy of the DOE Project Office approval letter to the author of the report. The Publications Manager sends the manuscript and distribution list to the print plant for publication. A copy of the published document is provided to the QA Manager as part of the report distribution.

If the report contains an appendix intended for submittal to the YMP Site and Engineering Properties Data Base, the Publications Manager prepares a separate transmittal letter for the appendix. The transmittal is to the Data Base Administrator at Sandia National Laboratories and is signed by the YMP Leader.

If magnetic media are submitted in addition to the appendix hard copy, a description and/or instructions for its use is included.

### 3.3.6 ADDITIONAL NOTES

Requirements dealing with authorship positions within the Project, subcontractor documentation and open literature publications are described.

#### 3.3.6.1 Chain of Review Coordinators

- a. If the author is organizationally located below YMP Task Leaders, then the Review Coordinator is his or her Task Leader. The cognizant Technical Area Leader also reviews the document and initials next to Task Leader's signature.
- b. If the author is a Task Leader, then the Review Coordinator is his or her Technical Area Leader.
- c. If the author is a Technical Area Leader, then the Review Coordinator is the Deputy Project Leader.
- d. If the author is the Project Leader or Deputy Project Leader, then the Review Coordinator is a Technical Area Leader.
- e. If this procedure is invoked for administrative documents (including quality assurance) the Review Coordinator is either the YMP Leader or the QA Manager. If the QA Manager is the author, then the Review Coordinator is the YMP Leader or his designee.

### 3.3:6.2 Technical Documents from YMP Subcontractors

Subcontractors whose deliverables include reports that fall within the scope of this procedure may or may not have their own technical document review procedure. In the case of those who have their own review procedure, YMP's Technical Contact would have the role of a reviewer in much the same manner as YMP includes DOE Project Office approval in its review procedure. It is also possible the YMP's Technical Contact is requested to serve as a technical reviewer for subcontractor reports (as in this procedure's First Review step). Whichever case, either as sponsor or technical reviewer, documentation of the review is submitted to the QA Manager for review.

Subcontractors who do not have their own technical document review procedure are required to follow the steps of this procedure. YMP's Technical Contact will be the Review Coordinator. YMP's Technical Contact may require, at his or her option, that this review procedure be applied to subcontractor reports whether or not subcontractors have their own technical document review procedure.

The documentation that must be submitted with the report and the time of submittal is to be specified in the contract or work-statement.

### 3.3.6.3 Technical Documents Published in the Open Literature

This procedure only considers review steps applicable to YMP sponsored work. These review steps are accomplished prior to the Laboratory's or any other technical document review processes, those processes being outside of YMP's purview and control. (e.g., A journal may use reviewers and referees outside the YMP community to review a submitted paper.)

However, it remains the Senior Author's responsibility to provide the QA Manager with a copy of the final published document (see Section 3.3.5.7) and all review comments that were written after YMP reviews.

### 3.3.7 RETAINED DOCUMENTATION

The manuscript as released after YMP reviews and all supporting documentation, the final published report, and the review correspondence resulting from other procedures subsequent to YMP reviews constitute a complete Q.A. Record of the technical publication.

Quality assurance records created by the implementation of this procedure are collected, stored, and maintained in accordance with Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records".

Quality assurance records include the following:

- o completed Technical Report Review Record for YMP Reports;
- o completed Technical Reviewer's Comment Forms;
- o published technical report;
- o review comments
- o review correspondence from other review processes.

REVIEW	WHO	ACTION	DOCUMENT
1ST	1.Sr. Author	Report to Review Coordinator. Coordinate comments & resolutions.	Report & DRS
	2.Rev. Coord.	Selects reviewers for technical content review.	Initiates Exhibits B,C
	3.Tech Review	Review for technical content. Report & Exh B to Rev. Coord.	Completes Exhibit B
	4.Rev. Coord.	Provides info pkg to Pub. Mgr.	
2ND	5.Pub. Mgr.	Coordinates all signatures, sends pkg to Tech Area/Task Leader.	
	6.Tech Area/ Task Leader	Assures content coord with similar tech work, return pkg to Pub. Mgr.	Signs Exhibit C
3RD	7.Pub. Mgr.	Pkg to Deputy Project Leader.	
	8.Sr. Author	Assures completion of LLNL Classification Review Form	LL-2956
	9.Dep Proj Ldr	Assures report ready for DOE, pkg to Pub. Mgr.	Signs Exhibit C
	10.Pub. Mgr.	Prepares xmtl letter for YMP Ldr, pkg & letter to YMP Leader	
	11.YMP Leader	Signs xmtl ltr, pkg to Pub. Mgr.	Letter to DOE
	12.Pub. Mgr.	Sends letter & report to DOE.	Transmittal
4TH	13.DOE	Assures report meets req's, issues approval letter & DRS (if req'd).	Approval Ltr, DRS
	14.Pub. Mgr.	If DRS, sends to Sr. Author, Steps 9,10,11 & 12 are repeated. If no DRS, pkg to YMP Leader.	
5TH	15.YMP Leader	Gives final Project approval, returns pkg to Pub. Mgr.	Signs Exhibit C
	16.Pub. Mgr.	Sends pkg to QA Mgr.	
6TH	17.QA Mgr.	Assures report is documented, requests add'l documents if req'd. Package to Pub. Mgr.	Signs Exhibit C
PRINT	18.Pub. Mgr.	Sends report to printing, <u>complete</u> <u>pkg to Document Control</u> , appv'l ltr to Sr. Author, distribution info to to author's secretary.	Print Order, Distribution List
	19.Pub. Mgr.	Prepares letter for YMP Leader to send data base appendix to SNL.	Xmtl Ltr to SNL

-----  
 DRS = Document Review Sheet, SNL = Sandia National Laboratories

EXHIBIT A  
 Review Sequence

**TECHNICAL REVIEWER'S COMMENT FORM**

Title of Paper: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Authors: \_\_\_\_\_  
 \_\_\_\_\_

- Recommendation:
- ( ) Publish as-is
  - ( ) Publish with minor revision as noted on text
  - ( ) Publish after revisions are re-reviewed
  - ( ) Publish only after noted major revisions have been re-reviewed
  - ( ) Not suitable for publication

Comments:

Note: Please return the draft; it is part of the Quality Assurance Records Management System.

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b> Page _____ of _____																																							
<b>TECHNICAL REPORT REVIEW RECORD FOR YMP REPORTS</b>																																								
Senior Author: _____ Ext.: _____ Task: _____ Activity No.: _____ Document Title: _____ Type of Report: UCRL-50,000 _____ UCRL 90,000 _____ UCID _____ Other _____																																								
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:30%;">1. Reviewer</th> <th style="width:15%;">Date</th> <th style="width:55%;">Remarks</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>	1. Reviewer	Date	Remarks																															Review Coordinator: _____ Cost Code: _____ <table style="width:100%;"> <tr> <td style="width:50%; padding: 5px;"> <b>2. Technical Approval:</b>            Approved by: _____            Date: _____         </td> <td style="width:50%; padding: 5px;"> <b>3. Project Approval:</b>            Approved by: _____            Date: _____         </td> </tr> <tr> <td style="padding: 5px;"> <b>4. DOE Project Office:</b>            Date Approved: _____         </td> <td style="padding: 5px;"> <b>5. Administrative Approval</b>            Approved by: _____            Date: _____         </td> </tr> <tr> <td style="padding: 5px;"> <b>6. Quality Assurance Review:</b>            Reviewed by: _____            Date: _____         </td> <td> </td> </tr> </table>	<b>2. Technical Approval:</b> Approved by: _____ Date: _____	<b>3. Project Approval:</b> Approved by: _____ Date: _____	<b>4. DOE Project Office:</b> Date Approved: _____	<b>5. Administrative Approval</b> Approved by: _____ Date: _____	<b>6. Quality Assurance Review:</b> Reviewed by: _____ Date: _____	
1. Reviewer	Date	Remarks																																						
<b>2. Technical Approval:</b> Approved by: _____ Date: _____	<b>3. Project Approval:</b> Approved by: _____ Date: _____																																							
<b>4. DOE Project Office:</b> Date Approved: _____	<b>5. Administrative Approval</b> Approved by: _____ Date: _____																																							
<b>6. Quality Assurance Review:</b> Reviewed by: _____ Date: _____																																								



## CHANGE NOTICE

CN No. 3.4-0-1Affected Document: QP 3.4, "Scientific Notebooks"Revision: 0Prepared By Ronald SchwartzApproved By N/A  
Technical Area Leader DateApproved By *R. G. E. Schultz* 3/15/89  
YMP QA Manager DateApproved By *J. M. Sullivan* 3/15/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 3.4.9, first paragraph:

Transmitted by the Principal Investigator/Task Leader to Document Control as QA records.

Changed to Read:

1. Section 3.4.9. new first and second paragraphs:  
(replace text above):

Quality Assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of 033-YMP-QP 17.0, "Quality Assurance Records."

Quality Assurance records transmitted by the Principal Investigator/Task Leader include the following:

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

SCIENTIFIC NOTEBOOKS

Approved:

Approved by: [Signature] 2/23/89  
YMP Project Leader

Approved by: [Signature] 2/23/89  
YMP Quality Assurance  
Manager

### 3.4.1 PURPOSE

The purpose of this Quality Procedure is to describe the use and control of scientific notebooks for the LLNL Yucca Mountain Project (YMP).

### 3.4.2 SCOPE

This procedure applies to all QA Level I and II scientific investigation activities using scientific notebooks. This procedure describes the controls to be used and content of scientific notebooks when they are used to document activities that are not controlled by technical implementing procedures (TIPs).

### 3.4.3 RESPONSIBILITIES

3.4.3.1 The Principal Investigator (PI), Task Leader (TL) or designee is responsible for:

- o Maintenance of scientific notebooks and other documentation until ready for transmittal as QA records.
- o Coordination of verification as described in paragraph 3.4.8, if specified by the next level of project management.
- o Transmittal of QA records as described in Procedure 033-YMP-QP 17.0, "Quality Assurance Records".

3.4.3.2 The next level of project management above the individual performing the work is responsible for assuring that:

- o Modification or changes to the work are within the limitations stated in paragraph 3.4.8.

- o Information contained in the scientific notebook represents a traceable path throughout the course of the work activity.
- o A checklist which may be affixed in the scientific notebook is complete and approved. He may also identify others to review and sign-off the checklist. A sample checklist is shown in Exhibit A.

3.4.3.3 The YMP Quality Assurance Manager or designee is responsible for:

- o Performing audits and surveillances to verify compliance with quality assurance requirements relating to the use of scientific notebooks.

3.4.4 SCIENTIFIC NOTEBOOKS

The scientific notebook is used to record data, information, analysis and work progress on a daily or as appropriate basis. It is the principal recording document from which work related to an activity can be traced.

The scientific notebook system is generally be used by qualified individuals who are using a high degree of professional judgement or trial and error methods, or both, in their work. The extent of documentation in the scientific notebook is such that another qualified individual can use the notebook to retrace the investigation and confirm the results or repeat the investigation and achieve the same results without recourse to the original investigator.

Scientific notebooks are assigned a unique identification number by Document Control.

3.4.5 ENTRIES IN SCIENTIFIC NOTEBOOKS

The scientific notebook is intended to be the primary recording document from which work can be traced. The notebook is securely bound and suitable for photocopying of the contents.

Entries comply with the following requirements:

- o Legible, indelible, and suitable for reproduction.
- o Securely affixed, if not written in directly.
- o Each page numbered sequentially.
- o No blank pages between entries.
- o To make corrections, line out with a single line so that original text is readable, then initial and date. Erasures and correction fluids are not permissible.

### 3.4.6 INITIAL ENTRIES IN SCIENTIFIC NOTEBOOKS

Prior to initiating the activity, the individual(s) responsible enters the following, as applicable, in the scientific notebook either directly or by reference.

The level of detail varies on a case by case basis but is appropriate for the work to be performed and in sufficient detail that a reviewer with comparable qualifications could review and understand the entries.

1. Title and activity number of the activity.
2. Name of the qualified individual or individuals performing the activity.
3. Dated signature of the individual(s) making the initial entries.
4. Description of the activity's objective or objectives, and the proposed approach or procedure for achieving those objectives.

Reference may be made to the appropriate planning document(s) which controls the work for the remaining items:

5. Equipment and materials to be employed during the activity including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
6. Calibration requirements not covered by Procedure 033-YMP-QP 12.0, "Control of Measuring and Test Equipment."
7. Special personnel training or qualification requirements.
8. Documentation of suitable and controlled environmental conditions.
9. Required levels of precision and accuracy.
10. Identification of potential sources of uncertainty and error which must be controlled and measured to assure the investigations are well controlled.

### 3.4.7 RECORDING OF WORK PROGRESS

Progress of work is recorded in the Scientific Notebook daily or as appropriate in sufficient detail that another competent experimenter or researcher could repeat the work. Information includes, as applicable:

- o Date and name(s) of individual(s) making entry.
- o Description of the activity attempted, including detailed step-by-step process followed; either by reference to TIPS or by actual entry into the notebook.
- o Description of any conditions which may adversely affect the results of the experiment or research.
- o Identification of samples used and any additional equipment and materials not included as part of the initial entries.

- o All data taken and a brief description of the results, including notation of any unacceptable results.
- o Any deviations from the planned experiment or research.
- o Any interim conclusions reached as appropriate.

Modifications may be made by the individual performing the work if the change or modification is 1) within the scope of the planning document(s) and 2) the investigation is repeatable and 3) the change or modification does not potentially impact the waste isolation capability of the site or interfere with other site characterization activities. Otherwise, revision and approval of the work per section 3.4.8 is required.

Certain types of information may be inappropriate to enter directly into the scientific notebook. This could include large volumes of data, computer printouts, etc. In these cases, references to the information may be recorded in the scientific notebook provided the information is adequately identified and controlled.

When a notebook is in use for periods over a year, completed pages are photocopied annually for retention by Document Control.

#### 3.4.8 REVIEW AND APPROVAL

Scientific Notebooks are primarily intended for recording data and do not go through the same review, approval and revision process as revision controlled planning documents. Nonetheless, if Scientific Notebooks are used as planning revision documents they must be approved. The next level of project management above the Principal Investigator completes and signs a checklist which he affixes in the scientific notebook. The YMP QA Manager and Technical Area Leader also sign this checklist as confirmation that quality and programmatic related items have been addressed. A sample checklist is shown in Exhibit A. The Technical Area Leader may also direct that a revision to the Activity Plan be initiated if the revision is evaluated as significant.

Final entries in the notebook are signed by the Principal Investigator or Task Leader and a competent technical reviewer.

#### 3.4.9 RETAINED DOCUMENTATION

- o Transmitted by the Principal Investigator/Task Leader to Document Control as QA Records.
  - Scientific Notebooks.
  - Data sheets or other records referenced in the notebook.

EXHIBIT A

Scientific Notebook Control Checklist

- |  | <u>Completed</u> | <u>N/A</u> |
|--|------------------|------------|
| o TIPS approved  | [ ]              | [ ]        |
| o Quality Procedures identified & implemented            | [ ]              | [ ]        |
| o Applicable prework activities complete                 | [ ]              | [ ]        |
| o Personnel training/qualification requirements complete | [ ]              | [ ]        |
| o Verification performed                                 | [ ]              | [ ]        |
| o Activities traceable through scientific notebook       | [ ]              | [ ]        |
| o Records identified                                     | [ ]              | [ ]        |
| o Activities meet objectives of planning document(s)     | [ ]              | [ ]        |
| o Interfaces identified & controlled                     | [ ]              | [ ]        |
| o Other  |                  |            |

Approvals

\_\_\_\_\_ Title \_\_\_\_\_ Date

\_\_\_\_\_ Title \_\_\_\_\_ Date

\_\_\_\_\_ Title \_\_\_\_\_ Date



## CHANGE NOTICE

CN No. 4.0-0-1Affected Document: QP 4.0, "Procurement Control and Documentation"Revision: 0Prepared By Ronald SchwartzApproved By N/A

Technical Area Leader

Date

Approved By *R. M. Schwartz* 3/15/89  
YMP QA Manager DateApproved By *J. M. Mellon* 3/15/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 4.0.5.4, first paragraph, first line:

The Resource Manager reviews the ...

2. Section 4.0.5.5, eighth paragraph, last sentence:

... a copy of procurement documents ... is sent to the DOE Project Office QA Manager.

Changed to Read:

1. Section 4.0.5.4, first paragraph, first line:

The Resource Planning and Control Manager (Resource Manager) reviews the ...

2. Section 4.0.5.5, eighth paragraph, last sentence:

... a copy of procurement documents ... is sent to the DOE Project Office QA Manager and the T&amp;MSS Project QA Department.

**NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT**

Change Notice 4.0-0-1

Currently Reads as Follows:

3. Section 4.0.5.11A(b), last sentence:

The technical representative ... sends for inclusion in the procurement action folder.

4. Section 4.0.7, add new second paragraph

(See below).

Changed to Read:

3. Section 4.0.5.11.A(b), last sentence:

The technical representative sends a copy of this documentation to Procurement and Quality Assurance for inclusion in the procurement action folder and to the supplier.

4. Section 4.0.7, add new second paragraph:

QA records generated by the implementation of this procedure vary based on the nature of the procurement action.

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

PROCUREMENT CONTROL AND DOCUMENTATION

Approved:

Approved by: *D. S. Seltman* 1/28/89  
 YMP Project Leader

Approved by: *R. L. E. Smith* 1/18/89  
 YMP Quality Assurance  
 Manager

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#### 4.0.1 PURPOSE

This procedure specifies the LLNL Yucca Mountain Project (YMP) control and documentation requirements for procurement actions. The procedure describes the implementation of these controls and the development of a procurement document package.

#### 4.0.2 SCOPE

This procedure addresses the quality requirements for the procurement of items and services for use in the YMP designs and scientific investigations. The following procurement classes are covered in this procedure:

- a) Exempt items and services - This procedure provides for the identification of exempt procurement activities.
- b) Commercial Grade - This procedure allows for the use of commercial grade items and services for any quality level, provided that the appropriate quality is provided by that item or service.
- c) Quality Level III - This procedure identifies this quality level as the LLNL standard practices.
- d) Quality Levels I and II - This procedure prescribes the requirements for procurement activities for those quality levels that have been determined in accordance with Procedure No. 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance."

#### 4.0.3 RESPONSIBILITIES

This procedure prescribes specific responsibilities for the originator of the procurement (the requestor), the technical representative, the appropriate Task Leader, the Resource Planning and Control Manager (Resource Mgr.), and the QA Manager.

The YMP Project Leader is responsible for the implementation of this procedure. The QA Manager is responsible for assuring that this procedure is implemented and remains effective.

To assure each YMP procurement is identified with the appropriate activity and the attendant Level of Quality Assurance, the QA Manager reviews documentation pertaining to each procurement action. For procurement actions supporting Level of Quality Assurance I and II activities and for commercial grade procurements, the QA Manager reviews the original procurement document. For procurement actions supporting Level of Quality Assurance III and exempt (administrative) activities, a review by the QA Manager of an informational copy of the procurement document is sufficient.

Disagreements concerning the activity with which a procurement action should be identified are resolved among the QA Manager, the Task Leader, and the Project Leader.

#### 4.0.4 TERMS AND DEFINITIONS

Exempt Activity: An exempt activity is one that need not comply with the requirements specified in this procedure. All administrative activities are exempt activities. See Exhibit B for a list of exempt activities.

Requestor: The individual originating the procurement action. If the requestor is a Task Leader or above, then that same individual has responsibility for fulfilling the responsibilities assigned to the Task Leader by this procedure.

Technical Representative: The individual assigned responsibility by the Task Leader for technical decisions related to the procurement action. The technical representative is likely to be the requestor, but need not be. The Task Leader can serve as the Technical Representative.

Commercial Grade Item: An item ordered from the manufacturer or supplier on the basis of specifications in the manufacturer's published product description.

SANL: The DOE established system that enables the Laboratory to obtain goods and services from DOE Weapons Complex integrated contractors, other DOE prime contractors, Federal agencies, and the military. The Special Materials Office of the Weapons Engineering Department handles these requests. The acronym "SANL" ("SAN" - San Francisco Regional Office/DOE and "L" - LLNL) is LLNL's identifier within this system.

#### 4.0.5 PROCEDURE

A procurement action supports the accomplishment of objectives for an activity (or activities) described in a Scientific Investigation Plan (SIP), work planning document, or Technical Implementing Procedures.

##### 4.0.5.1 General Procurement Requirements

Items and services governed by this procedure are procured either through the LLNL Procurement Department or the LLNL Special Materials Office. All procurements handled through the Procurement Department require completion of a Purchase Requisition Form (LL 2350-2). Additional forms may be required depending upon the type and amount of the procurement. Requests for placing a SANL are made by memorandum to the Special Materials Office.

When a commercial grade item is to be used as an integral part of a design, the item is identified in an approved design or design output document. An alternate commercial grade item may be supplied if the supplier provides verification that the alternate item will perform the intended function and will meet the requirements applicable to both the replaced item and its application.

Commercial grade items or services procured may be used to support designs or scientific investigation activities having any Level, provided, that a determination is made by the Task Leader and documented in work planning documents or activity records that the item or service procured is applicable to the activity, and that it provides the proper level of quality as called for by that activity. Calibration requirements for commercial grade items are met prior to use.

Note: Refer to Exhibit A for a graphic depiction of the Procurement Process showing identification as commercial item prior to QA level determination.

#### 4.0.5.2 Preparation of Procurement Documents

Once the need for the procurement action has been established, the requestor determines whether the procurement is for an exempt item (See Exhibit B) or service. If the procurement activity is for an exempt item or service the requestor notes that status on the procurement document, completes the procurement documentation, and forwards the procurement package to the Task Leader for review and approval.

If the item or service is not exempt, the requestor must then determine whether the item or service is of commercial grade. When a commercial grade item is to be procured, the procurement documents include or reference the manufacturer's published product description and catalog number. Provisions for inspections and, as appropriate, acceptance tests for its capabilities and/or characteristics not expressly stated in the manufacturer's catalog are stipulated in the procurement document. When the item or service is of commercial grade, the requestor notes that status on the procurement documentation, and forwards the procurement package to the Task Leader for review and approval.

If the procurement is neither exempt nor commercial grade, the requestor then determines the QA Level applicable to the procurement. The requestor verifies the quality assurance level of the activity for which the procurement will be placed in accordance with Procedure No. 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance." If the procurement will support more than one activity, the most stringent QA level assigned to an activity the procurement will support is applicable.

The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by LLNL. Procurement activities that fall into this category are identified as such by the requestor on the procurement documents which are then forwarded for review and approval to the Task Leader.

If the procurement supports a QA Level I or II activity, the requestor identifies the QA Level on the procurement document and attaches a Procurement Document Review Form (Exhibit E). The following specifications are included in the procurement package:

- A. Scope of Work -- The scope of work defines the work to be accomplished and includes a statement an schedule of deliverables and their documentation.
- B. Technical Requirements -- The technical requirements include specifications, standards, codes and procedures that are to be followed. In-process reviews and acceptance tests necessary to evaluate conformance of an item or service to the technical requirements are specified.
- C. Subcontractor Quality Assurance Requirements -- Subcontractors are to provide or follow a quality assurance program consistent with pertinent provisions of the YMP QAPP. The quality assurance program requirements, including record retention, deposition, and time of submittal, are specified in a statement attached to the procurement document (see Exhibit C). The extent of the program required depends upon the type and use of the item or service being procured. The procurement documents require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.
- D. Right of Access -- All procurement actions in support of Level of Quality Assurance I and II activities must provide for access to the supplier's facilities and to procurement-related records by LLNL personnel and its authorized representatives (see Exhibit D). Right of access assures access for the purposes of conducting inspections, audits, and surveillances of the supplier's facilities and quality-related records.

Access to YMP participating organizations, NTS Support Contractors, and DOE prime contractors is through the appropriate DOE regional office. DOE Project Office access to subtier contractor facilities is arranged by LLNL.

- E. Spare Parts -- Appropriate spare and replacement parts or assemblies and the appropriate technical and quality related data required for ordering these parts or assemblies are identified. The technical and quality assurance requirements of spare and replacement parts must be equal to the original item procured. If the QA or technical requirements of the original item cannot be determined, then an engineering evaluation is conducted by qualified individuals to establish the requirements. The evaluation considers the interchangeability, function, and safety of the item. The evaluation is documented.
- F. Maintenance Contracts -- The terms of a maintenance contract may be made part of the procurement document.
- G. Shipping - Instructions for handling, shipping, and storage are included if required. Requirements are identified in Procedure No. 033-YMP-QP 13.0, "Handling, Storage and Shipping."

The requestor forwards the completed procurement document package to the Task Leader of the activity (or activities) for review and approval.

#### 4.0.5.3 Task Leader's Review

The Task Leader reviews the procurement document package to assure that the procurement is appropriate and that the document contains all required information.

After completing his review, the Task Leader prepares and signs the Procurement Document Review Form (see Exhibit E) and attaches the form to the procurement document or packages.

The Task Leader forwards the procurement document package to the Resource Manager.

#### 4.0.5.4 Resource Planning and Control Manager's Review

The Resource Manager reviews the Procurement Document Review Form to verify that all appropriate information has been entered by the Task Leader. Questions concerning this information are resolved with the Task Leader. The Resource Manager completes and signs the Procurement Document Review Form.

If the procurement action is for technical services pertaining to a scientific investigation, then the document package is forwarded to the YMP Project Leader for review and approval. Approval is indicated by signature on the Procurement Document Review Form. The document package is then returned to the Resource Manager.

For QA Level I and II procurements and commercial grade procurements, the Resource Manager forwards the procurement document package to the QA Manager. For procurement actions supporting Quality Assurance Level III or exempt (administrative) activities, the Resource Manager forwards an informational copy of the procurement document to the QA Manager.

#### 4.0.5.5 QA Manager's Review

The QA Manager reviews all procurement document packages to assure each is identified with the appropriate activity and the attendant Level of Quality Assurance or exempt status.

The QA Manager assures that the required information prescribed by this procedure is contained in the procurement package, including:

- a. For QA Level I and II procurements, provisions for reviewing and approving QA Program Plans of subcontractors are provided.
- b. For commercial grade procurements, provisions for verifying technical characteristics of items are provided.

The QA Manager assures that qualified personnel are assigned for any necessary QA Level I and II pre-award surveys, audits, or source inspections. The QA Manager assures that there are adequate acceptance and rejection criteria.

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When the document package satisfies the requirements of this procedure, the QA Manager signs the Procurement Document Review Form. For QA Level I and II, and commercial grade procurement, the QA Manager stamps the procurement document with a request that the Procurement Department return copies of the contract award documents to YMP Quality Assurance. SANLs are stamped with a message that the Special Materials Office is to return copies of processed SANLs to the Resource Manager.

For QA Level III and Exempt procurements, the QA Manager verifies that the assigned status is consistent with the activity for which procurement is being conducted. If it is not, the responsible Task Leader is notified and the issue is resolved.

For QA Level I and II procurements, and commercial grade procurements, the QA Manager creates and maintains a separate folder (the procurement action folder) for each procurement action. The QA Manager makes a copy of the procurement document package and places it in the appropriate folder.

For QA Level III and Exempt procurements, the QA Manager retains the information copy of the procurement document for a minimum of one year in order to support routine audits and surveillances.

The QA Manager retains the original Procurement Document Review Form in the appropriate folder. When purchases involve Quality Assurance Level I and II items and services, a copy of procurement documents identifying the vendor, the scope of work, and when work is to start is sent to the DOE Project Office QA Manager.

The QA Manager maintains Procurement and SANL Logs (Exhibits F and G). The QA Manager enters the Procurement requisition or SANL memorandum number (assigned by the Special Materials Office) and applicable information on the appropriate log.

#### 4.0.5.6 Changes to Procurement Documents

Changes to QA Level I or II procurement documents or SANLs at any point during the procurement process are subject to review by the Task Leader, Resource Manager, and QA Manager, consistent with all the procedures prescribed under Section 4.0.5. The review of such changes and their effect is completed and documented prior to contract award. The review of changes includes the following considerations: additional or modified scope of work; exceptions or changes requested or specified by the supplier. A determination is made of the effect such changes have on the intent of the procurement and the quality of the item or service being procured. If there are changes to the procurement documents during the review process, a copy of the revised document package is sent to the requestor and the responsible Task Leader. The DOE Project Office QA Manager is sent copies of changes to QA Level I procurement documents relating to vendor identification, work scope, or work start schedule.

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#### 4.0.5.7 Procurement Categories

Procurement actions fall into one of four categories: (A) sole source procurement actions of greater than \$10K value handled by the Procurement Department, (B) memorandum request actions (SANLs) handled by the Special Materials Office, or (C) procurement actions subject to bid, and (D) procurements of less than \$10K value for off-the-shelf items. Depending upon the individual procurement action, Section 4.0.5.7A, 4.0.5.7B, or 4.0.5.7C is referenced.

##### 4.0.5.7A Sole Source Procurement Actions Handled by the Procurement Department

The QA Manager follows up with the LLNL Procurement Department every 30 days from the point the procurement action is forwarded until the requested copies of the purchase award documents are obtained from the Procurement Department or the requestor.

When the copies are received by Quality Assurance, the copies are compared with the original request. If the award documents include the provisions of the original request, the Procurement Log is updated and the award documents are added to the procurement action folder.

If the award documents returned by the Procurement Department do not reflect the provisions of the original request, the QA Manager notifies the Task Leader. The QA Manager, assisted by the Task Leader and the requestor, resolves the matter with the Procurement Department. Upon resolution, the log is updated and the award documents are added to the procurement action folder.

##### 4.0.5.7B Procurement Actions (SANLs) Handled by the Special Materials Office

Upon receipt of the processed SANL document from the Special Materials Office, the Resource Manager forwards a copy to the QA Manager and the Task Leader.

The QA Manager compares the SANL with the original request. If the SANL includes the requested provisions, the log is updated and the copy of the SANL is added to the procurement action folder.

If the copies returned by the Special Materials Office do not reflect the requirements that were originally requested, the QA Manager notifies the Task Leader. The QA Manager, assisted by the Task Leader and requestor, resolves the matter. Upon resolution, the log is updated and the copy of the SANL is added to the procurement action folder.

##### 4.0.5.7C Procurement Actions Subject to Bid

A bid evaluation team may be formed by the LLNL Procurement Department's Liaison to evaluate the bids. Bid evaluation teams are composed of the technical representative(s), and the LLNL Procurement Department's Representative. Prior to the evaluation, the team establishes written evaluation criteria. As applicable to the item or service being procured, the following quality assurance criteria are established and applied: (a) technical considerations; (b) QA requirements; (c) supplier's personnel; (d) supplier's production capabilities or research facilities; (e) supplier's experience or past performance; (f) alternates; (g) exceptions; and (h) other criteria as appropriate.

Before the award of the contract, unacceptable quality assurance conditions identified during the bid evaluation are resolved or a commitment to resolve the unacceptable conditions is obtained from the supplier.

The QA Manager is responsible for approving the successful bidders QA program.

#### 4.0.5.8 Source Evaluation

Source evaluations, when deemed appropriate by the Task Leader and/or the QA Manager, are conducted through the Procurement Department to determine a potential supplier's ability to provide an item or service in accordance with the procurement requirements. The determination of the supplier's capabilities is conducted and documented prior to the award. The determination of the supplier's capabilities is made by qualified personnel (as determined and verified by the technical representative) based on one or more of the following:

(a) evaluating the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. Current capability of the supplier is evaluated;

(b) conducting a pre-award survey of the supplier's technical and quality capabilities; and

(c) evaluating the supplier's current quality assurance records supported by documented qualitative and quantitative information that can be objectively evaluated.

The method of determining the supplier's capabilities is documented by the requestor (or technical representative) and the Procurement Department Contract Administrator. The documentation is provided to Quality Assurance for inclusion in the procurement action folder.

A qualified suppliers list is maintained by the YMP Program. Each evaluation of a supplier is documented and maintained in a file accessible by appropriate index identities. Provision is also made for the incorporation into the qualified suppliers list of other organizations evaluation data, provided that the other organization selected the supplier based on a quality assurance program meeting the requirements of YMP. The intent of this provision is to allow the use of supplier evaluation information obtained by other participants in the YMP Program.

#### 4.0.5.9 In-Process Evaluations

When required, the Technical Representative and the QA Manager conduct Verification activities as early as practicable. LLNL's verification activities do not relieve the supplier of its responsibilities for verification of quality achievement.

As specified in the procurement document package, the technical representative and the QA Manager conduct in-process evaluations of the supplier's performance. The technical representative, with assistance from the QA Manager, is responsible for establishing methods to monitor the supplier's performance. Examples of methods that can be used include:

- (a) requiring the supplier to identify planning techniques to fulfill the procurement objective;
- (b) reviewing supplier documents that were created to fulfill the procurement objective;
- (c) establishing the extent of in-process source surveillance and inspections; and
- (d) conducting audits.

The technical representative and the QA Manager prepare documentation of the in-process monitoring activities. The technical representative sends a copy of this documentation to Quality Assurance for inclusion in the procurement action folder.

#### 4.0.5.10 Nonconformances

Nonconformances are controlled at the time of discovery in accordance with the supplier's applicable quality assurance procedures. The supplier is required to notify the technical representative of any nonconformance. This includes any violation of a technical or material requirement; a violation of a requirement in the supplier documents; a nonconformance that cannot be corrected by continuation of the original manufacturing process or by rework; or when the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired. The supplier's submittal includes a proposed disposition and technical justification for the proposed disposition. The technical representative notifies the QA Manager that a nonconformance has been discovered and proposes a disposition. The QA Manager evaluates the proposed disposition. (In instances where the proposed disposition could have a cost impact on the order, the QA Manager consults with the Procurement Department Representative regarding the proposed disposition.) When deemed appropriate by the QA Manager, a Corrective Action Report is filed consistent with Procedure No. 033-YMP-QP 16.0, "Corrective Action." The technical representative and the QA Manager verify disposition implementation. The technical representative is responsible for documenting the nonconformance, the disposition, and the verification of implementation. The technical representative sends a copy of this documentation to Quality Assurance for inclusion in the procurement action folder. Upon receipt of this documentation and independent verification, the QA Manager closes the nonconformance. These documented steps are retained in the procurement action folder.

An item or service cannot be accepted and/or the procurement action closed if there is an open nonconformance pertaining to the procurement.

#### 4.0.5.11 Acceptance

Procurement actions are for one of three types of commodities: (A) items other than commercial grade, (B) commercial grade items, or (C) technical services. Depending on the individual procurement action, Section 4.0.5.11A, 4.0.5.11B, or 4.0.5.11C is referenced. Means are implemented to assure that the submittal of documents generated by the supplier is accomplished in accordance with the procurement document requirements. These measures provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

##### 4.0.5.11A Items Other than Commercial Grade

The technical representative is responsible for acceptance of the procured item by one or more of the following:

(a) Certificate of Conformance -- The certificate, issued by the supplier, identifies the purchased material or equipment and the specific requirements (such as codes, standards, or other specifications) met. The certificate identifies any procurement requirements that have not been met together with an explanation and the means by which to resolve the nonconformances.

The certificate is attested to by a person who is responsible for this QA function and whose function and position are described in the supplier's QA program. The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, are described in the supplier's QA program. Means are established by the technical representative to assure the validity of the supplier's certification. The technical representative sends a copy of this documentation to Procurement and Quality Assurance for inclusion in the procurement action folder.

(b) Source Verification -- Source verification consists of inspections, examinations, and/or tests performed during the manufacturing stage ("in-process"). Source verification may also be an acceptance test of an item at the supplier's facility. Source verification is performed by qualified personnel whose qualifications are determined, verified, and documented by the technical representative. Source verifications are performed using written procedures that specify the requirements and criteria for acceptance of an item. If source verification is used then it is performed at intervals that are consistent with the importance and complexity of the item or service and it is implemented to monitor, witness, or observe activities. All source verifications are documented by the technical representative. The technical representative sends a copy of this documentation to Procurement and Quality Assurance for inclusion in the procurement action folder.

(c) Receiving Inspection -- A receiving inspection ("end item") is performed at the destination (i.e., location of receipt) to evaluate an item for shipping damage, loss of parts, or any other problem that might affect the item's performance. A receiving inspection is performed by qualified personnel whose qualifications are determined and verified by the technical representative. Receiving inspections are performed using written procedures that specify the requirements and criteria for acceptance of an item. Receiving inspections are coordinated with review of supplier documentation when procurement documents require such documentation be furnished prior to the receiving inspection. Receiving inspections associated with engineered items are planned, performed, and documented in accordance with the Procedure No. 033-YMP-QP 10.0, "Inspections". Personnel selected for receipt inspection activities have experience or training commensurate with the scope, complexity, or special nature of the activities. When required, personnel are also indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable. All receiving inspections are documented by the technical representative. The technical representative sends a copy of this documentation to Procurement and Quality Assurance for inclusion in the procurement action folder.

(d) Post-Installation Testing -- Post-installation testing is performed using written procedures that specify the requirements and criteria for acceptance of an item.

When post installation testing is used, test requirements and acceptance documentation is established mutually by LLNL and the supplier. Post-installation testing is performed by qualified personnel whose qualifications are determined and verified by the technical representative. Post-installation test results are documented by the technical representative. The technical representative sends a copy of this documentation to Procurement and Quality Assurance for inclusion in the procurement action folder.

Upon receipt of this documentation by Quality Assurance, the procurement action is considered closed for quality assurance related purposes.

#### 4.0.5.11B Commercial Grade Items

A visual inspection of the item when received is performed by the LLNL Receiving Department to verify that there was no damage during shipping and that the item received was the item ordered. When additional acceptance testing is specified in the procurement document, tests are performed using written procedures. The acceptance testing is documented by the technical representative. The technical representative sends a copy of this documentation to Quality Assurance for inclusion in the procurement action folder.

If applicable, acceptance of the item may be accomplished via a calibration program in accordance with the Procedure No. 033-YMP-QP 12.0, "Control of Measuring and Test Equipment." If acceptance testing is not required, the technical representative sends a copy of the receiving document to Quality Assurance for inclusion in the procurement action folder.

Upon receipt of this documentation by Quality Assurance, the procurement action is considered closed for quality assurance related purposes.

#### 4.0.5.11C Technical Services

The Technical Representative may accept technical services by any or all of the following methods:

- (a) verifying the data or results produced;
- (b) conducting a surveillance and/or audit of the activity; and
- (c) reviewing objective evidence for conformance to the requirements specified in the procurement documents.

Acceptance methods are performed by qualified personnel whose qualifications are determined and verified by the technical representative. The technical representative documents the service acceptance and sends a copy of this documentation to Procurement and Quality Assurance for inclusion in the procurement action folder.

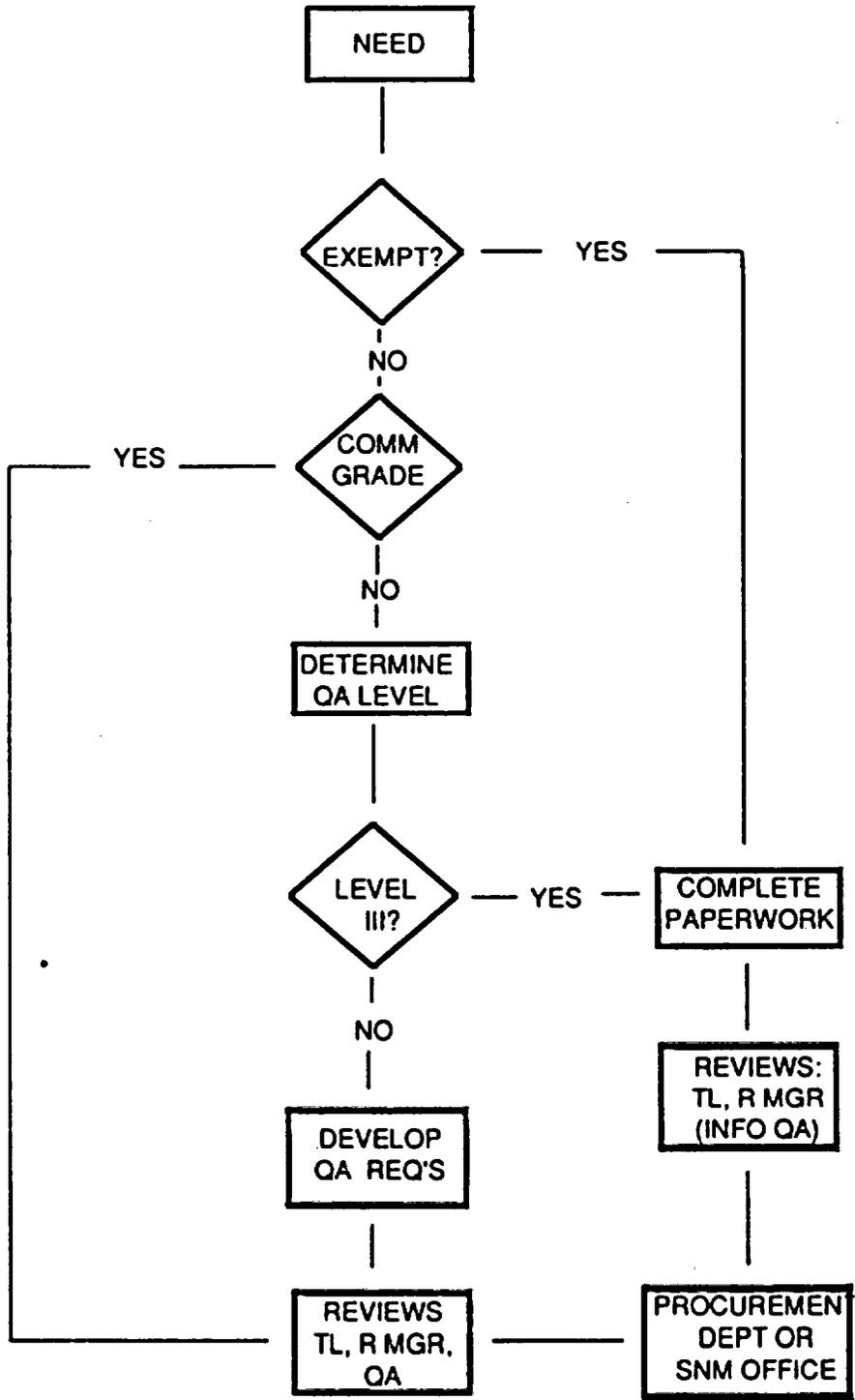
Upon receipt of this documentation by Quality Assurance, the procurement action is considered closed for quality assurance related purposes.

#### 4.0.6 USE OF PROCURED MATERIAL AND EQUIPMENT

Where required by code, regulation, or contract requirement, documentary evidence that material and equipment conform to the procurement requirements is available at the location where the material or equipment is to be used prior to the installation or use of such material and equipment. The documentary evidence is sufficient to identify the specific requirements, such as codes, standards, or specifications, that are to be met by the purchased material and equipment.

#### 4.0.7 RETAINED DOCUMENTATION

Documents contained in a procurement action folder become quality assurance records when the procurement action is closed. The Procurement Log and SANL Log maintained by the QA Manager are also quality assurance records. These records are collected, stored, and maintained in accordance with Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."



**EXHIBIT A  
PROCUREMENT ACTIVITY SEQUENCE**

Activities associated with the following are exempt:

<u>Account</u>	<u>WBS</u>	<u>Title</u>
6067	1.2.2.1	WP Management
6074	1.2.5.2.3	Regulatory Compliance Documentation
6075	1.2.5.2.5	Study Plan Coordination
6076	1.2.5.2.6	SCP Program Reports
6085	1.2.5.2.1	Regulatory Interactions
6086	1.2.5.2.2	SCP
6094	1.2.9.1.4	Records Management
6095	1.2.9.1.1	YMP Project Management
6098	1.2.9.2	Project Control
6099	1.2.9.3	Quality Assurance

**EXHIBIT B**  
**EXEMPT ACTIVITIES**



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EXHIBIT D

Right of Access

Statements of Work include the following language, or its equivalent, regarding "right of access:"

The Lawrence Livermore National Laboratory and its authorized representatives shall have the right to inspect Government property and the work and activities of the Subcontractor/Seller and his Subcontractor(s) under this Subcontract/Order at such time and in such manner as the University shall deem appropriate. The Subcontractor/Seller shall include in all subcontracts and purchase orders under this Subcontract/Order a similar provision making this paragraph applicable to his subcontractor or vendor.

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	YUCCA MOUNTAIN PROJECT Page _____ of _____
<b>PROCUREMENT DOCUMENT REVIEW FORM</b>	
Technical Contact: _____ Ext.: _____ Activity Number: _____ QA Level _____ <input type="checkbox"/> Goods <input type="checkbox"/> Services <input type="checkbox"/> Both <input type="checkbox"/> Commercial Grade <input type="checkbox"/> Procurement <input type="checkbox"/> SANL    Est. Cost: _____ Procurement No.: _____ Account No. _____ Procurement Objective: _____ _____ _____ _____ _____	
I have reviewed the attached procurements and concur that they are technically adequate to meet the stated procurement objective. _____ Date: _____ Account Manager/Task Leader	
I have reviewed the attached procurement documents and concur that they are complete and accurate. _____ Date: _____ Resource, Planning and Control Manager	
<u>TECHNICAL SERVICE CONTRACTS</u> I have reviewed and approve this Technical Services Contract. _____ Date: _____ YMP Project Leader	
I have reviewed the attached procurement documents and concur that they contain the necessary Quality Assurance requirements to meet the stated procurement objective. _____ Date: _____ YMP Quality Assurance Manager	
Copied/Logged by QA: _____ Date: _____	

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**EXHIBIT E  
PROCUREMENT DOCUMENT REVIEW FORM**

EXHIBIT F  
PROCUREMENT LOG

<u>Account</u>	<u>Purchase Requisition</u>	<u>Purchase Order</u>	<u>Procurement Date</u>	<u>Procurement Cost</u>	<u>Requestor</u>	<u>Level</u>	<u>To WMPO</u>	<u>Follow-Up Date</u>	<u>Closed</u>
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(Note: This is a suggested format only.  
Final format is the responsibility of the user.)

EXHIBIT G  
SANL LOG

<u>Account</u>	<u>SANL Number</u>	<u>Request Date</u>	<u>SANL Cost</u>	<u>Requestor</u>	<u>Subcontractor</u>	<u>Level</u>	<u>To WMPO</u>	<u>Follow-up Date</u>	<u>Closed</u>
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(Note: This is a suggested format only.  
Final format is the responsibility of the user.)

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:  
Quality Assurance Requirements Specifications

Approved:

Approved by: [Signature] 3/14/89  
YMP Project Leader

Approved by: [Signature] 3/13/89  
YMP Quality Assurance  
Manager

#### 4.1.1 PURPOSE

This procedure establishes the methods for developing, controlling and using Quality Assurance (QA) Requirements Specifications for subcontractors performing work in support of the Yucca Mountain Project, and for approving subcontractor QA Programs.

#### 4.1.2 SCOPE

This procedure applies to QA Level I and II activities that are subcontracted by the LLNL-Yucca Mountain Project where the supplier is required to prepare and implement a Quality Assurance Program. As used in this procedure, the term subcontractor includes organizations performing work under DOE Letter Agreements through various DOE Operations Offices.

#### 4.1.3 DEFINITIONS

Generic QA Requirements Specification: A document containing all relevant requirements from the LLNL-YMP Quality Assurance Program Plan that may be applicable to the activities of a subcontractor.

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**Subcontract QA Requirements Specification:** A document derived from the Generic QA Requirements Specification that has been tailored to the specific requirements applicable to a subcontractor derived from the QA Level Assignments of the activities to be accomplished by that subcontractor.

#### 4.1.4 RESPONSIBILITIES

The YMP Project Leader is responsible for approving the Generic QA Requirements Specification and the Subcontract QA Requirements Specifications prepared for each subcontractor.

The YMP QA Manager is responsible for preparing and maintaining the Generic QA Requirements Specification, reviewing and approving Subcontract QA Requirements Specifications provided to subcontractors, and approving subcontractor QA Programs.

The Technical Area Leaders(TALs) are responsible for reviewing and approving Subcontract QA Requirements Specifications for subcontractors performing work within their area of responsibility.

The Task Leaders(TLs) are responsible for preparing Subcontract QA Requirements Specifications for subcontractors whose work they supervise.

The Records Manager is responsible for issuing control numbers and revision numbers to QA Requirements Specifications.

#### 4.1.5 PROCEDURE

##### 4.1.5.1 Preparation of the Generic QA Requirements Specification

The YMP QA Manager prepares the Generic QA Requirements Specification. This document includes the requirements contained in the LLNL-YMP QAPP that may be applicable to subcontractors performing work for the YMP. The completed specification is forwarded to the YMP Project Manager for approval. Upon approval, the YMP QA Manager obtains a control number and revision number for the approved Generic QA Requirements Specification from the Local Records Center, and distributes copies to the following:

- a. The YMP Project Manager;
- b. The YMP Deputy Project Manager;
- c. The YMP QA Manager; and
- d. All Technical Area Leaders.

##### 4.1.5.2 Preparation of QA Requirements Specifications

The cognizant Task Leader prepares the Subcontract QA Requirements Specification based upon the QA Level Assignments prepared in accordance with Procedure No. 033-YMP-QP 2.8, "Assigning Levels of Quality Assurance." The draft specification is submitted to the cognizant TAL and the YMP QA Manager for review.

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The YMP QA Manager and the cognizant TAL review the draft specification to assure adequate inclusion of QA Program requirements taking into consideration the scope of work, the QA Level Assignments and any other pertinent considerations. Comments are resolved directly with the Task Leader.

Upon resolution of the comments, the YMP QA Manager prepares the final Subcontract QA Requirements Specification and forwards it to the Task Leader.

The Task Leader reviews and approves and then submits the final Subcontract QA Requirements Specification to the cognizant TAL, the YMP QA Manager and the YMP Project Leader for approval. A copy of any comments and their resolution accompanies the document during the approval cycle.

Upon approval by the YMP Project Leader, the Task Leader obtains a control number and revision number from the Local Records Center, and forwards a copy of the specification to the Resource Manager for inclusion as a requirement in the subcontractor procurement package.

#### 4.1.5.3 Approval of Subcontractor QA Programs

The Task Leader obtains a controlled copy of the subcontractor's internally approved Quality Assurance Plan and Procedures and submits them to the YMP QA Manager for review and approval.

The YMP QA Manager reviews the submitted subcontractor QA Plan and Procedures to verify implementation of the requirements specified in the Subcontract QA Requirements Specification.

Comments are documented and forwarded to the Task Leader and subcontractor for resolution. A prequalification surveillance of the subcontractor's facility(ies) is performed. Upon satisfactory resolution of comments and any items identified during the surveillance, the QA Manager issues a memorandum to the Task Leader documenting approval of the subcontractor's QA Program and containing reference to the specific revision of the Subcontract QA Requirements Specification used as the source of requirements.

Work may not proceed until approval of the subcontractor's QA Program unless specifically authorized in writing by the YMP QA Manager.

#### 4.1.5.4 Changes to QA Requirements Specifications

Upon approval of each revision of the LLNL-YMP QAPP, the YMP QA Manager reviews the Generic QA Requirements Specification to assure that it contains the current requirements identified in the QAPP. If changes are necessary, they are processed in accordance with Section 4.1.5.1.

The YMP QA Manager notifies affected Task Leaders that the Generic QA Requirements Specification has been revised and assures that they receive a copy of the approved document.

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Affected Task Leaders review the revised Generic QA Requirements Specification and the existing Subcontract QA Requirements Specifications to assure that the Subcontract QA Requirements Specifications contain the requirements identified in the Generic QA Requirements Specification that are applicable to specific subcontracts.

Task Leaders also review Subcontract QA Requirements Specifications each time there is a change in the scope of work, or once each year to verify the continuing applicability of the Subcontract QA Requirements Specification. Changes to Subcontract QA Requirements Specifications are processed in accordance with sections 4.1.5.2 and 4.1.5.3. If no changes are required, the Task Leader prepares a memorandum to the YMP QA Manager stating that conclusion.

#### 4.1.6 RETAINED DOCUMENTATION

##### 4.1.6.1 QA Records

The following documents that result from the implementation of this procedure are QA Records and are forwarded to the Local Records Center upon completion for processing in accordance with QP 17.0, QA Records:

- a. Approved Generic QA Requirements Specifications and revisions thereto;
- b. Approved Subcontract QA Requirements Specifications and revisions thereto, including a copy of any resolved comments, or a memorandum stating that there were no comments;
- c. Memoranda approving specific subcontractor QA Programs, including a copy of any resolved comments, or a memorandum stating that there were no comments;
- d. Memoranda documenting reviews of Subcontract QA Requirements Specifications where no changes to the specification are necessary.

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

TECHNICAL IMPLEMENTING PROCEDURES

Approved:

Approved by: *[Signature]* 2/4/89  
YMP Project Leader

Approved by: *[Signature]* 1/12/89  
YMP Quality Assurance  
Manager

#### 5.0.1 PURPOSE

The purpose of this procedure is to describe methods for preparation and use of Technical Implementing Procedures (TIPs) in support of Quality Level I and II activities.

#### 5.0.2 SCOPE

TIPs are documented, approved procedures which provide detailed direction for the performance of work. They include instructions, procedures, plans, sketches, drawings or other information to define and control operations which do not require technical judgement and may be performed by qualified personnel.

#### 5.0.3 RESPONSIBILITIES

The Principal Investigator (PI), Task Leader (TL) or designee is responsible for:

- o Preparation and revisions of TIPs.
- o Overall conduct of work and reporting of results as described in the TIP.
- o Verification of personnel qualifications.
- o Assuring that the prerequisites defined in Paragraph 5.0.5 have been met.

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- o Maintaining scientific notebooks and other documentation until ready for transmittal as QA records.
- o Transmittal of QA records as described in Procedure 033-YMP-QP 17.0, "Quality Assurance Records."

The next level of project management above the individual performing the work is responsible for assuring that prior to and during the progress of work:

- o The work is proceeding according to the TIP.
- o Modifications or changes to the work are within the limitations stated in paragraph 5.0.9.2.
- o Revisions which may be required to the TIP are identified and implemented in a timely manner to allow the work to continue according to an approved plan.
- o The data collected and/or analysis performed meet the objectives of the TIP and will lead to a supportable conclusion.
- o Any required verifications have been performed.
- o Information contained in the recording documentation represents a traceable path throughout the course of the work activity.

The Technical Area Leader is responsible for:

- o Verification that TIPs meet the objectives of the Scientific Investigation Plans or other project planning documents.
- o Approval of TIPs.

The YMP Quality Assurance Manager is responsible for:

- o Verification that the TIP identifies and implements the applicable quality assurance requirements.
- o Approval of TIPs and revisions.

The YMP Project Leader is responsible for:

- o Approval of TIPs

#### 5.0.4 DESCRIPTION

TIPs are generally used when qualified personnel are performing repetitive work that does not include the use of professional judgement or trial and error methods. TIPs are used when it is not possible to deviate from a prescribed sequence of actions, without compromising the quality of the results that will be obtained from the work. Scientific notebooks, data sheets or both may be used to record data and document the performance of the work.

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TIPs are prepared, reviewed and approved prior to use to provide detailed instructions for such activities as:

- o Measurements such as chemical analysis, physical and mechanical properties, etc.,
- o Control of samples and materials described in Procedure 033-YMP-QP 8.0, "Identification and Control of Items, Samples and Data."
- o Control of processes involving use of equipment or engineered systems described in Procedure 033-YMP-QP 9.0, "Control of Processes".

5.0.5 Technical Implementing Procedures include the following as applicable:

1. Title of the procedure;
2. Requirements, objectives, methods and characteristics to be tested or observed.
3. A stepwise or detailed description of the procedure sequence. The description must be sufficiently complete to assure that a person with the specified qualifications and with the specified materials and equipment will be able to reproduce the results of the test without additional information.
4. Special training or qualification requirements for personnel performing the procedure.
5. A list of materials to be used. The purchase of these materials is to comply with the requirements of 033-YMP-QP 4.0, "Procurement Control and Documentation".
6. Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions are established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the activity. For instrumentation and/or equipment used in data collection consideration is given to whether failure or malfunction of the instrumentation during the activity will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, procedures include any special provisions for equipment/instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.
7. Methods of documenting or recording data and results, including precision and accuracy.
8. Methods of data reduction if performed by other than the Task Leader or Principal Investigator.

9. Details of provisions to comply with the applicable sections of:

- o 033-YMP-QP 8.0 "Identification and Control of Items, Samples and Data"
- o 033-YMP-QP 9.0 "Control of Processes"
- o 033-YMP-QP 10.0 "Inspection"
- o 033-YMP-QP 11.0 "Test Control"
- o 033-YMP-QP 12.0 "Control of Measuring and Test Equipment"
- o 033-YMP-QP 13.0 "Handling, Storage and Shipping"
- o 033-YMP-QP 14.0 "Inspection, Test and Operating Status"

10. Personnel responsibilities.

11. Acceptance and rejection criteria and limits including required levels of precision and accuracy if performed by other than the Task Leader or Principal Investigator

12. Mandatory verification points (as required).

13. Quality Assurance Records that will be generated by the TIP are identified and include a description of how data and information will be recorded and identified for record purposes.

#### 5.0.6 ADDITIONAL CONSIDERATION

Procedures are complete to the extent that another qualified individual may, at a later date, reproduce the results.

Any potential sources of uncertainty and error that must be controlled and measured to assure that scientific investigations are controlled are identified. Parameters that need to be measured and/or controlled to minimize such uncertainties or error, and to ensure adequate control, are addressed explicitly in the procedures.

Any procedural deviations encountered during activities are authorized and documented by change notices as described in paragraph 5.0.8.3.

#### 5.0.7 EXISTING PROCEDURES

In lieu of specially prepared procedures, appropriate sections of existing procedures, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, or approved drawings may be used. If the referenced material does not completely describe the test being conducted, sufficient additional information must be developed or cited to ensure completeness.

## 5.0.8 PREPARATION, REVIEW AND APPROVAL OF TECHNICAL IMPLEMENTING PROCEDURES

### 5.0.8.1 Preparation

The TIP is prepared as a revision controlled document by the Principal Investigator, Task Leader or designee. The Title Page is as shown in Exhibit A.

### 5.0.8.2 Procedure Identification

Each Technical Implementing Procedure is identified by a number which is related to the originating technical area as follows:

TIP-CD N for Container Design  
TIP-GM N for Geochemical Modeling  
TIP-PE N for Package Environment  
TIP-PA N for Performance Assessment  
TIP-RR N for Release Rate  
TIP-QA N for Quality Assurance  
TIP-YM N for multiple technical areas

The TIP preparer assigns the appropriate technical area. The number N is assigned by Document Control.

### 5.0.8.3 Review

TIPs are reviewed, approved and revised as described in Procedure 033-YMP-QP 2.1, "Preparation, Approval and Review of Quality Procedures and Requirements." TIPs pertaining to multiple technical areas (TIP-YM) or Quality Assurance (TIP-QA) are approved by the YMP Project Leader and YMP QA Manager.

### 5.0.8.4 Status Control

Document Control maintains a log of TIP revisions and Change Notices. Controlled distribution is maintained through Document Control 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.

## 5.0.9 Documenting Work Progress

5.0.9.1 The method of documenting work progress is identified in the TIP. If a scientific notebook is used, entries are made in sufficient detail that another competent experimenter/researcher could repeat the work. Information includes, as applicable:

- o Date and name(s) of individual(s) making entry.
- o Description of the activity attempted, including detailed step-by-step process followed.

5.0.9.2 Modifications may be made by the individual performing the work if the change or modification is 1) within the scope of the planning document(s) and 2) the investigation is repeatable and 3) the change or modification does not potentially impact the waste isolation capability of the site or interfere with other site characterization activities. Otherwise, revision and approval of the work planning document(s) is required.

Certain types of information may be inappropriate to enter directly into the scientific notebook. This could include large volumes of data, computer printouts, etc. In these cases, references to the information may be recorded provided the information is adequately identified and controlled.

5.0.9.3 Entries shall comply with the following requirements:

- o Be legible, indelible and suitable for reproduction.
- o Securely affixed, if not written in directly.
- o Each page numbered sequentially.
- o No blank pages between entries.
- o To make corrections, line out with a single line so that original text is readable, then initial and date. Erasures and correction fluids are not permissable..

5.0.10 Retained Documentation

- o Retained by originator until at least the next revision:  
Returned review copies,
- o Transmitted by Document Control to sponsor as QA Records:  
Current and previously issued TIPs and Change Notices.  
Comment resolution meeting minutes.

**EXHIBIT A - TITLE PAGE  
for Technical Implementing Procedures**

<p><small>University of California</small>    <b>Lawrence Livermore National Laboratory</b></p> <p><b>NUCLEAR WASTE MANAGEMENT PROGRAM</b></p> <p>CONTROLLED COPY NO. _____</p>	<p>No.: TIP-PE-1</p> <p>Revision: 0</p> <p>Date:</p> <p>Page: _____ of _____</p>
<p>Subject: <b>PREPARATION OF ROCK SAMPLE WAFERS</b></p>	<p>Approved: <b>YMP Project Leader</b></p>
<p>Approved by: _____ Approved by: _____</p> <p>Technical Area Leader YMP Quality Assurance Manager</p> <hr/> <p align="center"><b>S A M P L E</b></p>	

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

DOCUMENT CONTROL

Approved:

Approved by:

*J. Spellan* 2/10/89  
YMP Project Leader

Approved by:

*R. W. Smith* 2/10/89  
YMP Quality Assurance  
Manager

### 6.0.1 PURPOSE

This procedure establishes the method for issue of controlled documents. The controls are established to assure proper documents prescribing work are available at the work location. These controls are also established to assure that documents have been appropriately approved and that procedures or records reflecting the documents' distribution are maintained. Separate procedures address the preparation, review, and approval of individual document types as well as coordination of interface documents.

### 6.0.2 SCOPE

This procedure applies to all controlled documents and their revisions required for activities by the Yucca Mountain Project (YMP) at Lawrence Livermore National Laboratory (LLNL). Controlled documents are identified in procedures which govern their preparation. Maintenance of master lists for controlled documents is addressed in this procedure.

Documents that are not subject to the document control requirements of this procedure may be subject to the records control requirements of Procedure 033-YMP-QP 17.0, Quality Assurance Records.

### 6.0.3 RESPONSIBILITIES

Responsibility and authority for the implementation and continued effectiveness of document control is delegated to the LLNL-YMP Records Manager.

The preparation, review and approval of documents subject to document control is discussed in individual procedures contained in the Quality Procedures manual. It is the responsibility of the originating task to assure that such documents are prepared, reviewed and approved in accordance with applicable procedure(s) and that the documents have been reviewed for technical adequacy, completeness, correctness and inclusion of appropriate quality requirements.

Recipients of controlled documents are responsible for maintaining their assigned copy; promptly returning signed receipt acknowledgments; returning, marking, or destroying obsolete or superseded documents; notifying the Local Records Center (LRC) of changes in name, position, address and employment status; and assuring that controlled documents are available at the work place.

#### 6.0.4 TERMS AND DEFINITIONS

**Controlled Document:** A document that prescribes an activity that has been assigned a Level of Quality Assurance I or II and is subject to revision and cancellation control, or that has been designated as controlled in accordance with requirements and procedures or by management of the YMP. Controlled documents include documents containing or specifying quality requirements, and documents that prescribe activities affecting quality.

See Appendix A of the Quality Procedures Manual for additional definitions.

#### 6.0.5 PROCEDURE

##### 6.0.5.1 General

Detailed procedures for receipt control, handling, distribution, issuing and retention of documents are discussed in implementing administrative procedure(s).

Documents received by or created by LLNL-YMP personnel (Record Source) will be processed in a centralized project local records center (LRC). Documents received are checked by the LRC for completeness against the transmittal, table of contents (if any), and for listed attachments and references; they are checked for legibility for microfilming and are verified that they are properly authorized against the signature authentication list. Incomplete or illegible documents or transmittals will be rejected by the LRC and returned to the Record Source for correction or completion and resubmittal.

##### 6.0.5.2 Controlled Document Types

The Records Manager will maintain a list of controlled document types which will include as a minimum:

- QA Program Plan
- Quality Procedures
- Technical Implementing Procedures
- Work Planning Documents
- Scientific Investigation Plans
- YMP Criteria Documents
- DOE Project Office Criteria Documents
- Computer Software Programs

### 6.0.5.3 Controlled Distribution

For controlled distributions, individuals will be assigned a unique control copy number and distribution will be made using a Receipt Acknowledgement Form (Exhibit 6.0 - A). Follow-up by telephone or memo will be made by the LRC in 10 working days for receipt acknowledgement forms not returned and the distribution list will be annotated for that contact.

If after another 10 working days the signed receipt has not been returned the LRC will contact the copy holder's manager for assistance in securing return of the signed receipt and will annotate the distribution list.

After an additional 10 working days if the signed receipt acknowledgement has still not been returned, the concurrence of the LLNL-YMP Project Leader will be obtained for the LRC to submit a nonconformance report to the Quality Assurance Manager in accordance with Quality Procedure 15.0.

It may be necessary for the LRC to issue controlled packets of documents, such as individual procedures rather than complete manuals. These will be issued in accordance with this section, using receipt acknowledgements and a document packet distribution list.

### 6.0.5.4 Obsolete or Superseded Documents

Distributed controlled documents that are made obsolete or are superseded shall be removed or marked to prevent inadvertent use. Document holders on controlled distribution will be contacted by the LRC and collection of documents will proceed in accordance with Section 6.0.5.5.

The document master list (Section 6.0.5.8) is updated and distributed to reflect the deletion of the document.

### 6.0.5.5 Removal of Individuals from Controlled Distribution

Individuals may be removed from a controlled distribution on completion of assignment, termination and for a document if that document is inappropriate for their function. With the exception of program management, authorization for the LRC to remove an individual from controlled distribution must come from the individual's supervisor or management. A Request for Collection of Document form (Exhibit 6.0 - B) will be sent to the individual requesting return of the controlled document to the LRC along with any quality assurance records created with the use of the controlled document. If requested, the LRC may provide the individual uncontrolled copies of the documents, stamped "uncontrolled".

### 6.0.5.6 Changes to Controlled Documents

Changes to documents are categorized as major or minor changes. Major changes require the same level of review and approval, and access to pertinent background data, as the original issue. The reviewing organization will, if applicable, specifically consider whether or not the activities being changed are repeatable, have the potential to impact the waste isolation capability of the site or interface with other site characterization activities.

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Minor changes do not require the same review and approval as the original document. Minor changes include spelling and grammar corrections, and inconsequential editorial corrections. The original record will be corrected by the record source by scribing a single line through the incorrect information using an indelible pen, preferably black ink, entering the correct information in close proximity, dating and signing or initialing the change. The incorrect information shall remain legible. Concurrence and approval to issue the change will be made by the LLNL-YMP Project Leader or Quality Assurance Manager. Minor changes will normally be issued by memorandum advising the document holder to mark the change in ink on the document or to replace a page of the document. For controlled distributions the revised document or change notice will be distributed to control copy holders in accordance with Section 6.0.5.3 with a receipt acknowledgement required.

Interim changes or change notices may be made to any controlled document with the approval of those who approved the original document. The change is placed at the front of the affected document and is issued along with a revised table of contents in accordance with Section 6.0.5.3.1. Interim changes remain in effect until the next revision of the document or until cancelled.

#### 6.0.5.7 Release of Preliminary Draft and Unverified Documents

It may be necessary to issue uncontrolled copies of controlled documents, such as procedures. To handle such requests, the LRC will stamp these copies "uncontrolled" prior to issue. Uncontrolled copies will not necessarily be reissued on subsequent revisions of the document.

The YMP may be required to issue for use a preliminary draft of a document containing data or conclusions that have not been verified. For the Yucca Mountain Project, for those documents assigned a Quality Level of I or II, the unverified portion of the document will be identified and controlled prior to transmittal. A copy of the document, with the unverified portion identified, will be delivered to the LRC with a Release Prior to Verification Form (Exhibit 6.0 - C) indicating the reason for the issue and bearing the approval of the LLNL-YMP Project Leader and the Quality Assurance Manager for release of the unverified information.

The LRC will stamp the document "Unverified - For Information Only" and issue the document on a controlled distribution. The LRC will maintain a log of releases of unverified documents. Such documents, when verified and approved, will be redistributed to copy holders.

#### 6.0.5.8 YMP Master Lists

The LRC develops and maintains document master lists for all controlled document categories, such as scientific investigation plans, procedures, and computer software programs. The master lists will reflect the current revision of documents and for the Yucca Mountain Project, will be distributed to the YMP Project Quality Manager, the SAIC/T&MSS Project Quality Assurance Department Manager and to designated LLNL-YMP personnel at least monthly.

The YMP master lists are the control for revision status of controlled documents. It is the responsibility of YMP document users to assure that they are working with the correct documents in accordance with the lists.

#### 6.0.6 INTERFACE DOCUMENTS

Documents received from sponsor organizations and other project participants will be processed through the LRC. The LLNL-YMP Project Leader or the Quality Assurance Manager may designate an interface document for controlled distribution. Such documents will be processed in accordance with Section 6.0.5.3.

#### 6.0.7 REFERENCES

DOE (U.S. Department of Energy), 1988. Nevada Nuclear Waste Storage Investigations Project Quality Assurance Plan, NNWSI/88-9, Revision 2.

NNWSI (Nevada Nuclear Waste Storage Investigations Project), 1988. Nevada Nuclear Waste Storage Investigations Project Records Management Plan, July 1988, NNWSI/88-15.

NNWSI Administrative Procedure AP - 1.5Q Issuance and Maintenance of Controlled Documents.

#### 6.0.8 RETAINED DOCUMENTATION

- o The original and all revisions of completed controlled documents generated by the YMP will be retained in Records and a controlled copy will be transmitted to the DOE Project Office in accordance with Procedure 033-YMP-QP 17.0.
- o Controlled distribution receipt acknowledgements, distribution lists and requests for collection of documents forms will be retained as part of the record package and will be transferred to the DOE Project Office when completed.
- o Release prior to verification forms and log, along with a stamped copy of the document, will be retained in Records and a copy will be transmitted to the DOE Project Office.
- o Document master lists will be retained in records and a copy will be transmitted to the DOE Project Office routinely.



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**REQUEST FOR COLLECTION OF DOCUMENTATION**

**REQUEST FOR COLLECTION OF DOCUMENTATION**

TO: \_\_\_\_\_ L - CODE \_\_\_\_\_ EXT. \_\_\_\_\_

THIS IS A REQUEST TO RETURN DOCUMENT NUMBER: \_\_\_\_\_

TITLE/ DESCRIPTION: \_\_\_\_\_

REASON: \_\_\_\_\_

WE ASK THAT YOU INDICATE BELOW WHICH OPTION YOU WILL USE FOR THE COLLECTION AND IDENTIFICATION OF DOCUMENTATION GENERATED THROUGH THE USE OF THIS DOCUMENT.

PLEASE IDENTIFY THE DOCUMENTATION WITH THE DOCUMENT'S NUMBER, REVISION NUMBER, AND THE ACTIVITY NUMBER THAT THE DOCUMENTATION SUPPORTS.

CHOOSE ONE OF THE THREE OPTIONS BELOW:

- ( ) SUBMIT ALL OF THE DOCUMENTATION IN ITS ORIGINAL FORMAT. PLACE THE RECORDS IN A BOX WITH A TRANSMITTAL AND SEND TO YMP LOCAL RECORDS CENTER.
- ( ) SUBMIT A DUPLICATE SET OF ALL DOCUMENTATION AS ABOVE.
- ( ) SUBMIT A LIST OF DOCUMENTATION, ITS LOCATION AND PROPOSED SUBMITTAL DATE TO YMP LOCAL RECORDS.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IF YOU WOULD LIKE A COPY OF THE DOCUMENT OR ITS ASSOCIATED DOCUMENTATION RETURNED TO YOU, PLEASE CONTACT YMP LOCAL RECORDS.

BY \_\_\_\_\_ (LRC) \_\_\_\_\_ (Date)



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NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0102

Subject:

CONTROL OF PURCHASED ITEMS AND SERVICES

Approved:

Approved by: *D. A. Ballan* 1/20/89 YMP Project Leader  
Approved by: *R. G. E. Smith* 1/18/89 YMP Quality Assurance Manager

Quality assurance requirements for control of purchased items and services are satisfied by the provisions of Procedure No. 033-YMP-QP 4.0, "Procurement Control and Documentation."

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

No.: 033-YMP-QP 8.0

Revision: 0

Date: **FEB 24 1989**

Page: 1 of 5

Subject:

IDENTIFICATION AND CONTROL OF ITEMS,  
SAMPLES, AND DATA

Approved:

Approved by:

*A. Bellan* 2/4/89  
YMP Project Leader

Approved by:

*R. E. Shultz* 1/19/89  
YMP Quality Assurance  
Manager

### 8.0.1 PURPOSE

The purpose of this procedure is to establish methods for the identification and control of items, samples, and data used in the Yucca Mountain Project (YMP). The establishment of controls and methods of identification will prevent the use of incorrect or defective materials, parts, and components.

### 8.0.2 SCOPE

This procedure applies to those items, samples, and data that must have their identity traceable to some point of origin and maintained to end-use. This procedure also applies to items or samples with a limited shelf or operating life.

### 8.0.3 RESPONSIBILITIES

The Task Leader (TL) whose activities warrant the use of this procedure is responsible for implementing the controls. The TL is also responsible for writing Technical Implementing Procedures (TIP's) required. TIP's are prepared, reviewed, and approved in accordance with the procedure 033-YMP-QP 5.0, "Technical Implementing Procedures." Procedures are issued in accordance with the procedure 033-YMP-QP 6.0, "Document Control".

The YMP Quality Assurance Manager (QA Manager) is responsible for monitoring the implementation of this procedure and for assuring the continued effectiveness of the applicable controls.

#### 8.0.4 IDENTIFICATION AND CONTROLS

This section describes the identification and controls necessary to be used for items (e.g. materials, parts, and components), samples, and data. Identification of items, samples, and data is verified prior to installation or use to assure traceability. This section is divided into three subsections: the first covers items; the second covers samples; and the third covers data.

##### 8.0.4.1 Identification and Control of Items

Controls are developed and implemented to assure that items are identified and controlled in a manner consistent with their intended use. Items are identified to assure that only correct and acceptable items are used or installed. These controls may be in the form of a TIP or stated as part of the work planning document as described in procedure 033-YMP-QP 3.0, "Scientific Investigation Control."

Items are identified when they are received, fabricated, stored, worked on, or shipped. This identification relates the material, part, or component to applicable documentation such as drawings, design specifications, drilling logs, test records, inspection documents, or nonconformance reports. When it becomes necessary to transship items to other destinations, controls are established to assure that their identities are maintained throughout the handling, shipping, and storage activities.

##### 8.0.4.1.1

Physical identification is used where practical. Where physical identification is either impossible or impractical, records or other methods are used, but traceability to the actual item is maintained.

##### 8.0.4.1.2

Identification markings are applied using materials and methods that provide clear and legible identification and do not adversely affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided. Markings are not obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. Methods are described and implemented to assure that items are not inadvertently mixed with like items.

##### 8.0.4.1.3

If codes, standards, or specifications include the requirement for unambiguous identification or traceability (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or inspection, test, or other records), measures are defined to provide identification and traceability control. Such identification and traceability control are intended to assure that materials, parts, and components are treated in a manner consistent with the intended use of the items and are traceable from receipt and fabrication of the items up to and including installation and use. The correct identification of materials, parts, and components is verified and documented prior to release for use.

#### 8.0.4.1.4

Items are handled and stored in a manner to prevent damage or deterioration due to aging or environmental exposure to the item identifier. Identifiers which are damaged or have deteriorated are replaced. A record is kept of all damaged or deteriorated identifiers. This record contains: the location and type of environment of the item identifier; describes the damage or deterioration; what is being done to prevent that from reoccurring; date of the occurrence; date the identifier is replaced; signature, initials or stamp of individual replacing the identifier. Traceability is maintained from the original item identifier through all subsequent replacement identifiers. Ways to protect items (materials, parts, and components) that might deteriorate from environmental exposure or that might be damaged during handling are defined and used. Additional detail for handling and storage on these procedures is found in procedure 033-YMP-QP 13.0, "Handling, Storage, and Shipping."

#### 8.0.4.1.5

Items having limited shelf or operating life are identified and controlled to preclude use of items whose shelf life or operating life has expired.

#### 8.0.4.2 Identification and Control of Samples

Controls are developed and implemented to assure that samples are identified and controlled in a manner consistent with their intended use. These controls define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation and records generation. These controls may be in the form of a TIP or stated as part of the work planning document as described in procedure 033-YMP-QP 3.0, "Scientific Investigation Control."

##### 8.0.4.2.1

Physical identification is used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods or records are described and used. Identification methods provide a means by which the sample(s) can be traced to the appropriate documentation such as drawing's, specifications, drilling logs, test records, inspection documents, and nonconformance reports.

##### 8.0.4.2.2

Samples are identified by placing the identification directly on the sample, on the sample container, and on the records. If it is impractical to place the identification on the sample or sample container, alternate methods for identification are described and used to assure that samples are not mixed with like samples and that the correct identification of samples is verified and documented prior to release for use.

#### 8.0.4.2.3

Controls are developed and implemented to assure that collection methods, techniques, and related equipment produce the intended sample. Sample identification and handling methods are developed, required, and utilized to assure that all samples meet the technical objectives dictated by the scientific investigation for which the samples are collected.

#### 8.0.4.2.4

Storage methods are developed and implemented to assure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long-term storage receive appropriate treatment to assure that they do not degrade during storage. (Long-term is not defined here and is defined by the responsible TL depending on the sensitivity of the sample to storage conditions.) Additional detail for storage is found in procedure 033-YMP-QP 13.0, "Handling, Storage, and Shipping."

#### 8.0.4.2.5

Transportation methods are developed and implemented to assure that samples are handled in an approved manner. Samples are transported in appropriate container which preclude damage due to environmental exposure or any unsafe conditions. When samples are transported, the use of, multiple organizations the responsibilities and the documentation requirements are described. Controls are developed and implemented to assure that sample identification is verified and maintained when samples are transported or transferred from one organization's responsibility to another.

#### 8.0.4.2.6

Measures are developed and implemented to maintain sample identification while in storage. These measures are consistent with the planned duration and conditions of storage. Samples are handled and stored in a manner to prevent damage or deterioration due to environmental exposure or aging to the sample identifier. Identifiers which are damaged or have deteriorated are replaced. A record is kept of all location and type of environment of the sample identifier; describes the damaged or deterioration; what is being done to prevent that from reoccurring; date of the occurrence; date identifier is replaced; signature, initials or stamp of individual replacing the identifier. Traceability is maintained from the original sample identifier through all subsequent replacement identifiers. When samples are handled their identification is verified.

#### 8.0.4.2.7

Actions to be taken where samples may have a maximum life expectancy while in storage are described. Controls are developed and implemented to assure that the identifiers for these samples specify the maximum life expectancy. A record of the identifiers is kept. This record contains: the sample name; sample type; sample identifiers; maximum life expectancy; and disposition of sample after maximum life expectancy is met. Controls are developed and implemented for the handling of samples after their maximum life expectancy has been exceeded.

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#### 8.0.4.2.8

Methods are developed and implemented to assure that like samples are not mixed. Physical segregation of samples is used to the maximum degree practical.

#### 8.0.4.2.9

Controls are developed and implemented for samples that are controlled by multiple organizations. These controls include organizational responsibilities and documentation requirements.

#### 8.0.4.3 Identification and Control of Data

Controls are developed and implemented to assure that data generated from scientific investigation is identified to assist in the determination of its correct use. Identification of such data is provided in all documents, information systems, or both, in which the data appear. Additional detail is found in procedure 033-YMP-QP 3.0, "Scientific Investigation Control."

##### 8.0.4.3.1

Identification of data includes a reference to the origin of the data (e.g. task, test, experiment, report, or publication) and the Quality Assurance Level assignment to the activity which produced the data.

##### 8.0.4.3.2

Control measures are established and implemented to assure that data are properly identified. These measures include verification of the identification of the data prior to release for use.

##### 8.0.4.3.3

Where data are the results of the efforts of more than one organization, TIP's describing the organizational responsibilities for that data are developed and implemented. The data resulting from the scientific investigation involving more than one organization are annotated to show which organization produced what portion of the data.

#### 8.0.5 RETAINED DOCUMENTATION

Quality assurance records are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- o records establishing item, sample, and data identification;
- o sample collection records;

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0102

Subject:

CONTROL OF PROCESSES

Approved:

Approved by: [Signature] 2/4/89  
YMP Project Leader

Approved by: [Signature] 1/19/89  
YMP Quality Assurance  
Manager

9.0.1 PURPOSE

The purpose of this procedure is to identify the requirements and establish the responsibilities for the control of processes and "Special Processes" that are used on engineered items and scientific investigations which affect the quality of Project produced deliverables for the Yucca Mountain Project (YMP).

9.0.2 SCOPE

The general process control requirements specified by this procedure apply to engineered items and scientific investigations. The "Special Process" control requirements apply only to engineered items, the use of which, affect the quality of LLNL produced deliverables for the Yucca Mountain Project.

9.0.3 DEFINITIONS

Listed below are key terms and phrases used in this procedure.

CONTROL MEASURE DOCUMENTS: As used in this procedure means those documents that identify and specify the control measure requirements for specifically identified processes and "Special Processes".

ENGINEERED ITEM: Any structure, system, or component identified in design documents as being a functional part of the completed facility.

PROCESS: A procedure, method, or technique followed in the execution of a scientific investigation or the design or manufacture of an engineered item.

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

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**QUALIFICATION (PERSONNEL):** The characteristics or abilities that are gained through education, training, or experience which are measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

**QUALIFIED PROCEDURE:** An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

#### 9.0.4. RESPONSIBILITIES

The Task Leader is responsible for:

- o Identifying the appropriate application and implementation of the requirements and instructions of this procedure.
- o Establishing and controlling the specific requirements for the qualification/certification of process procedures and personnel who use the "Special Process" procedure.
- o Assuring that required process and special process controls are passed on to contractors, subcontractors, and suppliers through appropriate specifications and drawings and other interface control documents.

The Technical Area Leader is responsible for:

- o Approval and disposition of processes and "Special Processes" procedures and submittal of the process control documents to appropriate distribution and Records Center.

The YMP Quality Assurance Manager or designee is responsible for:

- o Monitoring and assuring the effectiveness of the specified process controls, including review of the procedures and records for compliance to QA Program requirements.

#### 9.0.5 REQUIREMENTS

##### 9.0.5.1

The identification of and/or the need for a process or special process is addressed and documented as part of the work activity planning as prescribed in Procedure 033-YMP-QP 3.0, "Scientific Investigation Control".

##### 9.0.5.2

Control measures for process and special process are identified and documented. Procedure control requirements, as specified in Procedure 033-YMP-QP 5.0, "Technical Implementing Procedures" apply to process and special process procedures.

9.0.5.3

Documents used shall provide a means to identify process characteristics, attributes, variables, parameters and environmental conditions required to be controlled to attain a specified end result.

9.0.5.4

Qualification requirements for a special process, special process procedures, equipment and personnel who will use the special process procedures are identified and compliance requirements prescribed in control measures documents.

9.0.5.5

A master index of "Special Process Procedures" are received and maintained by the YMP Records Manager based on approved input provided by Technical Area Leaders.

9.0.5.6

Acceptance criteria are established and specified for the qualifications of:

- o Special processes.
- o Special process procedures.
- o Personnel who use the procedures.

9.0.5.7

Personnel assigned to use special process procedures are trained, qualified and certified in accordance with written procedures.

9.0.5.8

Recognized industrial codes and standards are used where applicable and practical to establish special process control and qualification requirements.

9.0.5.9

Welders and weld procedures are qualified prior to production to assure compliance of weldments to requirements of specifications, codes, standards, and regulations.

9.0.5.10

Production welds and the weld process are monitored to assure that only qualified personnel and qualified procedures are used.

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#### 9.0.5.11

Personnel performing nondestructive testing procedures, including those who witness the nondestructive testing application of others, are trained and qualified in accordance with the requirements of Procedure 033-YMP-QP 2.9, "Indoctrination and Training of Personnel" and Procedure 033-YMP-QP 2.10, "Qualification and Certification of Personnel".

#### 9.0.5.12

Special process procedures for QA Level I & II items or deliverables receive Yucca Mountain Project Office review and approval.

#### 9.0.5.13

Process development, qualification and use activities are monitored to assure compliance to established requirements.

### 9.0.6 PROCEDURE

#### 9.0.6.1

During the activity planning functions prescribed in Procedure 033-YMP-QP 3.0, "Scientific Investigation Control", all processes are identified and evaluated against the definition of "Special Process" and "Process" for application of this procedures's requirements.

#### 9.0.6.2

Procedure detail requirement for the development, preparation, qualification and use of process procedures are prescribed in a number of source documents:

- a) From work planning documents and procedure requirements established from implementation of Procedure 033-YMP-QP 3.0, "Scientific Investigation Test Control" prepared by the responsible Technical Area Leaders.
- b) From requirements established by Procedure 033-YMP-QP 5.0, "Technical Implementing Procedures".
- c) From applicable industrial Codes and Standards.
- d) From requirements prescribed in Scientific Investigation Plans (SIP) governing the process/special process activity.

#### 9.0.6.3

Process/special process specifications are prepared, reviewed and approved prior to start of qualification activities. This approved specification is treated as a controlled document and a Quality Assurance Record.

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#### 9.0.6.4

Process/special process qualification data and results are documented and independently reviewed for compliance to technical specification requirements and quality assurance program requirements.

#### 9.0.6.5

A Process/special process qualification report/record is prepared, reviewed, approved and submitted for distribution, and retention as a Quality Assurance Record.

#### 9.0.6.6

The responsible Technical Area Leader or designee notifies the YMP Records Manager of the qualification of a special process procedure for the following action:

- a) Inclusion of the identified special process procedure on the master index of special process procedures.
- b) Appropriate distribution of the special process procedure to users and records retention center.

#### 9.0.7 RETAINED DOCUMENTATION

Quality assurance records created by the implementing procedures are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records are specified in the approved special process procedure and shall include but are not limited to:

- a) Master index of all special process procedures.
- b) Copies of each approved special process procedure specification.
- c) Copies of each qualified and approved special process procedure.
- d) Copies of special process procedure qualifications records.
- e) Copies of personal qualifications records.

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

INSPECTION

Approved:

Approved by: [Signature] 1/20/89  
YMP Project Leader

Approved by: [Signature] 1/12/89  
YMP Quality Assurance  
Manager

#### 10.0.1 PURPOSE

This procedure establishes controls for the inspection of items produced for the Yucca Mountain Project (YMP). These controls are established to assure that items meet their stipulated requirements and that inspections are documented.

#### 10.0.2 SCOPE

This procedure applies to inspections of engineered items that are Quality Level I or II.

#### 10.0.3 RESPONSIBILITIES AND AUTHORITIES

The Task Leader (TL) whose activities warrant the use of this procedure is responsible for implementing the controls.

The method of implementation is by one or more administrative or technical procedures that are prepared, reviewed, and approved in accordance with procedure 033-YMP-QP 5.0, "Technical Implementing Procedures".

The YMP Quality Assurance (QA) Manager is responsible for supervising Quality Control inspections and monitoring the implementation of this procedure, and for assuring the continued effectiveness of the applicable controls specified in the procedure.

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#### 10.0.4 PROCEDURE

##### 10.0.4.1 Planning

Planning of inspection activities is accomplished and documented by inspection procedures, instructions, or checklists. Inspection procedures, instructions, or checklists provide for the following:

- o Criteria for determining when inspections are required.
- o Identification of characteristics to be inspected.
- o A description of the method of inspection.
- o Identification of the individuals or group responsible for performing the inspection, including the necessity for special expertise.
- o Acceptance and rejection criteria.
- o Identification of required procedures, drawings, and specifications and revisions.
- o Identification of the inspector and the results of the inspection.
- o Specification of the necessary measuring and test equipment, including accuracy requirements.

##### 10.0.4.2 Qualifications

Inspectors are qualified to perform the inspections to which they are assigned. Inspectors do not inspect work that they have accomplished, nor do inspectors report to personnel who are immediately responsible for the work. Inspectors have experience and/or training commensurate with the scope, complexity, or special nature of the inspection, including indoctrination concerning the technical objectives and requirements of codes and standards and the QA Program elements that are applicable.

Qualified individuals from outside the QA organization may be utilized for inspections when special expertise is necessary. However, the independence of the inspection function is maintained. Such individuals have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems, (2) initiate, recommend, or provide solutions to quality problems through designated channels, (3) verify implementation of solutions, and (4) assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When individuals from outside the QA organization are used, the QA Manager verifies the independence and need for special expertise, and reviews and monitors the inspection activity.

#### 10.0.4.3 Criteria and Documentation

Inspections are conducted using established criteria such as specifications, drawings, or those contained in other design documents. Acceptance or rejection criteria are based upon documented performance objectives.

#### 10.0.4.4 Sampling

When sampling is used to verify acceptability of a group of items, the sampling procedures are based on recognized and documented standard practices.

#### 10.0.4.5 Inspection Hold Points

Mandatory inspection Witness or Hold Points are established by the responsible TL, as necessary. When such Witness or Hold Points are established, work may not proceed without documented authorization by the responsible representative. These Witness or Hold Points are identified and defined in appropriate documents controlling the activity. Consent to waive any specified Witness or Hold Point is documented before work can be continued beyond the designated Point.

Methods of documenting inspection data and results that are obtained at these mandatory Hold Points are described in test plans and procedures, as are methods of data analysis.

#### 10.0.4.6 Potential Sources of Error

The potential sources of uncertainty and error in inspection procedures are controlled and measured.

#### 10.0.4.7 In-Process Inspection and Monitoring

Inspection of items during the manufacturing process (in-process) or while under construction is performed for work activities where necessary to verify quality.

If inspection of finished items is impossible or disadvantageous, indirect control is provided by monitoring of processing methods, equipment, and personnel. Where a combination of inspection and process-monitoring methods is used, these methods are applied in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved. Inspection and process monitoring are both used when other techniques cannot provide adequate control. Where required, controls are established and documented for coordinating and sequencing activities at established inspection points during successive stages of the manufacturing process or construction.

#### 10.0.4.8 Nonconformance and Final Inspection

Inspections include a review of all nonconformances identified during any previous inspections. For each nonconformance, there is a written resolution approved by the next higher level of management. Nonconformances are processed in accordance with procedure 033-YMP-QP 15.0, "Nonconformances".

Final inspections include a method to arrive at a decision as to when conformance to specified requirements is reached. Completed items are inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics, as required, to verify the item's conformance to the specified requirements. Quality Assurance records are examined for adequacy and completeness.

Modifications or repairs on items subsequent to final inspection, or their replacements, are reinspected, as appropriate, to verify acceptability.

#### 10.0.4.9 Acceptance

Final acceptance is documented and approved by someone at least one management level higher than the individual who inspected the item.

#### 10.0.4.10 In-Service Inspection

Required in-service inspections of structures, systems, or components are planned, documented, and monitored by the responsible Task Leader.

Inspection methods are established and executed to verify that the characteristics of an item remain within specific limits. Inspection methods include evaluation of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

#### 10.0.4.11 Contents of Inspection Reports

As a minimum, inspection reports identify the following:

- o A description of the item,
- o Date of the inspection,
- o Name(s) of individual(s) performing the inspection,
- o Name or names of personnel contacted during the inspection,
- o Description of the method of inspection,
- o Inspection criteria including identification of drawing, specification, etc. (and applicable revisions),

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- o Location of the item(s) inspected,
- o Organization responsible for production of the item(s),
- o Equipment used during the inspection,
- o Evidence of acceptability,
- o Acceptance statement.
- o References to information on action taken in connection with conditions adverse to quality, nonconformances and/or actions taken to resolve any discrepancies

#### 10.0.5 RETAINED DOCUMENTATION

Quality assurance records created by the implementing procedures are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- o Qualifications of persons assigned to perform inspections,
- o Inspection criteria and planning documents,
- o Nonconformance reports,
- o Acceptance documents,
- o Inspection reports.

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0102

Subject:

TEST CONTROL

Approved:

Approved by: *J. S. Ballan* 2/8/89  
YMP Project Leader

Approved by: *R. G. E. Schmitz* 2/8/89  
YMP Quality Assurance  
Manager

### 11.0.1 PURPOSE

This procedure describes the methods for test control of engineered items in support of the Yucca Mountain Project (YMP). The controls are established to assure that engineered items conform to specified requirements, perform satisfactorily, and that tests are performed by trained and qualified personnel.

### 11.0.2 SCOPE

This procedure applies to testing of engineered items and does not apply to scientific investigation activities. Engineered items are those structures, systems or components identified in design documents as being a functional part of the completed facility.

### 11.0.3 RESPONSIBILITIES

Procedures for test control are prepared as Technical Implementing Procedures and meet the requirements of the LLNL QAPP, 033-YMP-R 11.

Responsibility for preparation, review and approval of test procedures is as defined in Procedure 033-YMP-QP 5.0 "Technical Implementing Procedures." In addition, the next level of project management above the individual performing the work is responsible for identifying the need for a test procedure and assigning responsibility for its preparation.

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#### 11.0.4 TEST PROCEDURE FORMAT

Test procedures are prepared as Technical Implementing Procedures in accordance with Procedure No. 033-YMP-QP 5.0.

#### 11.0.5 RETAINED DOCUMENTATION

In addition to the records identified in Procedure No. 033-YMP-QP 5.0, test records include:

- o Item tested.
- o Date of test.
- o Tester or data recorder identification.
- o Type of observation.
- o Results and acceptability.
- o Action taken in connection with any deviations noted.
- o Person evaluating results.

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

CONTROL OF MEASURING AND TEST EQUIPMENT

Approved:

Approved by: [Signature] 1/27/89  
YMP Project Leader

Approved by: [Signature] 1/12/89  
YMP Quality Assurance  
Manager

#### 12.0.1 PURPOSE

This procedure describes requirements necessary to provide for the control of Measuring and Test Equipment (M&TE) used in support of the Yucca Mountain Project (YMP). These requirements are established to assure that the M&TE used in support of scientific investigations is appropriate, that the accuracy of the M&TE is maintained by periodic calibration, and that the calibration activities are documented.

#### 12.0.2 SCOPE

This procedure applies to M&TE used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known in support of YMP Level I and II Activities.

#### 12.0.3 RESPONSIBILITIES AND AUTHORITIES

The Task Leader (TL) whose activities warrant the use of this procedure is responsible for implementing the requirements of this procedure.

The YMP Quality Assurance Manager (QA Manager) is responsible for monitoring work to assure proper implementation of this procedure and assuring its continuing effectiveness.

#### 12.0.4 CONTROLS

Controls are established by written procedures or instructions prepared in accordance with procedure 033-YMP-QP 5.0, "Technical Implementing Procedures." Procedures are issued in accordance with procedure 033-YMP-QP 6.0, "Document Control."

#### 12.0.4.1 Selection

The Task Leader will ensure that M&TE selected is of the proper type, design, range, accuracy, and tolerance to accomplish its required function. The type, range, accuracy and tolerance required of a measuring device is specified in test or inspection procedures.

#### 12.0.4.2 Identification

Measuring and Test Equipment is identified by using a unique identification number. This identification number is used in calibration data records to assure traceability of the data to the equipment used. The identification number is also documented on the equipment calibration records. The identification number is recorded on the data sheet, laboratory note book, log, etc., along with the measurement taken to assure traceability to the M&TE used to make the measurement.

#### 12.0.4.3 Calibration

Standards used for calibration of measurement and test equipment are traceable to the National Institute for Standards and Technology (formally the National Bureau of Standards) or other nationally recognized standards. If no recognized standard exists, the basis for calibration is documented. Traceability requires the ability to relate individual measurement results through an unbroken chain back to NIST or other nationally recognized standard. The chain of calibration must be documented and auditable.

The method and interval for calibration and maintenance of the M&TE is based on the type of equipment, stability characteristics, precision, range, required accuracy and tolerance, intended usage, and other conditions that affect measurement control. Calibration is also performed whenever the accuracy of the equipment is suspect.

If M&TE is determined to be out of calibration, an evaluation is made to determine the validity of the test results obtained since the previous calibration. This evaluation is documented.

M&TE that is determined to be out of calibration is tagged and segregated in a hold area until recalibrated. M&TE consistently found to be out of calibration is repaired or replaced.

Records are maintained and equipment is marked to indicate the calibration status and the recalibration date. The Calibration Labs maintain records of M&TE calibrations and forward copies of all project calibration documentation to Project QA.

General measuring equipment such as rulers, tape measures, levels, or other such devices do not normally require calibration control.

M&TE incorporated in equipment specially designed and fabricated by LLNL, not used as M&TE, is not included in the calibration program.

#### 12.0.4.4 Handling and Storage

M&TE is properly handled and stored to maintain accuracy. These handling and storage instructions may be described in the test or inspection procedures that require the use of that equipment.

#### 12.0.4.5 Special Designs

M&TE that is specially designed for a particular scientific investigation is developed and manufactured in accordance with the requirements of the investigation. Calibration procedures are written by Task personnel and the equipment is calibrated to these procedures prior to use.

#### 12.0.4.6 M&TE for Long Running Experiments

In the event that the length of the experiment will exceed the normal recalibration interval of the M&TE required and the design of the experiment is such that it can not be replaced or calibrated during the experiment:

- o M&TE is calibrated just before and immediately after the experiment.
- o The M&TE accuracy tolerance is greater than data requirements, and is considered in the design of the experiment.
- o M&TE is selected that will have minimum drift. (Based on calibration history)
- o If the design of the experiment permits, then M&TE is duplicated.

#### 12.0.5 M&TE RECALL PROGRAM

The Task Leader is responsible for insuring that all M&TE used in the YMP is properly calibrated prior to the start of any QA Level I and II work.

The following information will be provided to the responsible Task Leader by Quality Assurance at least one month prior to calibration expiration:

- o Calibration expiration date.
- o The type of equipment.
- o The equipment identification number (SN).

The Task Leader is to be responsible for insuring that all newly acquired M&TE is submitted to the appropriate Cal Lab for initial calibration and entry into the recall system. QA will also be informed of M&TE procurements.

YMP QA is advised by the Calibration Labs of all:

- o M&TE submitted for first time calibration.
- o New recall dates of all calibrated M&TE so that the QA M&TE listing can be maintained.

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#### 12.0.6 QUALITY ASSURANCE RECORDS

Records are maintained and equipment suitably marked to indicate the calibration status. Calibration records identify the calibration procedure (including revisions) used to perform each calibration.

Quality Assurance records generated by this procedure are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality Assurance records include the following:

- o Certificates of traceability with supporting documentation.
- o Nonconformances and their resolution.
- o YMP Measuring and Test Equipment Listing.
- o YMP M&TE Recall List.

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

HANDLING, STORAGE, AND SHIPPING

Approved:

Approved by:

*D. S. Bellan* 1/21/89  
YMP Project Leader

Approved by:

*R. M. E. King* 1/12/89  
YMP Quality Assurance  
Manager

### 13.0.1 PURPOSE

This procedure establishes controls for the proper physical care of items during handling, storing, and shipping. These controls are established to assure that items important to the Yucca Mountain Project (YMP) are protected from damage, deterioration, and loss during handling, storage, and shipping.

### 13.0.2 SCOPE

This procedure applies to items and equipment that must be handled, stored, and shipped in a special manner to avoid the loss of one or more important characteristics.

### 13.0.3 RESPONSIBILITIES AND AUTHORITIES

The Task Leader (TL) whose activities warrant the use of this procedure is responsible for implementing the controls.

The YMP Quality Assurance Manager is responsible for monitoring the implementation and for assuring the continuing effectiveness of the applicable controls.

The method of implementation is by one or more administrative or technical procedures that are prepared, reviewed, and approved in accordance with Procedure No. 033-YMP-QP 5.0, "Technical Implementing Procedures." Procedures are issued in accordance with the Procedure No. 033-YMP-QP 6.0, "Document Control."

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#### 13.0.4 CONTROLS

##### 13.0.4.1 Instructions

Items are handled, stored, and shipped in such a way as to prevent damage, deterioration, or loss. Written instructions state how items and equipment are handled, stored, and shipped. These written instructions may specify special handling procedures and equipment, preservation methods, packaging, and marking requirements. These instructions are incorporated within procurement documents, shipping documents, etc.

##### 13.0.4.2 Controls

When it is necessary, special handling equipment or special environments are specified and provided. Special handling tools and equipment are inspected and tested in accordance with documented procedures and at specified time intervals to verify that the tools and equipment are maintained adequately. If special equipment requires specially trained or experienced operators, then that is specified and verified. All verifications are documented.

If special instructions for packaging, marking, and preservation are necessary, there is a verification to assure that the instructions are followed.

#### 13.0.5 QUALITY ASSURANCE RECORDS

Quality assurance records generated by this procedure are collected, stored, and maintained in accordance with Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- o handling, storage, and shipping procedures,
- o handling, storage, and shipping records.

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject: INSPECTION, TEST, AND OPERATING STATUS

Approved:

Approved by: *J. S. Sellen* 2/8/89  
YMP Project Leader

Approved by: *R. G. E. Selby* 2/8/89  
YMP Quality Assurance  
Manager

#### 14.0.1 PURPOSE

This procedure describes the methods for control of inspection, test and operating status of engineered items in support of the Yucca Mountain Project (YMP). The controls are established to assure that the status of inspection and test activities is identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently, installed, used or operated.

#### 14.0.2 SCOPE

This procedure applies to engineered items and does not apply to scientific investigation activities. Engineered items are those structures, systems or components identified in design documents as being a functional part of the completed facility.

#### 14.0.3 RESPONSIBILITIES

Procedures for control of inspection, test and operating status are prepared as Technical Implementing Procedures and meet the requirements of the LLNL QAPP, 033-YMP-R 14.

Responsibility for preparation, review and approval of procedures for inspection, test and operating status is as defined in Procedure 033-YMP-QP 5.0 "Technical Implementing Procedures." In addition, the next level of project management above the individual performing the work is responsible for identifying the need for such procedures and assigning responsibility for their preparation.

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#### 14.0.4 PROCEDURE FORMAT

Procedures for inspection, test and operating status are prepared as Technical Implementing Procedures in accordance with Procedure No. 033-YMP-QP 5.0 and include methods for:

- o indicating the operating status of systems and components of the facility such as tagging valves and switches to prevent inadvertant operation.
- o maintaining status indicators such as physical location and tags, markings, travelers, stamps, inspection records or other suitable means. Procedures describing status indicators and their use shall contain current actual examples of each type indicator.
- o application and removal of status indicating tags, markings, labels and stamps.

#### 14.0.5 RETAINED DOCUMENTATION

Records are identified in individual TIPs and include as applicable:

- o Operating/Maintenance status logs.
- o Disposition of nonconforming items.



## CHANGE NOTICE

CN No. 15.0.-0-1Affected Document: QP 15.0, "Nonconforming Items, Procedural Nonconformances  
and Conditions Adverse to Quality"Revision: 0Prepared By R. Oberle

N/A

Approved By \_\_\_\_\_

Technical Area Leader

Date

Approved By R. Oberle 3/3/89  
YMP QA Manager DateApproved By J. Spellan 3/3/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 15.0.5.3, fifth line, added language (see below)
2. Section 15.0.5.4, new first paragraph (see below)
3. Section 15.0.5.4, third paragraph, third line  
If a continuance of work involving a nonconforming item is warranted, justification for the continuance is documented and approved by the DOE Project Office.
4. Section 15.0.5.4, fourth paragraph, second line, added language (see below)

Changed to Read:

1. Section 15.0.5.3, fifth line, add sentence  
Tagging does not adversely affect the end use of the item.
2. Section 15.0.5.4, first line, add sentence  
Conditional release of nonconforming items is not authorized.
3. Section 15.0.5.4, third paragraph, third line  
Delete sentence.

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

**CURRENTLY READS AS FOLLOWS:**

5. Section 15.0.5.4,.C, added language (see below)
6. Section 15.0.5.4.F.  
If continuance has been requested, justification for the activity to continue has been documented and approved by the DOE Project Office.
7. Section 15.0.7, second paragraph, second and third sentences.  
YMP approval is obtained before the disposition is implemented unless, in the judgment of the YMP Project Leader, this would result in an unacceptable delay. When such a judgment is made, the rationale is documented by the YMP Project Leader and forwarded to the YMP QA Manager for inclusion in the NCR file folder.

**CHANGED TO READ:**

4. Section 15.0.5.4, fourth paragraph, second line, add sentence.  
Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area that they are evaluating, an adequate understanding of the requirements, and access to pertinent background information. This...
5. Section 15.0.5.4, C, add sentence  
A technical justification is required in the case of use-as-is or repair dispositions for items.
6. Section 15.0.5.4.F  
Delete sentence.
7. Section 15.0.7, second paragraph, second and third sentences.  
Delete sentences.

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

No.: 033-YMP-QP 15.0

Revision: 0

Date: FEB 24 1989

Page: 1 of 9

Subject: NONCONFORMING ITEMS, PROCEDURAL NONCONFORMANCES  
AND CONDITIONS ADVERSE TO QUALITY

Approved:

Approved by: *D. S. Sallon* 2/5/89  
YMP Project Leader

Approved by: *R. E. Smith* 1/12/89  
YMP Quality Assurance  
Manager

### 15.0.1 PURPOSE

This procedure describes the methods for documenting, reporting, controlling, and resolving nonconforming items, procedural nonconformances, and conditions adverse to quality. This procedure establishes measures to control items that do not conform to requirements in order to prevent their inadvertent installation and use.

### 15.0.2 SCOPE

This procedure applies to all YMP activities at LLNL and to all Project contractors.

### 15.0.3 TERMS AND DEFINITIONS

**Nonconformance:** A deficiency in characteristics, documentation, or procedures that renders the quality of an item unacceptable or indeterminate.

**Procedural Nonconformance:** Deviation from a controlled procedure, requirement, instruction, or drawing.

**Condition Adverse to Quality:** An all-inclusive term used in reference to any of the following: failure, malfunction, deficiencies, defective items, and nonconformance. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability.

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#### 15.0.4 RESPONSIBILITIES

All individuals assigned to the YMP are responsible for reporting nonconforming items, procedural nonconformances, and conditions adverse to quality to the YMP Quality Assurance Manager.

The YMP QA Manager and the YMP Project Leader have specific responsibilities, detailed in this procedure, for resolution and closure of nonconforming items, procedural nonconformances, and conditions adverse to quality.

The YMP Project Leader is responsible for implementing and assuring the effectiveness of this procedure.

The YMP QA Manager is responsible for monitoring the disposition of nonconforming items, procedural nonconformances, and conditions adverse to quality. The YMP QA Manager is also responsible for maintaining this procedure.

#### 15.0.5 PROCEDURES

##### 15.0.5.1 Reporting

A suspected nonconforming condition should be brought to the immediate attention of the responsible Task Leader.

The individual (originator) who discovers a nonconforming item, procedural nonconformance, or condition adverse to quality prepares the Nonconformance Report (NCR), see Exhibit A, to report this information. The originator completes Part I of the form and submits the original to the YMP QA Manager at:

Lawrence Livermore National Laboratory  
Yucca Mountain Project  
P.O. Box 808, L-204  
Livermore, California 94550

##### 15.0.5.2 Logging Nonconformances and Distribution of Nonconformance Reports

The YMP QA Manager assigns a sequential identification number (NCR-LLNL-001, 002, 003, etc.) to the NCR, and forwards a copy of the NCR to the YMP Project Leader, the appropriate Task Leader, and the DOE Project Office. The YMP QA Manager enters prescribed information regarding the NCR onto a Nonconformance Status Sheet, Exhibit B, and creates a separate file folder to maintain documentation relevant to the NCR. The Nonconformance Status Sheets are maintained in the NCR Logbook.

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### 15.0.5.3 Segregating Suspected Nonconforming Items

Items that are suspected of not conforming are tagged, and if possible, segregated by the responsible Task Leader until disposition of the nonconformance is complete. Items or their containers are tagged by the appropriate Task Leader, using Exhibit C. If tags are used, they are securely attached to avoid loss during handling. When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions are taken to preclude inadvertent use of a nonconforming item. Further processing, delivery, installation, or use of a nonconforming item is controlled pending an evaluation and an approved disposition by authorized personnel.

### 15.0.5.4 Disposition

The YMP QA Manager evaluates the NCR to determine if the matter is of a minor or serious nature. As appropriate, the YMP QA Manager consults with the responsible Task Leader and technical personnel as part of the evaluation process. The YMP QA Manager documents this evaluation in Part II of the Nonconformance Report.

If the YMP QA Manager concludes the NCR is of a minor nature (i.e., the matter will not adversely affect quality), the YMP QA Manager documents the cause and disposition of the NCR in Parts IV, V, and VI and closes the NCR. The YMP QA Manager sends a copy of the completed NCR form to the originator, the YMP Project Leader, the appropriate Task Leader, and the DOE Project Office. The YMP QA Manager enters the closure information on the Nonconformance Status Sheet.

If the YMP QA Manager considers the NCR to be of a serious nature (i.e., the matter can adversely affect quality), the YMP Project Leader is notified by memorandum. If a continuance of work involving a nonconforming item is warranted, justification for the continuance is documented and approved by the DOE Project Office.

The YMP Project Leader assigns an individual or individuals to determine the cause of the NCR and to propose an appropriate disposition. This information is documented by the YMP Project Leader in Part III of the NCR form. The YMP Project Leader may assign the responsibility for determining the cause of the NCR and proposing a disposition to the YMP QA Manager if the NCR pertains to responsibilities of the YMP QA Manager.

The response due date may not be more than 30 days after date of assignment.

The assigned individuals are responsible for assuring items A through J are accomplished.

- A. Nonconformance documentation adequately identifies and describes the nonconformance.

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- B. The cause of the nonconforming condition is described.
- C. Appropriate justification for the disposition of the nonconformance is documented. In instances involving nonconforming items, the disposition identifies and documents whether the item will be repaired, reworked, used as is, or rejected/scrapped.
- D. The disposition references approved design documents, procedures, plans, work orders, etc. to be used to correct the nonconforming condition.
- E. The technical details for correction of the nonconforming condition are adequate for the recommended disposition.
- F. If continuance has been requested, justification for the activity to continue has been documented and approved by the DOE Project Office.
- G. The disposition complies with existing design documents, test plans/procedures, reports, and regulatory requirements or denotes the required changes to these documents. Any changed documents are cross-referenced to the NCR.
- H. The disposition identifies the organization responsible for implementation.
- I. For NCRs resulting from Audit Findings, the action needed to preclude recurrence of the nonconforming condition is documented.
- J. The date by which corrective action will be completed.

Repaired or reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.

The assigned individuals coordinate with the responsible Task Leader to assure the proposed disposition is appropriate and workable. The information outlined in items A - J is then forwarded to the YMP Project Leader.

If the YMP Project Leader concurs with the proposed disposition, the YMP Project Leader completes Parts IV and V of the NCR form and forwards it to the YMP QA Manager for review and approval. The YMP QA Manager's approval of the proposed disposition is indicated by signature in Part V of the NCR form.

Disagreements concerning the disposition of an NCR are resolved among the YMP Project Leader, the Task Leader, and the YMP QA Manager. In instances where the matter cannot be resolved among these parties, the YMP Project Leader's decision is final.

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Upon approval of the proposed disposition, the YMP QA Manager notifies the responsible organization to proceed. If more than one organization must implement corrective action as part of the disposition, the YMP QA Manager initiates a Corrective Action Request for each participant in accordance with QP 16.0, Corrective Action.

When notified by the responsible organization that corrective action has been completed, the YMP QA Manager conducts a verification of the completion of the corrective action. The verification is documented in Part VI of the NCR form. The YMP QA Manager sends copies of the completed NCR to the YMP Project Leader, the cognizant Task leader, the originator and the DOE project Office. The QA Manager enters appropriate closure information in the Nonconformance Status Sheet.

If the implementation of corrective action is unacceptable, the YMP QA Manager notifies the responsible organization by memorandum of the additional actions that must be taken.

The NCR file remains open until the YMP QA Manager receives documentation that the specified corrective action has been implemented and verified. Upon receipt of this documentation, the YMP QA Manager submits the NCR file to the Records Management System in accordance with procedure 033-YMP-QP 17.0, Quality Assurance Records.

#### 15.0.6 CHANGES TO NONCONFORMANCES REPORTS

Changes to the information contained in NCRs are documented in a memorandum to the NCR file. If the change involves, or affects, the approved disposition of the Nonconforming Condition, the change is approved by the same level of management that approved the original disposition.

#### 15.0.7 FOR YMP PROJECT ONLY

The interface between YMP and the YMP Project Office is described below.

If the disposition of a nonconforming item associated with a Level of Quality Assurance I or II activity is "repair" or "use as is," then the YMP QA Manager forwards the NCR to the Yucca Mountain Project Office (YMP) for approval. YMP approval is obtained before the disposition is implemented unless, in the judgment of the YMP Project Leader, this would result in an unacceptable delay. When such a judgment is made, the rationale is documented by the YMP Project Leader and forwarded to the YMP QA Manager for inclusion in the NCR file folder.

Copies of all nonconformance reports provided to YMP PQM are also sent to the T&MSS Project QA Department (QA Engineering Division Manager).

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#### 15.0.8 MONITORING THE STATUS OF NONCONFORMANCE REPORTS

The status of nonconformance reports is monitored using the Nonconformance Status Sheet. The status sheets are reviewed monthly to assure that nonconformances are resolved and to identify and analyze trends. A monthly report is issued by the YMP QA Manager to the YMP Project Leader, Technical Area Leaders and Task Leaders indicating the status of all open NCRs and specifying adverse quality trends. The status of NCRs includes identification of NCRs within 30 days of the due date for completion of corrective action, and overdue responses or corrective action.

#### 15.0.9 RECURRING NONCONFORMANCES

When repetitive or recurring nonconforming conditions are identified, the YMP QA Manager conducts an evaluation of the need for further programmatic corrective action to preclude repetition. Such corrective action is beyond the scope of the action taken for the disposition of the existing NCRs and is processed in accordance with procedure 033-YMP-QP 16.0, Corrective Action.

#### 15.0.10 RETAINED DOCUMENTATION

NCRs, Nonconformance Status Sheets and supporting documents are quality assurance records. These records are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, Quality Assurance Records.

**EXHIBIT A - NONCONFORMANCE REPORT**

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>		<b>YUCCA MOUNTAIN PROJECT</b>		Page _____ of _____
<b>NONCONFORMANCE REPORT</b>				
<b>PART I ORIGINATOR COMPLETES ITEMS 1 through 4      QA COMPLETES ITEMS 5 and 6</b>				
1. Originator	2. Date Discovered:	5. Date reported to QA	6. NCR No.	
3. Reference Documents (if applicable):				
4. Nonconforming Condition:				
<b>PART II COMPLETED BY YMP QA MANAGER</b>				
7. <input type="checkbox"/> Minor <input type="checkbox"/> Serious		8. YMP QA Manager Signature:	9. Date:	
<b>PART III COMPLETED BY YMP PROJECT MANAGER</b>				
10. Assigned for Disposition	11. Signature of YMP Project Leader:		12. Date:	
<b>PART IV COMPLETED BY ASSIGNED TASK LEADER/QA MANAGER</b>				
13. Cause:				
14. Proposed Disposition:				
14A. Hardware: <input type="checkbox"/> Reject <input type="checkbox"/> Repair <input type="checkbox"/> Rework <input type="checkbox"/> Use-as-is		14B. All others:		
15. Corrective Action to Prevent Repetition:				
16. Estimated Completion Date of Corr. Act.:			17. Est Completion Date of Corr. Act to Prev. Rep.:	
<b>PART V COMPLETED BY YMP PROJECT LEADER AND YMP QA MANAGER</b>				
18. YMP Project Leader's Signature:			19. Date:	
20. YMP QA Manager's Signature:			21. Date:	
<b>PART VI COMPLETED BY QUALITY ASSURANCE</b>				
22. Verified by (Printed Name, Signature):			23. Date Verified:	



EXHIBIT C - NONCONFORMING MATERIAL TAG

<h1 style="text-align: center;">DO NOT USE</h1> <p style="text-align: center;"> <input type="checkbox"/> REJECTED    <input type="checkbox"/> HOLD STATUS         </p>		
<b>NCR FILED?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>NCR No.</b>	
<b>Originator</b>	<b>Date</b>	
<b>Item</b>	<b>REJECTED</b>	
	<b>NUMBER OF PACKAGES</b>	<b>QUANTITY</b>

S  
A



CHANGE NOTICE

CN No. 16.0-0-1

Affected Document: QP 16.0 "Corrective Action"

Revision: 0

Prepared By Ronald Schwartz

Approved By N/A

Technical Area Leader

Date

Approved By *R. E. Schulz* 3/3/89  
YMP QA Manager Date

Approved By *J. S. Salton* 3/3/89  
YMP Project Leader Date

Currently Reads as Follows:

1. Section 16.0.5.1.c  
Disposition of a finding resulting from an external audit or surveillance conducted by a sponsor, regulatory agency, or other entity.

Changed to Read:

1. Section 16.0.5.1.c  
Delete sentence.

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

CORRECTIVE ACTION

Approved:

Approved by: *S. Sallan* 4/3/89  
YMP Project Leader

Approved by: *R. H. E. Smith* 1/12/89  
YMP Quality Assurance  
Manager

**16.0.1 PURPOSE**

This procedure describes the steps for documenting, reporting, monitoring, implementing, and verifying the implementation of corrective action.

**16.0.2 SCOPE**

This procedure applies to all YMP activities at LLNL and to all LLNL-YMP subcontractors.

**16.0.3 TERMS AND DEFINITIONS**

**Corrective Action:** Measures taken to rectify a nonconforming item, procedural nonconformance, condition adverse to quality, audit finding, or a nonconformance associated with a procurement action, and, where necessary, to preclude repetition.

**16.0.4 RESPONSIBILITIES**

The Task Leader of the affected task is responsible for implementing the corrective action.

The YMP Project Leader is responsible for assuring the implementation and effectiveness of this procedure.

The YMP Quality Assurance Manager is responsible for initiating Corrective Action Reports and monitoring the implementation of corrective action. The YMP QA Manager is also responsible for maintaining this procedure.

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## 16.0.5 PROCEDURE

### 16.0.5.1 Initiating Corrective Action Reports

The YMP QA Manager is responsible for Initiating a Corrective Action Report, Exhibit A, when appropriate. A Corrective Action Report (CAR) may result from one of the following:

- A. Disposition of a nonconforming item, procedural nonconformance, or condition adverse to quality consistent with procedure 033-YMP-QP 15.0, "Nonconformances....";
- B. Disposition of an adverse quality trend identified as the result of trend analysis.
- C. Disposition of a finding resulting from an external audit or surveillance conducted by a sponsor, regulatory agency, or other entity.

The YMP QA Manager completes Part I of the CAR form, identifying the Task Leader responsible for the Corrective Action, the action to be taken and a scheduled completion date.

### 16.0.5.2 Logging Corrective Action and Distributing Copies of the Corrective Action Report

The YMP QA Manager assigns a sequential identification number (CAR-001,... CAR 010, etc.) to the CAR and forwards a copy of the CAR to the YMP Project Leader, the appropriate Task Leader, and the DOE Project Office.

The YMP QA Manager enters prescribed information regarding the CAR on a Corrective Action Log Sheet, Exhibit B, and creates a separate file folder for maintaining documentation relevant to the CAR. Corrective Action Log Sheets are maintained in the CAR Logbook.

### 16.0.5.3 Implementing Corrective Action

The Task Leader of the affected work implements the corrective action specified in the CAR. The YMP Project Leader assures that implementation of the corrective action takes place. When the corrective action is implemented, the Task Leader completes Part II of the CAR and sends it to the YMP Project Leader for review. The Project Leader indicates concurrence by his signature in Part II of the CAR. The Project Leader then forwards the CAR to the YMP QA Manager for verification.

### 16.0.5.4 Verification

Upon notification by the Project Leader, the YMP QA Manager verifies, implementation of the corrective action prescribed in the CAR. The YMP QA Manager documents the verification in Part III of the CAR.

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Once implementation of the corrective action is verified, the YMP QA Manager closes the corrective action by making any necessary entries on the CAR form. The YMP QA Manager sends a copy of the completed CAR to the YMP Project Leader, the appropriate Task Leader, and the DOE Project Office.

The YMP QA Manager enters the appropriate close-out information on Exhibit B.

#### 16.0.6 CHANGES TO CORRECTIVE ACTION REPORTS

Changes to information recorded on a CAR are documented on a memorandum to the CAR file. Changes to the Corrective Action to be taken, or to the scheduled completion date require the documented approval of the YMP QA Manager.

#### 16.0.7 MONITORING THE STATUS OF CORRECTIVE ACTION REPORTS

The status of the CARs are monitored using the Corrective Action Log Sheets. The Log Sheets are reviewed monthly by the YMP QA Manager to assure that corrective actions and the resulting closure are implemented and to analyze trends. A report is issued monthly by the YMP QA Manager to the YMP Project Leader indicating the status of all open CARs and identifying any adverse quality trends.

#### 16.0.8 FOR YMPO PROJECT ONLY

Copies of all CARs provided to the Yucca Mountain Project Office (YMPO) are also sent to the T&MSS Project QA Department upon issuance and closure.

#### 16.0.9 RETAINED DOCUMENTATION

The CAR, the CAR Log Sheets and supporting documents are quality assurance records. These records are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, Quality Assurance Records.

**EXHIBIT A  
CORRECTIVE ACTION REPORT**

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>		<b>YUCCA MOUNTAIN PROJECT</b>	Page _____ of _____
<b>CORRECTIVE ACTION REPORT</b>			
<b>PART I COMPLETED BY THE QA MANAGER</b>			
CAR No.:	Date Originated:		
Reference Documents:			
Condition:			
Corrective Action to be Taken:			
Responsible task Leader:	Responsible Technical Area Leader:		
Recommended Completion Date:			
<b>PART II COMPLETED BY THE RESPONSIBLE TASK LEADER</b>			
Corrective Action Taken:			
Date Completed:			
Signature of Responsible Task Leader:			Date:
Signature of Project Leader:			Date:
<b>PART II COMPLETED BY THE QA MANAGER</b>			
Date Verified:		Signature:	
Comments (if any):			
Closed By (signature of QA Manager):			Date:

**EXHIBIT B  
CORRECTIVE ACTION LOG SHEET**

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>	<b>YUCCA MOUNTAIN PROJECT</b>	Page _____ of _____	
<b>CORRECTIVE ACTION LOGSHEET</b>			
CAR No.: _____		Title: _____	
Date Originated: _____			
Ref. Document(s): _____			
_____			
_____			
Responsible Task Leader: _____			
Recommended Completion Date: _____			
<b>STATUS CHECK</b>			
Date / Initials	Date / Initials	Date / Initials	Date / Initials
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Date Completed: _____			
Date Verified: _____			
Date Closed: _____			
Copies Transmitted:			
Date	Recipient		
_____	_____	Originator	
_____	_____	YMP Project Leader	
_____	_____	Responsible Technical Area Leader	
_____	_____	DOE Project Office (YMPO)	
_____	_____	T&MSS Project QA Office	
_____	_____	Original to QA Records	

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

PROCESSING OF EXTERNALLY ORIGINATED  
CORRECTIVE ACTION DOCUMENTS

Approved:

Approved by: *D. Sallan* 4/4/89 YMP Project Leader  
Approved by: *R. E. Johnson* 1/12/89 YMP Quality Assurance Manager

**16.1.1 PURPOSE**

The purpose of this procedure is to provide for the processing of externally originated corrective action documents to assure that YMP provides an appropriate response and obtains closure.

**16.1.2 SCOPE**

This procedure applies to all documents transmitted to YMP that mandate corrective action on the part of YMP as part of the response to the documents. Such documents include, but are not limited to, Nonconformance Reports, Standard Deficiency Reports (SDR's), Audit Findings and Audit Observations.

**16.1.3 RESPONSIBILITIES**

The YMP Project Leader is responsible for identifying the appropriate YMP personnel who provide responses to externally originated corrective action documents and who implement corrective action.

The YMP QA Manager is responsible for tracking the status of externally originated corrective action documents and for maintaining file copies of official correspondence related to the responses to the documents, completion of corrective action and closure.

#### 16.1.4 PROCEDURE

##### 16.1.4.1 Receipt of Corrective Action Documents

YMP personnel who receive correspondence containing documents that identify the need for YMP to take corrective action in response to an identified problem or deficiency forward these documents to the YMP QA Manager for processing. These documents include, but are not limited to, Standard Deficiency Reports (SDR's), Audit Findings and Observations, Nonconformance Reports and Corrective Action Reports.

##### 16.1.4.2 Processing of Corrective Action Documents

Upon receipt of an externally originated corrective action document, the YMP QA Manager:

- a. Enters the document into a status tracking system;
- b. Establishes a file for collection of documentation associated with the document;
- c. Notifies the YMP Project Leader and obtains an assignment of a Respondent who is tasked with responding to the document;
- d. Forwards a copy of the document to the designated Respondent along with a due date for the response. The due date is the lesser of the due date specified on the document or thirty calendar days from date of receipt by the YMP QA Manager.

The Respondent prepares the response, including identification of cause and proposed corrective action, as appropriate, by the specified due date and forwards the documentation to the YMP QA Manager.

The YMP QA Manager reviews the documentation and, if acceptable, forwards it to the YMP Project Leader for approval. If the response is inappropriate, or inadequate, the documentation is returned to the Respondent accompanied by a listing of comments and a revised due date.

If the response is acceptable, the YMP Project Leader approves the response and transmits it to the originating organization. A copy of the transmittal is forwarded to the YMP QA Manager for retention. If the response is not approved, it is returned to the YMP QA Manager accompanied by a listing of comments for transmittal to the Respondent as in the previous paragraph.

Recipients of correspondence related to YMP's responses to corrective action documents forward this correspondence to the YMP QA Manager for routing to cognizant personnel and retention of file copies.

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#### 16.1.4.3 Closure of Corrective Action Documents

When corrective actions are completed, the Respondent notifies the YMP QA Manager. The YMP QA Manager verifies that the corrective action is complete. If the corrective action is inadequately implemented, or incomplete, the YMP QA Manager notifies the Respondent and provides a listing of specific actions that must be taken. If the corrective action is acceptable, the YMP QA Manager notifies the Project Leader.

The YMP Project Leader notifies the originating organization in writing that corrective action or other resolutions, as appropriate, have been completed. A copy of such correspondence is retained in the QA file.

Upon notification by the originating organization that the corrective action document is considered closed, the YMP QA Manager forwards the filed correspondence to the Records Management System for retention.

#### 16.1.4.4 Monitoring and Reporting

The YMP QA Manager publishes a monthly status of externally originated corrective action documents. The status report identifies those documents for which specific actions are overdue. Cognizant Respondents and the Project Leader are notified in writing when any specified due date becomes overdue.

#### 16.1.5 RETAINED DOCUMENTATION

##### 16.1.5.1 Records

The following documents resulting from the implementation of this procedure are Quality Assurance Records. These records are collected, stored and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records".

- a. Externally originated corrective action documents;
- b. YMP responses to corrective action documents;
- c. Other correspondence related to the resolution of deficiencies identified in externally originated corrective action documents;
- d. Correspondence from the originating organization related to the acceptability of YMP responses and final closure of the document.

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Subject: TREND ANALYSIS

Approved:

Approved by: *[Signature]* 3/14/89 YMP Project Leader  
Approved by: *[Signature]* 3/13/89 YMP Quality Assurance Manager

### 16.2.1 PURPOSE

This procedure establishes the methods to be used for Trend Analysis for the Yucca Mountain Project (YMP).

### 16.2.2 SCOPE

This procedure applies to the analysis of information contained in LLNL-YMP Nonconformance Reports, QA Audit and Surveillance Observations, subcontractor provided documents that identify deficiencies in the Quality Assurance Program, and other externally originated documents that identify deficiencies in the QA Program or mandate corrective action.

The purpose of this trend analysis is to:

- a. Identify root causes;
- b. Classify and categorize root cause(s);
- c. Identify repetitive conditions or trends;
- d. Determine effects of identified trends; and
- e. Identify corrective measures.

### 16.2.3 RESPONSIBILITIES

The YMP QA Manager is responsible for collecting and analyzing information that may result in the identification of adverse trends in the implementation of the Quality Assurance Program, and for reporting the results to management.

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## 16.2.4 PROCEDURE

### 16.2.4.1 Collection and Analysis of Data

The YMP QA Manager reviews Nonconformance Reports, QA Audit and Surveillance Observations, and subcontractor provided deficiency reports, and externally originated corrective action documents. Pertinent information is extracted from the reports and is documented on the Trend Analysis Worksheet, Exhibit A. Instructions for completion of the Trend Analysis Worksheet are included as Exhibit B. Information documented on the Trend Analysis Worksheets is entered and maintained in a data base and analyzed to identify any adverse trends that may have developed.

### 16.2.4.2 Reporting the Results of Trend Analysis

The YMP QA Manager issues a report of the results of Trend Analysis activities to Project Management in January and July of each year. This report is distributed to the following personnel:

- a. The YMP Project Manager;
- b. The YMP Deputy Project Manager;
- c. Technical Area Leaders;
- d. Task Leaders; and
- e. Project Administrator.

### 16.2.4.3 Corrective Actions

Upon detection of an adverse trend, as defined below, the YMP QA Manager initiates a Corrective Action Report in accordance with QP 16.0, Corrective Action. An adverse trend is considered to exist when any of the following conditions are present:

- a. Four common cause events within the previous six months, or six common cause events within the previous twelve months for the YMP Project;
- b. Three common cause events in the previous six months, or four common cause events within the previous twelve months for any single Technical Area;
- c. Two common cause events within the previous six months, or three common cause events within the previous twelve months for any single Task Area.

Common cause events may be derived from either the primary or secondary causes.

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**16.2.5 RETAINED DOCUMENTATION**

**16.2.5.1 QA Records**

The Trend Analysis Reports are Quality Assurance Records and are submitted to the Local Records Center for retention in accordance with procedure QP 17.0, QA Records.

**16.2.5.2 Other Documents**

The completed Trend Analysis Worksheets are retained by the QA Organization for a minimum of one year from the date of origination.



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**EXHIBIT B**  
**Trend Analysis Worksheet Instructions**

The Trend Analysis Worksheet is to be completed in the following manner:

**Block 1: Enter Today's Date.**

**Block 2: Enter Your Last Name.**

**Block 3: Enter the type of Document from the following Table:**

**NCR; LLNL Originated Nonconformance Report**

**OBS; QA Audit or Surveillance Observation, either internal or external in origin**

**ECA; Externally Originated Corrective Action Document**

**OCA; Subcontractor Furnished Corrective Action Document**

**SDC; Surveillance deficiency corrected during the surveillance.**

**Block 4. Enter the Number of the Referenced Document (Max. of 10 Digits).**

**Block 5. Enter the origination date of the Document.**

**Block 6. Enter the Effect Code From the Following Table:**

**1 1 Data or Information Lost or Unusable**

**1 2 Item Unusable**

**2 1 Data Unreliable/Additional Analysis or Confirmation Required Before Further Use**

**2 2 Item Requires Rework or Repair**

**2 3 Item Usable-As-Is**

**3 1 Repeat Work Activity (All or Part)**

**3 2 Commitment Date Missed or Modified**

**4 1 No Discernible Effect**

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**EXHIBIT B. Continued**

**Block 7. Enter a primary and secondary Cause Code From the Following Table. If no secondary cause is identified, enter 000.**

- 101 No Approved Procedure
- 102 Procedure Not Implemented
- 103 Procedure Inadequate
- 104 Procedure Noncompliance
- 201 Inadequate Indoctrination, Training, or Qualification of Personnel
- 210 M&TE Not Calibrated
- 211 M&TE Out of Interval
- 212 M&TE Out of Tolerance
- 301 Design Deficiency (Hardware Only)
- 302 Planning Deficiency (Inadequate, Plan Not Followed)
- 401 Inadequate or missing Documentation or Records
- 402 Traceability Not Maintained/Verified
- 501 Other (Explain in the Remarks Section)

**Block 8: Enter the Organization Code From the Following Table:**

- 1000 Program Management/Administration
- 1001 QA Organization
- 2000 Package Environment Technical Area
- 2001 Waste Package Environment Geochemistry
- 2002 Waste Package Environment Hydrology
- 2003 Engineered Barrier System Field Tests
- 2004 Man Made Materials
- 2050 Geochemical Modeling Technical Area
- 2051 EQ 3/6 Code Development

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**EXHIBIT B Continued**

- 2052 Data Base Development
- 2053 Thermodynamic Data Determination
- 2054 Geochemical Modeling
- 3000 Container Design Technical Area
- 3001 Metal Barrier
- 3002 Design and Prototype Testing
- 3003 Alternate Container Materials
- 3050 Release Rate Technical Area
- 3051 Spent Fuel
- 3052 Glass
- 3053 Integrated Testing
- 4000 Performance Assessment Technical Area
- 4001 Deterministic Waste Package Performance
- 4002 Probabilistic Waste Package Performance
- 4003 Regulatory Interactions
- 4004 SCP
- 5000 Subcontractor Activities
- 5001 ANL
- 5002 PNL
- 5003 B&W
- 6000 Other (Requires Explanation in the Remarks Section)

**Block 9 Enter Any Pertinent Remarks**



## CHANGE NOTICE

CN No. 17.0-0-1Affected Document: qp 17.0 "QUALITY ASSURANCE RECORDS"Revision: 0Prepared By Ron SchwartzApproved By N/A

Technical Area Leader

Date

Approved By R. M. E. Smith 3/3/89  
YMP QA Manager DateApproved By J. S. Sellan 3/3/89  
YMP Project Leader DateCurrently Reads as Follows:

1. Section 17.0.5.6, second paragraph, second line.  
... at LLNL in Building 832E, Site 300. Building 832E, a single storage facility ...
2. Section 17.0.5.6, sixth paragraph.  
Copies of records ...
3. Section 17.0.5.6, seventh paragraph.  
Records stored in Building 832E are ...

Changed to Read:

1. Section 17.0.5.6, second paragraph, second line.  
... at LLNL. A single storage facility will ...
2. Section 17.0.5.6, sixth paragraph.  
Copies of records submitted to the DOE Project Office and one-of-a-kind records are stored in a facility where access is controlled at all times.
3. Section 17.0.5.6, seventh paragraph.  
Records stored in the facility are stored ...

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

CURRENTLY READS AS FOLLOWS:

4. Section 17.0.5.6, ninth paragraph, third line.  
... microfilm from the Sponsor.
5. Section 17.0.6, References, add language (see below).
6. Terms and Definitions, Microfilm and Archival Storage Service Facility.  
An entity within Holmes and Narver, Inc. (H&N) that is ... The MASSF is  
maintained by H&N.

CHANGED TO READ:

4. Section 17.0.5.6, ninth paragraph, third line.  
... microfilm from the DOE Project Office.
5. Section, 17.0.6, References, new fourth reference.  
LLNL-YMP Administrative Procedures pertinent to Records Management.
6. Terms and Definitions, Microfilm and Archival Storage Service Facility.  
An entity within YMP is ...  
Delete last sentence.

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

QUALITY ASSURANCE RECORDS

Approved:

Approved by:

*[Signature]* 2/4/89  
YMP Project Leader

Approved by:

*[Signature]* 1/19/89  
YMP Quality Assurance  
Manager

**17.0.1 PURPOSE**

This procedure describes the Lawrence Livermore National Laboratory (LLNL) Yucca Mountain Project (YMP) records management system for the collection, identification, and processing of Quality Assurance records; the on-site temporary hardcopy storage of records; the transmittal of records to the Project Sponsor; and the retrieval of information at any point in the system.

Requirements and responsibilities are established in this procedure for transmittal, receipt, distribution, retention, maintenance, and disposition of QA records. For purposes of record retention, all YMP Quality Assurance records, including superseded records, are classified as lifetime records and are required to be retained for the life of the Project.

**17.0.2 SCOPE**

This procedure applies to all quality assurance records created as the result of work accomplished by the members of the YMP. This includes quality assurance records created by subcontractors engaged in work in support of YMP. The term "records" used throughout this procedure is to be interpreted as "quality assurance records."

**17.0.3 RESPONSIBILITIES**

The LLNL-YMP Records Manager is delegated responsibility and authority for establishing a Local Records Center (LRC) and systems and procedures for document control and records management activities and continued effective operation of the systems.

The LLNL-YMP Quality Assurance Manager, or designee, is responsible for reviewing completed quality assurance records in accordance with the requirements of the quality procedure for such records. The review is to verify independently that the record was prepared and reviewed in accordance with appropriate procedure(s), and to provide comment and concurrence with respect to quality related aspects of the record. The review includes a check of the record for inclusion of appropriate quality assurance requirements.

The Task Leader/Record Source is responsible for collecting and submitting to the LRC records received and generated by YMP activities, authentication of records, and preparation and submittal to the LRC of a listing of records that will be generated as a result of the activity.

#### 17.0.4 TERMS AND DEFINITIONS

See attached Exhibit 17.0-A.

#### 17.0.5 PROCEDURE

##### 17.0.5.1 General

Detailed procedures for receipt control, handling, distribution, issuing and retention of records are discussed in implementing administrative procedures(s) and/or Technical Implementing Procedures(s).

Records that furnish documentary evidence of quality are identified in the "Retained Documentation" section of individual procedures contained in this Quality Procedures Manual. The Task Leader/Record Source will furnish to the LRC a listing (from work planning documents, procurement documents, Technical Implementing Procedures, or other documents) which specifies the records to be generated, supplied or maintained for the DOE Project Office, and will update the listing as appropriate. The Record Source will also furnish to the LRC a listing of QA record types to be generated and will provide the LRC with updates.

The DOE Project Office may issue administrative procedures outlining the records management requirements of a specific Project. LLNL-YMP procedures will be matched to the DOE Project Office procedures when the latter are received and approved for implementation. Any conflicts between LLNL-YMP procedures and DOE Project Office procedures/requirements will be resolved by the LLNL-YMP Project Leader. Various regulatory agencies have requirements concerning records that are within the scope of this procedure. The most stringent requirements shall be used to determine final dispositions.

##### 17.0.5.2 Transmittal of Records to Local Records Center

Once an activity has been completed, the Task Leader is responsible for the collection and transmittal to the LRC of all records generated by that activity. The Task Leader is also responsible to assure that the records package for that activity contains all documentation needed to reconstruct actions taken, decisions made, or conclusions reached.

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The Task Leader verifies the record is legible, identifiable to the activity it relates to, accurate, complete, reproducible, microfilmable and that it is appropriate to the work accomplished.

Sufficient records will be specified, prepared, and maintained to furnish documented evidence of activities that affect quality. The records will include at least (as appropriate) the following: scientific notebooks, results of technical and peer reviews, inspections, tests, audits, data sheets, interim and final reports, computer codes, materials analyses, and closely related data such as qualifications of personnel, processes and equipment. Readily available references such as encyclopedias, dictionaries, engineers' handbook, etc. do not have to be maintained in the records system.

#### 17.0.5.3 Receipt and Acceptance of Records at Local Center

Record transmittals received by the LRC are inspected to assure they are legible, identifiable, complete, suitable for microfilming and are verified for proper approval against the signature authentication list maintained by the LRC. Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. These records may be originals or reproduced copies. Authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.

##### 17.0.5.3.1 Rejection of Records by the LRC

Any problems encountered on receipt inspection will be resolved with the Task Leader before the record is accepted into the records system. Records requiring further completion or correction will be rejected by the LRC and returned to the Task Leader utilizing the Transmittal Form.

Corrections to completed records that have not been processed by the LRC will be made by the Records Source by scribing a single line through the incorrect information using an indelible pen, preferably black ink, entering the correct information in close proximity and signing or initialing and dating the correction. The incorrect information will remain legible. Erasures or correction fluid will not be used as a form of correcting information on records.

If a corrected copy of the record is not received within 10 working days, the LRC will contact the Record Source to obtain a schedule for resubmittal of the record. A log of rejected record transmittals will be maintained by the LRC. Record transmittals not returned as scheduled will be referred to the LLNL-YMP Project Leader or Quality Assurance Manager for resolution.

##### 17.0.5.3.2 Acceptance of Records by the LRC

The LRC indicates receipt and acceptance of records into the records system by initialing and dating the transmittal form and returning a copy to the Task Leader/Record Source.

Records accepted by the LRC are logged using a computer based document logging system. An LRC identification number is assigned to the record. This number is a unique, sequential number which identifies the record to an YMP project activity, and which is not repeated elsewhere in the project. For the Yucca Mountain Project the DOE project office or designee will review and approve the records identification system.

Information that will be logged from the transmittal and the record includes; record date, date received, LRC I.D. No., record I.D. No. (if any), title or subject, author name and/or organization, recipient name and/or organization, QA designation, WBS No. to at least the third level, file location, and other information specific to that record.

#### 17.0.5.4 Record Distribution

Records accepted into the record system will be distributed internally using a standard distribution matrix whenever possible. The distribution matrix will be maintained by the LRC in consultation with LLNL-YMP management and task leaders.

Those documents requiring controlled distribution will be processed in accordance with Procedure 033-YMP-QP 6.0, Document Control, Section 6.0.5.3.2.

#### 17.0.5.5 Transmittal of Records to the Project Sponsor

As directed by the LLNL-YMP Project Leader or the Quality Assurance Manager, the LRC will prepare timely submittals of records to the Project Sponsor record facility.

#### 17.0.5.6 Storage and Preservation of Records

The Task Leader/Record Source is responsible for assuring that from the time of creation and validation of a record until it is delivered to the LRC, the record is protected from damage, deterioration and loss.

Records received by the LRC are promptly copied with the original submitted to the Project Sponsor and the copy filed temporarily at LLNL in Building 832E, Site 300. Building 832E, a single storage facility, will also be used for the temporary storage at LLNL of one-of-a-kind records and special processed records.

The original and copy of a record are stored in a manner to prevent damage from moisture, temperature, and pressure. Records are firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. Special processed records are stored in a manner to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

The LRC maintains a list of personnel who are authorized access to records and record copies. The list includes the LLNL-YMP Project Leader, the Quality Assurance Manager, the Records Manager and other LRC personnel, and for the Yucca Mountain Project the Records Administrator, YMPO.

Records maintained, or not yet transferred, by the YMP at LLNL or other locations are accessible to the DOE Project Office or its designated alternate upon request.

Copies of records submitted to the DOE Project Office and one-of-a-kind records are stored in Building 832E which is kept locked at all times. Access to the building is restricted and there is 24-hour surveillance, motion detectors and closed circuit camera surveillance. The LLNL Security Department has master key access to all Lawrence Livermore facilities.

Records stored in Building 832E are stored in boxes or other containers assigned an identification number for retrievability. The record control log is indexed to reflect the document location. Records may be removed from storage with proper authorization. An original or one-of-a-kind record may be released by the LRC with the use of a record release form signed by the appropriate Task Leader and the Quality Assurance Manager. Prior to releasing a record, the LRC will assure a record copy is made for those records that can be copied.

Corrections to completed records that have been processed will be made by the Records Source who will secure necessary approval to retrieve the record from the LRC in accordance with this Section, make the correction in accordance with Section 17.0.5.3.1 and resubmit the record to the LRC for processing. The LRC will file the corrected record with the prior copy of the record.

If it becomes necessary to restore records at the LRC, it will be accomplished in one of two ways. For records already processed to the DOE Project Office the LRC will request a replacement microfilm from the Sponsor. If records submitted to the DOE Project Office are lost or damaged, a copy will be made from the record copy retained at LLNL and the record copy will be submitted to the DOE Project Office. These measures can be accomplished within 90 days.

#### 17.0.5.7 Retrieval of Records

Requests for retrieval of records will be handled in one of two ways. For those records processed to the DOE Project Office the microfilm copy of the record will be located by accessing the record data base and conducting a search to locate the proper microfilm cartridge stored in the LRC.

For records in process at the LRC, or where the original record has not been processed by the DOE Project Office and a microfilm prepared, the storage location of the record will be determined from the record data base.

Retrieval of records in either case will be made within 10 working days. LRC personnel will make any necessary copies of requested records and return the record copy or microfilm to file.

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#### 17.0.6 REFERENCES

DOE (U.S. Department of Energy), 1988. Nevada Nuclear Waste Storage Investigations Project Quality Assurance Plan, NNWSI/88-9, Revision 2.

NNWSI (Nevada Nuclear Waste Storage Investigations Project), 1988. Nevada Nuclear Waste Storage Investigations Project Records Management Plan, July 1988, NNWSI/88-15.

NNWSI Administrative Procedure AP-1.7Q Records Management, 8/15/88.

#### 17.0.7 RETAINED DOCUMENTATION

- o Completed Records Transmittal Forms
- o QA Record Type Lists
- o Record Release Forms
- o Record Status Logs
- o Record Master Lists
- o Signature Authorization List
- o Record Access Authorization Lists
- o Record Storage Access Log

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**EXHIBIT 17.0-A  
TERMS AND DEFINITIONS**

**ABSTRACT:** A summary record that identifies the prominent points, results, conclusions, or other subject matter that constitutes record contents.

**ACCESSION NUMBER:** A unique identifier for each indexed Yucca Mountain Project record. The accession number is composed of a three-character data element (followed by a period) for location, a two-character data element for year, a two-character data element for month, a two-character data element (followed by a period) for day, and a four-character data element for a sequential identification number (e.g., NNA.880601.0025).

**ACTIVITY:** Any work, including but not limited to, scientific investigations, analysis, procurements or designs, that is directed towards the achievement of the objectives stated in the YMP scope of work.

**AUTHENTICATION:** The act of attesting, by initialing, stamping, or signing and dating a record, that the information contained therein is accurate and appropriate to the work accomplished. A record becomes a Quality Assurance (QA) record when authenticated.

**AUTOMATED RECORDS SYSTEM (ARS):** The OCRWM program-wide computerized index, search, and retrieval system for records management for the Yucca Mountain Project. The ARS provides the means to store the index and abstracts of records at OCRWM/HQ and the project office(s). The complete text of the records is on microfilm at OCRWM/Headquarters (HQ), the project office(s), and the NNWSI Project participants LRCs. The ARS provides for on-line access to the index and abstracts.

**CENTRAL RECORDS FACILITY (CRF):** An entity within the Technical and Management Support Services (T&MSS) Contractor that is responsible for receiving, processing, storing, preserving, and retrieving YMP records, except for those records collected by the Yucca Mountain Project Office (YMPO) Mail and Records Facility (MRF). In addition, the YMP CRF is responsible for assigning a "NNA" prefix accession number to YMP Project records. The YMP CRF is maintained by the T&MSS Contractor.

**DOCUMENT:** Any written or pictorial information describing defining, specifying, reporting or certifying activities, requirements, procedures or results.

**DRAFT DOCUMENT:** A document (other than a final document) that proposes or reflects a YMP position, policy, plan, or intended purpose and that is transmitted by a supervisory official of the originating organization for formal concurrence within the YMP, or formally transmitted outside the YMP for review and/or comment, or, in the case of YMP participants, provided to the YMPO as a scheduled deliverable. Draft document also includes a nonfinal document circulated for concurrence or signature which did not become a final record due to objections or revisions by someone other than the original author and in which the original author or others in the concurrence process have nonconcurred.

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**PRELIMINARY DRAFT DOCUMENT:** A document that is under development or preparation reflecting work in progress. The process of finalization may require iterations and revisions that may be transmitted freely within DOE (including the YMP participants) if the document is stamped "PRELIMINARY DRAFT." Preliminary drafts are excluded from capture in the records system and will not be retained beyond completion of a subsequent iteration.

**INDETERMINATE:** A designation for record packages that have been reviewed but a Quality Level (QL) could not be assigned at the time of review. The record package may be evaluated at a later date to obtain a QL designation.

**LIMITED VALUE MATERIAL:** Those classes of documentary or other material which will not be captured by the ARS and which may be disposed of without special authority, include, but are not limited to, the following:

1. Information copies of correspondence on which no documented administrative action is taken.
2. Materials documenting such fringe activities as employee welfare activities and charitable fund drives.
3. Reading file copies of correspondence.
4. Tickler, follow-up, or suspense copies of records.
5. Duplicate copies of all records maintained in the same file.
6. Extra copies of printed or processed material, official copies of which have been retained for record purposes.
7. Superseded manuals or other directives maintained outside the originating office.
8. Routing slips.
9. Working papers.
10. Transmittal sheets (bucksheets, record rejection forms).
11. Blank forms.
12. Transcribed stenographic material.
13. Processed or published material received from other activities or offices, which require no action and are not required for documentary purposes (the originating office or activity is required to maintain record copies).
14. Catalogs, trade journals, and other publications or papers that are received from Government agencies, commercial firms, or private institutions, which require no action and are not part of a case upon which action is taken.

15. Correspondence and other materials of short term value that, after action has been completed, have neither programmatic nor informational value, such as requests for publications and communications on hotel reservations.
16. Reproduction materials such as stencils and offset masters.
17. Physical exhibits, artifacts, and material lacking documentary value.

Local Records Center Mail and Records Facility Microfilm and Archival Storage.

**LOCAL RECORDS CENTER (LRC):** An entity within each YMP Project participant's organization that is responsible for collecting and receiving YMP Project participant records, verifying the completeness of records, protecting QA records in accordance with the YMP QAP, Section 17.0, transmitting YMP records to the YMP CRF, and retrieving YMP records in response to internal YMP Project participant requests.

**MAIL AND RECORDS FACILITY:** An entity within the YMPO that is responsible for collecting YMP records from the YMPO, verifying the completeness of YMP records, protecting QA records in accordance with the YMP QAP, processing YMP records, and retrieving YMP records for the YMPO. In addition, the MRF is responsible for assigning a "NN1" prefix accession number to YMP records collected or received from the YMPO. The MRF is maintained by the Project Support Documentation Office (PSDO).

**MICROFILM AND ARCHIVAL STORAGE SERVICE FACILITY (MASSF):** An entity within Holmes & Narver, Inc. (H&N) that is responsible for performing microfilming and storage of YMP records in accordance with the YMP QAP. MASSF functions include, but are not limited to, source document preparation, camera operations, filming, entering microfilm location indexing, microfilm processing, film quality verification, duplication, and storage. The MASSF is maintained by H&N.

**NON-PROCESSED MATERIALS:** Materials that will not be captured by the records system including the following:

1. Pre-award information and documents (i.e., information on a procurement prior to contract award, Source Evaluation Board materials, proposal information, etc.) except as required as a QA record. This material must be clearly marked "Pre-Award."
2. Personnel records, except as required as QA records (e.g., qualification and training records).
3. Proprietary information and business sensitive (financial or commercial) information, which is so marked.
4. Information which has been classified pursuant to an Executive Order or statute, which is so marked. Hard copies of such material, when used in the conduct of YMP Project business, will be stored and handled in accordance with DOE 5635.1.

5. Personal correspondence, which is so marked (unless submitted for processing).
6. Informal (preliminary) drafts or working papers, facsimiles, and records circulated or transmitted for information purposes, when so marked.
7. Circulation/direct distribution mail, subscriptions, periodicals, press releases, and news clippings.
8. International draft correspondence, documents, brochures, and literature. Final reports and official documents are not excluded.
9. Travel vouchers, travel authorizations, purchase orders, training requests, personnel actions, and similar administrative material, where a record copy is retained by another organization (e.g., the personnel department).
10. Contractor-generated contract progress reports and telephone logs, except when included as part of a required records turnover package.
11. Documents prepared by another DOE organization, not DOE/HQ-OCRWM and submitted to the project for routine concurrence or coordination, whose subject matter does not relate specifically or exclusively to the project.

NOTE: To be considered Non-Processed Material, the record itself and/or its transmittal envelope must be clearly marked "informal input," "preliminary draft," "sensitive," "restricted," "personal," etc.

ONE-OF-A-KIND RECORDS: Quality assurance records that cannot be duplicated or microfilmed are considered one-of-a-kind items. Such records include, but are not limited to, the following: core samples, photographic negatives, radiographic films, multi-colored maps, and map overlays.

PARTICIPANT INTERNAL RECORDS: Records directly associated with the participant's contract work whose distribution remains internal to the participant, including the following:

1. Training/seminar approvals.
2. Participant concurrence copies of letters.
3. Interoffice memos related to a project (but not copies to personnel other than the individual project participant's organization) unless transmitted by official letterhead as an attachment.
4. Unpublished reports and documents, unless transmitted to the sponsor for formal review.

**QA RECORD:** An individual record or record package that has been executed, completed, and approved and that furnishes evidence of (1) the quality and completeness of data (including raw data), items, and activities affecting quality; (2) records prepared and maintained to demonstrate implementation of QA programs (e.g., audit, surveillance, and inspection reports); (3) procurement records; (4) other records such as plans, correspondence, documentation of telecons, specification, technical data, books, maps, papers, photographs, and data sheets; (5) items such as magnetic media; and (6) other materials that provide data and record quality regardless of the physical form or characteristics. A completed record is a document or item (and documentation) that will receive no more entries, whose revisions would normally consist of a reissue of the record, and that is signed and dated by the originator and, as applicable, by approval personnel.

**RECORD:** All books, documents, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government or in connection with the transaction of public business and preserved or judged appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data contained therein. Library and museum materials made or acquired and preserved solely for reference or exhibition purposes, extra copies of records preserved only for convenience of reference and stocks of publications and of processed documents are not included. A record is not considered a quality assurance record until it satisfies the definition of a quality assurance record.

**RECORD PACKAGE:** A collection of records supporting one topic (subject) which are filed as a case file (i.e., QA audit file, contract or procurement file, engineering drawing package). The file will be held by the originating office or individual until the transaction is completed. It will then be indexed and processed as one record.

**RECORD SOURCE:** Any individual or organizational entity employed by a project participant who is responsible for generating records or receiving records from an entity outside the project.

**RECORDS TURNOVER PACKAGE:** A collection of Project records which, under the terms of a contract, interagency agreement, memorandum of understanding, or similar instrument, are submitted by a YMP participant at intervals, not to exceed annually, to the YMP CRF prior to closeout of the contract or other agreement. A records turnover package consists of all data first produced or specifically used in the performance of the contract.

**SPECIAL PROCESSED RECORDS:** Records that cannot be microfilmed on 16 mm rolls of film. These records may be filmed on aperture cards (i.e., oversized maps and logs) or they may be duplicated and stored in dual storage (i.e., negatives, color photographs, magnetic media).

**VALIDATION:** The act of reviewing a QA record (authenticated record) to assure that it is legible, identifiable, reproducible, and microfilmable (when required).

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**WORKING FILES:** Project-related files kept or created by a project employee in the performance of his or her official duties on the project. To be designated as such, the files must be in the possession of the individual, completely segregated from, and in addition to, the official office files.

See Appendix A of the Quality Procedures Manual for additional definitions.

**YMP PARTICIPANT:** An all inclusive term used to describe (generically) the various organizations involved in the Yucca Mountain Project. This term includes the YMPQ, Participating Organizations, and Nevada Test Site (NTS) Support Contractors.

**YMP RECORDS:** All records generated or received by YMP Project participants except for those that are designated as YMP Project participant internal, non-processed, or limited-value material.



CHANGE NOTICE

CN No. 18.0-0-1

Affected Document: QP 18.0 "Audits"

Revision: 0

Prepared By Ronald Schwartz

Approved By N/A  
Technical Area Leader Date

Approved By *R. E. Adams* 3/3/89  
YMP QA Manager Date

Approved By *P. Sallan* 3/3/89  
YMP Project Leader Date

Currently Reads as Follows:

1. Section 18.0.5.2, second paragraph, second sentence  
The technical specialist may be selected from the audited organization.

Changed to Read:

1. Section 18.0.5.2, second paragraph, second sentence  
Delete sentence.

**NOTE:** THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0102

Subject:

AUDITS

Approved:

Approved by: *J. Sallan* 1/20/89  
YMP Project Leader

Approved by: *R. E. Adams* 1/12/89  
YMP Quality Assurance  
Manager

#### 18.0.1 PURPOSE

This procedure establishes the formal audit program for LLNL-YMP activities.

#### 18.0.2 SCOPE

This procedure applies to YMP activities at LLNL and to Project subcontractors.

#### 18.0.3 RESPONSIBILITIES

YMP Quality Assurance Manager is responsible for assuring that this procedure is implemented and remains effective.

#### 18.0.4 TERMS AND DEFINITIONS

**Audit:** A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, codes, standards, instructions, drawings and other applicable requirements, and the effectiveness of implementation.

**Audit Finding:** The result of a review of objective evidence associated with an activity, task or product, such as Drawings, Documents, Calculations, Facts, Circumstances, or Conditions, that establishes the existence of a significant condition adverse to quality as defined in NNWSI/88-9, a failure of a control system to achieve the intended purpose, or a violation of an established policy, procedure, or instruction requirement that would reasonably be expected to result in a reduced quality of the specified end product. An Audit Finding may summarize small anomalies of the same or similar type in the same or different areas, which collectively create a significant condition adverse to quality.

**Observation:** A discovered condition which, in the opinion of the auditor, may lead to a nonconformance if uncorrected.

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## 18.0.5 PROCEDURES

### 18.0.5.1 Audit Schedules

The frequency with which an activity is audited is a function of its importance to the overall success of the Yucca Mountain Project (YMP). Audits are performed as early in the life of an activity as practical and are continued at intervals consistent with the schedule for accomplishing the activity. The frequency may also depend on the specific quality assurance program elements that have to be audited to provide continued assurance of compliance and effectiveness. All activities, however, are audited at least annually, or at least once during the life of the activity, whichever is shorter.

#### 18.0.5.1.1 Audit Numbering

Audits are numbered when the schedule is first issued. The number begins with the fiscal year designation (e.g., 87), followed by a sequentially assigned number. If an audit is rescheduled, its number remains the same. If an audit is added to the schedule, it is given the next number in the sequence, regardless of when the audit is scheduled. If an audit is deleted its number is not reassigned.

#### 18.0.5.1.2 Internal Audit Schedule

At the beginning of each fiscal year the YMP QA Manager issues a 12-month internal audit schedule to the YMP Project Leader, Technical Area Leaders, Task Leaders, and the DOE Project Office. The schedule identifies those Tasks to be audited, the months in which the audits are scheduled to take place, and the requirements against which the audits will be conducted. The YMP QA Manager may schedule audits of a Task's subcontractors at the same time as an audit of the Task's internal activities to provide for a more complete and coherent review of the Task. If this is done, the scheduled audit of the subcontractor(s) appears on both the internal and external audit schedules.

#### 18.0.5.1.3 External Audit Schedule

Subcontractors who do work at Level of Quality Assurance I or II in support of LLNL's YMP are audited annually or once during the life of the activity, whichever is shorter.

An exception is made when subcontractors are to complete their work in less than four months. Such audits are performed at the option of the YMP QA Manager. The justification for not performing audits of suppliers whose activities are less than four months in duration is documented and approved by the YMP QA Manager.

At the beginning of each fiscal year the YMP QA Manager issues a 12-month external audit schedule to the YMP Project Leader, Technical Area Leaders, Task Leaders, and The DOE Project Office. This schedule shows which subcontractors are to be audited, the months in which the audits are scheduled to take place, and the requirements against which the audits will be conducted.

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When feasible, audits of subcontractors are coordinated with other organizations performing work for YMPO. In such cases, copies of audit reports are distributed to all participants.

Audits of other DOE Integrated Contractors are conducted with the approval of the cognizant DOE Operations Office and are included on the external audit schedule.

#### 18.0.5.1.4 Changes to Audit Schedules

The audit schedule is monitored, evaluated and revised, as necessary, to assure that audit coverage remains current. The evaluation includes an assessment of the effectiveness of the program based upon:

- a. Previous audit results and the effectiveness of corrective actions;
- b. Nonconformance reports;
- c. Information from other sources such as the American Society of Mechanical Engineers (ASME), Nuclear Regulatory Commission, etc.

Changes to either the internal or external audit schedule during the year in which it is effective are approved by the YMP QA Manager. Copies of the audit schedule, and any subsequent changes, are sent to the YMP Leader, Project Leader, Technical Area Leaders, Task Leaders, and the DOE Project Office.

#### 18.0.5.1.5 Scheduling of Additional Audits

The YMP QA Manager may schedule additional audits when:

- a. Significant changes are made in functional areas of the quality assurance program or in a Task (such as significant reorganization or procedure revisions); or
- b. It is suspected that the quality of an item or service is in jeopardy because of deficiencies in the quality assurance program; or
- c. Assessment of the program effectiveness is considered desirable; or
- d. One is requested by the YMP Project Leader, or a YMP Technical Area Leader; or
- e. In the opinion of the YMP QA Manager, they are necessary.

Additional audits are added to the appropriate audit schedule in accordance with Section 18.0.5.1.4.

#### 18.0.5.2 Audit Team Selection

Audits are performed by Personnel qualified in accordance with procedure 033-YMP-QP 18.2, "Qualification of Quality Assurance Audit Personnel." The YMP QA Manager designates the Lead Auditor. The Lead Auditor designates the other members of the audit team. Audit team members are independent of any direct technical responsibility for the task to be audited. Also, personnel who have direct responsibility for performing the activity to be audited are not involved with audit team selection. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective.

The audit team may include one or more technical specialists. The technical specialists may be selected from the audited organization.

Multidisciplinary audit teams are employed when activities to be audited involve more than a single technical area.

Prior to commencing the audit, the Lead Auditor documents an assessment that assigned personnel have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. This assessment is documented on the Audit Planning Worksheet, Exhibit A.

#### 18.0.5.3 Lead Auditor

The Lead Auditor is responsible for preparing the audit plan, conducting the opening and closing meetings, and managing the audit. The Lead Auditor is also responsible for the preparation and approval of the audit report.

#### 18.0.5.4 Audit Planning

An audit plan is prepared for each audit. The plan includes the scheduled date(s) of the audit, the audit's scope, the Task to be audited, the specific requirements to which the Task is to be audited, the organizations to be contacted (if external to LLNL-YMP), and the names of the auditors. The scope of the audit is established by considering the results of previous audits, the nature and frequency of identified deficiencies, and significant changes in personnel, organization, or in the QA Program. Each audit plan includes a checklist. The checklist is based on quality assurance requirements pertaining to the Task's activities that are to be audited. The checklist also includes questions pertaining to the disposition of previous audit findings and nonconforming items, procedural nonconformances, and conditions adverse to quality that were filed during the period since the Task's last audit. The audit plan is prepared in accordance with the format shown in Exhibit B, Audit Plan Format.

The audit plan, including the audit checklist, is sent to the YMP Project Leader, the appropriate Technical Area Leader, and the appropriate Task Leader prior to the audit.

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#### 18.0.5.5 Performance of the Audit

##### 18.0.5.5.1 Opening Meeting

Each audit begins with an opening meeting attended by the audit team members and members of the Task to be audited. The opening meeting is scheduled by the YMP QA Manager. During this meeting, the audit objectives are reviewed and any questions regarding performance of the audit are answered. A schedule of events is established by mutual agreement.

##### 18.0.5.5.2 Audit Performance

Objective evidence is examined and interviews are conducted, as necessary, to determine whether Quality Assurance requirements are being implemented effectively and are adequate for effective control for the particular activity. Conditions that require prompt corrective action are reported immediately to the appropriate Task Leader. The audit team assures that all checklist questions are addressed and that this is documented on the checklists.

In external audits, the audit results are documented by the audit personnel and discussed with management having responsibility for the area audited. Conditions that require prompt corrective action are reported immediately to the management of the audited organization and to the cognizant YMP Technical Area Leader.

Audits of suppliers are documented and take into account, where applicable, (1) review of supplies furnished, documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

##### 18.0.5.5.3 Closing Meeting

Each audit ends with a closing meeting. All audit findings are discussed to assure understanding of what was observed. Audit findings and observations include all deficiencies, nonconformances, and potential quality problems identified during the audit.

Audit Findings are further documented and processed in accordance with procedure 033-YMP-QP 15.0, Nonconforming Items, Procedural Nonconformances and Conditions Adverse to Quality.

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#### 18.0.5.6 Audit Report

The results of audits are documented in an audit report, which contains the following information: audit number; audit scope; identification of members of the Task audited and of the audit team; a succinct statement of each finding accompanied by a discussion of the finding; a statement concerning the effectiveness of the implementation of the QA elements that were audited; and reference to Nonconformance Reports originated as the result of audit findings. The audit report follows the format outlined in Exhibit C. The Lead Auditor approves the audit report.

The audit report may also contain observations that may be a comment or recommendation based on an auditor's experience. Observations do not require a response.

The audit report is due 15 calendar days after the closing meeting to the Project Leader, the appropriate Technical Area Leader, and the appropriate Task Leader.

#### 18.0.6 AUDIT REPORTING TO SPONSORS

When the audit is closed the YMP QA Manager forwards a copy of the audit report to the DOE Project Office.

#### 18.0.7

Audits are considered closed upon distribution of the audit report and issuance of any Nonconformance Reports that result from audit findings. Evaluation of the adequacy of the dispositions is conducted in accordance with procedure QP 15.0, Nonconformances.... Further review and evaluation is conducted in accordance with paragraph 18.0.5.4 of this procedure.

#### 18.0.8 AUDIT RECORDS

Quality assurance records resulting from the implementation of this procedure are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Audit records include the following:

- Audit Planning Worksheet;
- Audit plan;
- Checklists;
- Audit reports.









## CHANGE NOTICE

CN No. 18.1-0-1Affected Document: QP 18.1 "Surveillance"Revision: 0Prepared By Ronald SchwartzApproved By N/A

Technical Area Leader

Date

Approved By R. M. E. Schwartz 3/15/89

YMP QA Manager

Date

Approved By [Signature] 3/15/89

YMP Project Leader

Date

Currently Reads as Follows:

1. Section 18.1.5.2, add new third paragraph  
(See below).

Changed to Read:

1. Section 18.1.5.2, add new third paragraph:

The YMP QA Manager will identify for the DOE Project Office support activities supplied to LLNL-YMP by other participating organization and NTS Support Contractors and request the DOE Project Office to conduct a surveillance of the organization performing the work.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

SURVEILLANCES

Approved:

Approved by: *J. Bellan* 1/20/89  
YMP Project Leader

Approved by: *R. M. E. Shaw* 1/12/89  
YMP Quality Assurance  
Manager

**18.1.1 PURPOSE**

This procedure describes the controls necessary to establish and implement a surveillance program for LLNL Yucca Mountain Project (YMP) activities.

**18.1.2 SCOPE**

This procedure applies to all YMP activities at LLNL and to YMP subcontractors.

Surveillances are used to verify compliance with Quality Assurance Program requirements based upon an activity's importance to the YMP. They may be used:

- o To monitor activities while they are in progress;
- o To review completed documentation;
- o To verify completion of corrective action;
- o To investigate known or suspected nonconforming conditions or problems;
- o For other purposes as deemed appropriate by the YMP QA Manager.

**18.1.3 RESPONSIBILITIES**

The YMP Quality Assurance Manager is responsible for and has the authority to establish and implement the provisions of this procedure. The YMP QA Manager is also responsible for maintaining and assuring the effectiveness of this procedure.

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#### 18.1.4 TERMS AND DEFINITIONS

**Surveillance:** The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

**Nonconformance:** A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

**Observation:** A discovered condition which, is the opinion of the Surveillance Leader, may lead to a nonconformance if left uncorrected.

#### 18.1.5 PROCEDURE

##### 18.1.5.1 Surveillance Personnel Selection

Surveillances are conducted by personnel selected by the YMP QA Manager. The surveillance is led by a person qualified as an auditor for the YMP in accordance with procedure 033-YMP-QP 18.2, "Qualification of Quality Assurance Audit Personnel." Additional personnel may be selected based on their technical expertise, and do not have to be qualified as auditors or as Lead Auditors. Surveillance personnel are not to be in positions that report directly to the immediate supervisors of the activity being surveilled, but must be familiar with the Scientific Investigation Plan (SIP) that governs the activity. The surveillance team determines the number and frequency of surveillances for scientific investigations to which they are assigned.

##### 18.1.5.2 Surveillance Scheduling

At the beginning of each fiscal year the YMP QA Manager issues a 12-month surveillance schedule to the YMP Project Leader, Technical Area Leaders, Task Leaders and the DOE Project Office. This schedule identifies those YMP and subcontractor activities for which surveillances are planned. As required, the schedule is updated and reissued.

Unscheduled surveillances may be conducted to supplement scheduled surveillances.

##### 18.1.5.3 Surveillance Numbering

Surveillance numbers are assigned as each surveillance plan is approved. The number consists of the capital letter "S" followed by the fiscal year designator and a sequential number. For example, the first surveillance of FY89 would be numbered as S89-1. A surveillance log is maintained to monitor the issuance of surveillance numbers and to monitor the status of ongoing surveillance activities.

#### 18.1.5.4 Surveillance Planning

Surveillance planning consists of the identification of activities or characteristics that are important to the attainment of Quality Assurance Program objectives. Specific items or activities to be verified are identified. When necessary, qualitative or quantitative acceptance criteria are specified.

The individual leading the surveillance prepares a checklist that includes the following:

- o The assigned number;
- o The name(s) of personnel conducting the surveillance and reference to their qualifications, if not already on file with YMP;
- o The activity(ies) or other characteristics and items to be observed;
- o Observation methods to be used;
- o Acceptance criteria;
- o Reference to the procedures or other documents that specify the applicable requirements;
- o Provision for recording objective evidence of results;
- o M&TE requirements, including accuracy requirements;
- o Provisions for approval by the YMP QA Manager.

Exhibit A provides an example Surveillance Checklist.

#### 18.1.5.5 Surveillance Report

Surveillance results are documented on the Surveillance Report. If not corrected prior to completion of the surveillance, conditions that do not conform to applicable requirements are documented on the Nonconformance Report in accordance with procedure 033-YMP-QP 15.0, "Nonconformances."

The surveillance report contains the following:

- o The surveillance number;
- o The date(s) of the surveillance;
- o Identification of the persons conducting the surveillance;
- o Identification of the activity and characteristics observed;
- o Identification of the acceptance criteria;
- o Identification of persons contacted during the surveillance;

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- o Identification of the procedures or other documents that specify requirements relevant to the surveillance;
- o Identification of equipment used during the surveillance;
- o A succinct summary statement of the results of the surveillance that includes reference to any Nonconformance Reports initiated as a result of the surveillance, identification of nonconforming conditions corrected prior to completion of the surveillance, and any other observations that warrant management attention. Exhibit B provides an example of the Surveillance Report format.

The surveillance report is submitted to the YMP QA Manager not later than five working days after completion of the surveillance.

#### 18.1.5.6 Review of the Surveillance Report

The YMP QA Manager reviews and accepts each surveillance report and issue copies to the appropriate Task Leader and to the YMP Project Leader. The YMP QA Manager may upgrade any surveillance observation to a Nonconformance.

The YMP QA Manager performs an analysis of surveillance results in order to identify any adverse trends affecting quality. A quarterly summary report is issued that specifies the status of surveillances in progress and any adverse trends that have been identified. Such trends are further processed in accordance with 033-YMP-QP 16.0, "Corrective Action."

#### 18.1.6 RETAINED DOCUMENTATION

Quality assurance records resulting from the implementation of this procedure are collected, handled, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- o Surveillance schedules;
- o Surveillance logs;
- o Surveillance reports, including completed checklists.

**EXHIBIT A  
SURVEILLANCE CHECKLIST**

**SURVEILLANCE CHECKLIST**

Surveillance No.: _____		Approved by: _____		Date: _____		Page: _____ of _____	
Subject: _____		(First page only)					
Prepared by: _____		M&TE needed, including Accuracy Requirements				<b>LEGEND:</b> Sat = Satisfactory Unsat = Unsatisfactory COS = Corrected During Surveillance	
ITEM	ACTIVITY AND CHARACTERISTICS:	PROC.D.REF.:	METHOD OF OBSERVATION:	ACCEPTANCE CRITERIA:	RESULT:		
Conducted by: _____				Persons Contacted: _____			

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EXHIBIT B  
SURVEILLANCE REPORT FORMAT

SURVEILLANCE NO.:

DATE(S) PERFORMED:

CONDUCTED BY: (Name and organization)

ACTIVITY AND CHARACTERISTICS OBSERVED:

PERSONS CONTACTED: (Name, title, organization)

REFERENCE DOCUMENTS: (Number, title, revision)

EQUIPMENT USED: (Enter only if appropriate)

SUMMARY OF RESULTS:

Prepared by: \_\_\_\_\_  
(signature, title)

Date: \_\_\_\_\_

Accepted by: \_\_\_\_\_  
(signature, title)

Date: \_\_\_\_\_


**CHANGE NOTICE**

 CN No. 18.2-0-1

 Affected Document: QP 18.2 "Surveillance"

 Revision: 0

 Prepared By Ronald Schwartz

 Approved By N/A  
 Technical Area Leader Date

 Approved By *R. M. E. Schmitz* 3/3/89  
 YMP QA Manager Date

 Approved By *J. M. Hallan* 3/3/89  
 YMP Project Leader Date

Currently Reads as Follows:

1. Section 18.2.4.2.b, second sentence  
 Training in the following areas based upon...

Changed to Read:

1. Section 13.2.4.2.b, second sentence  
 Training in the following areas is based upon...

**NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT**

**NUCLEAR WASTE MANAGEMENT PROGRAM**

CONTROLLED COPY NO. 0102

Subject:

QUALIFICATION OF QUALITY ASSURANCE AUDIT PERSONNEL

Approved:

Approved by: *D. Sallan* 1/20/89  
YMP Project Leader

Approved by: *R. E. Schatz* 1/12/89  
YMP Quality Assurance  
Manager

**18.2.1 PURPOSE**

This procedure provides requirements for the qualification of Auditors and certification of Lead Auditors for LLNL's Yucca Mountain Project (YMP).

This procedure also provides requirements for individuals having special expertise who may be members of an audit team, such as technical experts, management representatives, and auditors in training.

**18.2.2 SCOPE**

This procedure applies to individuals who are selected to be members of teams assigned to conduct audits of Tasks described in the scope of Procedure 033-YMP-QP 18.0, Audits.

**18.2.3 RESPONSIBILITY**

Overall responsibility for assuring implementation of this procedure is assigned to the YMP Quality Assurance Manager.

**18.2.4 PROCEDURE**

Quality assurance audits are performed by one or more auditors. The audit is led by a Lead Auditor certified by the YMP Project Leader. Other audit participants have either experience or training in performing audits or technical knowledge commensurate with the scope, complexity, and nature of the activities to be audited.

#### 18.2.4.1 Qualification of Auditors and Technical Specialists

The YMP QA Manager is responsible for training personnel to perform the various auditing functions by one or both of the methods given below:

- a. Orientation and training in audit performance. Training topics include fundamentals, objectives, characteristics, organization, performance, and results of quality assurance auditing. A commercially available training program may be used if approved by the YMP QA Manager. Training also covers the content of 10CFR60, the YMP Project QA Plan, and applicable codes, standards, and guides.
- b. On-the-job training and guidance under the direct supervision of a Lead Auditor. Such training includes planning, performing and reporting of audits.

The YMP QA Manager maintains a file for each Auditor to document training and audit participation. Audit participation is documented on the Auditor Participation Form, Exhibit A, and is included as part of each Auditor's file.

The YMP QA Manager maintains a file for each Technical Specialist or other audit team participant to document qualifications, training and audit participation. Applicable technical knowledge and experience is documented on a resume or by reference to YMP Personnel Qualification Report. Audit participation is documented on the Auditor Participation Form, Exhibit A.

#### 18.2.4.2 Lead Auditor Evaluation

Each candidate for YMP Lead Auditor is evaluated by the YMP QA Manager in accordance with criteria described below. The evaluation for each candidate is documented on the Lead Auditor Certification Worksheet, Exhibit B.

##### a. Communication Skills

The prospective Lead Auditor demonstrates effective oral and written communication skills as determined by the YMP QA Manager.

##### b. Training

The prospective Lead Auditor is trained to the extent necessary to assure competence in auditing skills. Training in the following areas based upon evaluation of the particular skills of each prospective Lead Auditor:

- o Knowledge and understanding of the YMP QAPP documents, 10 CFR Part 60, and other nuclear and/or DOE related codes, standards, regulations and regulatory guides, as applicable to the YMP.
- o General structure of Quality Assurance programs and applicable elements as defined in the YMP Quality Assurance Program documents.

- o Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closure of audit findings.
- o Audit planning in the functions related to quality for the following activities: site characterization (scientific investigations), design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.
- o On the job training to include applicable elements of the audit program.

c. Evaluation of Education/Training and General Auditing Experience

The prospective Lead Auditor possesses verifiable evidence that a minimum of ten (10) credits under the following scoring system have been accumulated.

(1) Education (4 Credits Maximum)

Associate degree from an accredited institution: score one (1) credit or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) credits; or

A bachelor's degree from an accredited institution: score two (2) credits or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) credits; in addition, score one (1) credit for a masters degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

(2) Experience (9 Credits Maximum)

Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) credit for each full year with a maximum of five (5) credits for this aspect of experience.

If 2 years of this experience have been in the nuclear field, score one (1) additional credit; or

If 2 years of this experience have been in quality assurance, score two (2) additional credits; or

If 2 years of this experience have been in auditing score three (3) additional credits; or

If 2 years of this experience have been in nuclear quality assurance, score three (3) additional credits; or

If 2 years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.

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(3) Other Credentials of Professional Competence (2 Credits Maximum)

For certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency or National Professional or Technical Society: score two (2) credits.

(4) Rights of Management (2 Credits Maximum)

The Lead Auditor's employer may grant up to two (2) credits for other performance factors applicable to auditing. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.

d. Nuclear Auditing Experience

The Prospective Lead Auditor has participated in at least five quality assurance audits within the three years prior to the date of certification, one audit of which is a nuclear quality assurance audit conducted within the year prior to certification.

e. Lead Auditor Examination

The Prospective Lead Auditor successfully completes an examination that evaluates comprehension and ability to apply the body of knowledge identified in this procedure. The examination may be oral, written, performance evaluation, or any combination thereof.

The YMP QA Manager is responsible for the development and administration of this examination. An exam question data base is maintained by the LLNL Quality Assurance Office (QAO) under an agreement with YMP. The LLNL QAO administers the examinations in accordance with their procedures. The YMP QA Manager is notified in writing upon successful completion of the examination by a prospective Lead Auditor. The letter certifying successful completion and a copy of the examination answer sheet are included in the individual's certification folder.

18.2.4.3 Lead Auditor Certification

An Auditor is certified by the YMP Leader as a Lead Auditor when the criteria in Section 18.2.4.2. are met. The certification, which is valid for one year, is documented on the Record of Lead Auditor Qualification, Exhibit B.

The YMP QA Manager may recommend that Lead Auditors who are certified by organizations external to YMP be certified as Lead Auditors for YMP. Such recommendations are to be in writing to the YMP Project Leader and are to include documentation pertaining to the individual's certification and a completed Record of Lead Auditor Qualification, Exhibit B.

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#### 18.2.4.4 Maintenance of Certification

Lead Auditors retain their certification by maintaining their proficiency by regular participation in the audit process, keeping abreast of regulatory quality assurance requirements, and keeping informed of developments in the field of quality audits. The YMP Project Leader reviews the certification for each Lead Auditor annually and either extends or cancels the certification. These reviews are documented. Lead Auditors who fail to maintain their proficiency for a period of two years or more must requalify in accordance with Section 18.2.4.2.

#### 18.2.5 RETAINED DOCUMENTATION

Quality assurance records resulting from the implementation of this procedure are collected, handled, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, Quality Assurance Records.

Quality assurance records include the following:

- Auditor training records,
- Audit participation records,
- Lead Auditor Certification Worksheets and supporting documents.



**EXHIBIT B  
YMP LEAD AUDITOR CERTIFICATION WORKSHEET**

UNIVERSITY OF CALIFORNIA <b>Lawrence Livermore National Laboratory</b>		<b>YUCCA MOUNTAIN PROJECT</b>	Page _____ of _____
<b>YMP LEAD AUDITOR QUALIFICATION WORKSHEET</b>			
<b>RECORD OF LEAD AUDITOR QUALIFICATION</b>	Name	Date	
<b>EMPLOYER:</b> Lawrence Livermore National Laboratory/ Yucca Mountain Project			
<b>QUALIFICATION POINT REQUIREMENTS</b>			<b>CREDITS</b>
<b>Education - University/Degree/Date</b>			4 Credits Max.
<ul style="list-style-type: none"> <li>1. Undergraduate Level</li> <li>2. Graduate Level</li> </ul>			
<b>Experience - Company/Dates</b>			9 Credits Max.
<ul style="list-style-type: none"> <li>Technical (0 - 5 credits) and Nuclear Industry (0 - 1credit ), or Quality Assurance (0 - 2 credits), or Auditing (0 - 4 credits)</li> </ul>			
<b>Professional Accomplishment - Certificate/Date</b>			2 Credits Max.
<ul style="list-style-type: none"> <li>1. P.E.</li> <li>2. Society</li> </ul>			
<b>Management - Justification/Evaluator/Date</b>			2 Credits Max.
<b>Explain:</b>  Evaluated By: (Name and Title) _____			Date _____
<b>Total Credits</b>			_____
<b>AUDIT COMMUNICATION SKILLS</b>			
Evaluated By (Name and Title) _____			Date _____
<b>AUDIT TRAINING COURSES</b>			
Course Title or Topic:			Date
1. _____			
2. _____			
<b>AUDIT PARTICIPATION</b>			
	<b>Location</b>	<b>Audit</b>	<b>Date</b>
1.			
2.			
3.			
4.			
<b>EXAMINATION:</b>		<b>PASSED:</b>	<b>DATE:</b>
AUDITOR QUALIFICATION CERTIFIED BY: (Signature and Title)			Date Certified
<b>ANNUAL EVALUATION</b> (Signature and Date)			