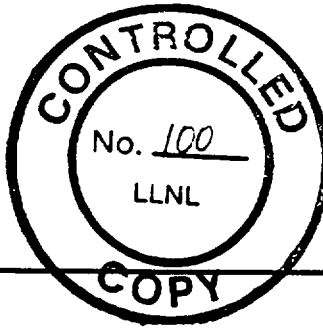


University of California



**UCCA MOUNTAIN PROJECT**  
**Quality Procedures**



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Subject:

**DESIGN CONTROL**

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Date

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### 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.

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 (TIPs) in accordance with Procedure No. 033-YMP-QP 5.0, "Technical Implementing Procedures." These TIPs 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 QA Grading

Prior to the initiation of design activities associated with LLNL's YMP, QA Grading of each activity is performed. In the case of an activity for which LLNL-YMP has primary responsibility, QA Grading is performed in accordance with Procedure No. 033-YMP-QP 2.8, "Quality Assurance Grading." In the case of an activity for which an external YMP organization has primary responsibility, the QA Grading performed by that organization is applied to work.

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### 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 and the QA Manager. 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 QA controls applied to the activity normally are 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;

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- (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 Quality Affecting 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 previously proven designs. Known problems affecting standardized, or previously 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 previously 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 rationale for using the originator's supervisor is documented and approved by the Project Leader. The QA Manager reviews and approves this rationale.

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 review 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 Quality Affecting 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.

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### 3.1.5.7 Design Interface Control for Quality Affecting 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 Quality Affecting 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.

### 3.1.5.9 Design Output Review and Approval by YMPO

YMPO shall review design outputs and documents containing proposed changes to the Project Technical Baseline.

The appropriate YMPO Division Director shall sign and date all design output documents which are to be submitted to the State of Nevada as backup for a permit application. A separate DOE signature block will be provided on the drawing for this purpose. Completed documents shall be forwarded to State officials only through YMPO.

A decal ("DOE/Project ACCEPTANCE FOR CONSTRUCTION") shall be affixed to all design documents intended for use in construction. The YMPO E&DD Director shall sign and date the decal and indicate "N/A" in any other DOE signature area on the document. These documents will be placed in the Project Baseline and be issued, distributed, and controlled by YMPO.

### 3.1.5.10 Engineering Plans

Engineering Plans shall be prepared for each element of design (e.g., Waste Package Conceptual Design, WPACD, WPLAD). Engineering Plans shall, as a minimum, include the following:

1. Purpose, scope, and understanding of work required.
2. Description of work to be performed.
3. Methods and procedures to be used.
4. Responsibility of personnel assigned by activity or task.

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5. Integration and interface requirements.
6. Technical input requirements.
7. Reviews planned.
8. Deliverables.
9. Quality assurance.
10. Task schedule.
11. Task budget.
12. Criteria for YMPO acceptance of deliverables.

Engineering Plans shall be approved by YMPO prior to initiation of detailed design activities unless this requirement is waived by YMPO.

### 3.1.6 QUALITY ASSURANCE RECORDS

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:

**QA Grading documentation package,**  
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.