University of California

Lawrence Livermore National Laboratory

CONTROLLED COPY No. 089 LLNL

YUCCA MOUNTAIN PROJECT

QUALITY ASSURANCE PROGRAM PLAN

No.:	033-YMP-R 3
Revision:	1
Effective Date:	6/1/92
Page:	1 of 18

Subject:

SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

APPROVED: APPROVED FOR INTERIM USE

Training Required: Yes [X] No [ ]

Comment: Incorporation of five previously approved change notices; alternatives to bound logbooks or notebooks may be used.

Approved by: W. L. Clarke 4/28/92
Yucca Mountain Project Leader — Date

Approved by: Dean Wolfe 4-28-92
YMP Quality Assurance Manager — Date

1.0 SCIENTIFIC INVESTIGATION CONTROL

1.1 PREPARATION OF PLANS

1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Prior to the start of any scientific investigation, a scientific investigation planning document for that investigation is developed. Scientific investigations categorized as site characterization activities as defined in the Nuclear Waste Policy Act (as amended) utilize study plans as the scientific investigation planning document. **Scientific** planning documents contain or reference the following:

1.1.1.1 Description of Work to be Performed

A description of the work to be performed in the scientific investigation and the proposed methodology for accomplishing the work, including a discussion of the overall purpose for the work is provided in the scientific investigation planning documents. References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items, for which the work is to be performed are provided. This discussion identifies all of the factors and concerns that are important for the planning or the performance of the scientific investigation, including identification, explanation, and justification for areas where scientific notebooks are to be used.

1.1.1.2 Description of Previous Work

A description of any previous work which will be used in support of the scientific investigation, including the identification of Quality Assurance (QA) controls, under which that previous work was performed. Note: This requirement does not apply to study plans.

1.1.2 PLANNING DOCUMENTS

For Site Characterization activities the purpose and key milestones of study plans are described in the SCP. The format and content of study plans meet the requirements of 033-YMP-R Appendix K.

1.2 REVIEW AND APPROVAL PROCESS

1.2.1 RESPONSIBILITY

The LLNL-YMP conducts a technical review of the scientific investigation planning document. This review is performed by any qualified individual(s) other than those who developed the original planning document. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the LLNL-YMP QA Manager. The results of this technical review, and the resolution of any comments by the reviewer or reviewers, are documented, and become a part of the QA records.

1.2.2 PEER REVIEW

A peer review of the scientific investigation planning document is conducted when deemed necessary by the **LLNL-YMP Leader.**

1.3 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS

1.3.1 INTERPRETATION/ANALYSIS DOCUMENTS

Interpretation/analysis is performed in a planned, controlled, and documented manner. Interpretation/analysis are performed and 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 are legible and in a form suitable for reproduction, filing, and retrieval. Calculations are identifiable by subject, originator, reviewer and date.

1.3.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS

Documentation of interpretation/analysis includes the following:

- Definition of the objective of the interpretation/analysis.
- Definition of input and their sources.
- A listing of applicable references.
- Results of literature searches or other background data.
- Identification of assumptions.
- 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.
- Signatures and dates of review and approval by appropriate personnel.

1.4 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application are documented and controlled as specified in **Section** 3.0 and 033-YMP-R Appendix H. The documentation and control measures are consistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

1.5 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES

1.5.1 DOCUMENTATION

There are two methods which can be used for the quality assurance, documentation, and control of scientific work. These are the scientific notebook system and the technical implementing procedure system.

The scientific notebook system is used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the study plan or scientific investigation planning document is the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. Alternatively, the technical implementing procedure system is used when qualified personnel are performing repetitive work which does not include the use of a high-degree of professional judgment or trial and error methods in the performance of the work. Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. Modifications may be made to these procedures as detailed in **Section** 1.5.2. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work.

1.5.2 TECHNICAL IMPLEMENTING PROCEDURES

Detailed technical implementing procedures together with appropriate logbooks and other supporting documents are used whenever the work is repetitive. Such technical implementing procedures are developed in accordance with the requirements given in 033-YMP-R 5 and reviewed in accordance with this section of the QAPP. Modifications may be made to the technical aspects of technical implementing procedures by the individual utilizing the procedure. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval is obtained from an appropriately qualified reviewer.

Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, are provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.

Technical procedures utilized for scientific investigations provide for the following as appropriate:

- Requirements, objectives, methods and characteristics to be tested or observed.
- Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.
- 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 assure validity of data throughout the scientific investigation.
- Mandatory verification points.

- Acceptance and rejection criteria, including required levels of precision and accuracy (NOTE: "Accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)
- Methods of documenting or recording data and results, including precision and accuracy.
- Methods of data reduction.
- Provision for assuring that prerequisites have been met.
- Special training or qualification requirements for personnel performing the scientific investigation.
- Personnel responsibilities.

1.5.2.1

Procedures are complete to the extent that another qualified individual may, at a later date, reproduce the results.

1.5.2.2

The potential sources of uncertainty and error in technical implementation procedures which must be controlled and measured to assure that scientific investigations are well controlled are identified. Parameters that need to be measured and/or controlled to minimize such uncertainties or error, and to assure adequate control, are addressed explicitly in test procedures.

1.5.2.3

For instrumentation and/or equipment used in data collection consideration is given to whether failure or malfunction of the instrumentation during scientific investigation 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.

1.5.2.4

Any procedural deviations or nonconformances, encountered during activities are documented, reported, and evaluated for significance.

1.5.3 SCIENTIFIC NOTEBOOKS

Scientific notebooks along with other appropriate documents may be used to document scientific investigations and experiments. In such cases, this documentation is sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI.

1.5.4 FORMAT FOR DOCUMENTATION

Documentation of scientific work (i.e., experiments and research) is **normally** performed using bound logbooks or notebooks to provide written record of the experiment or research. **However, the use of bound logbooks or notebooks is not mandatory when controls are provided to prevent undetected tampering or changing of logbook entries.**

1.5.4.1 Initial Entries

Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, are made.

- Title of the experiment or research.
- Name of the qualified individual or individuals performing the experiment or research.
- Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work.
- Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- Calibration requirements.
- Dated signature of the individual or individuals making the initial entries.
- Special training or qualification requirements.
- Documentation of suitable and controlled environmental conditions, if applicable.
- Required levels of precision and accuracy are identified.
- The potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are appropriately controlled are identified.

The initial entries described above are considered to be a "general" procedure and are entered into the scientific notebook prior to beginning an investigation. Modifications may be made by the individual performing the investigation.

If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval is obtained from an appropriately qualified reviewer.

1.5.4.2 In-process Entries

Entries made during the experiment or research, daily or as appropriate, are sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and include:

- Date and name of individual making the entry.
- Provisions for assuring prerequisites have been met.
- Description of the experiment or research attempted, including detailed step-by-step process followed; either by reference to implementing procedure or by actual entry into the notebook.
- Description of any conditions which may adversely affect the results of the experiment or research.
- Identification of samples used and any additional equipment and materials not included as part of the initial entries prescribed by **Section** 1.5.4.1.
- All data taken and a brief description of the results, to include notation of any unaccepted results.
- Any deviations from the planned experiment or research.
- Any interim conclusions reached, as appropriate.

1.5.4.3 Final Entries

The final entries in the record have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

1.5.4.4 Final Results

Final results and a summary of the outcome of the experiment or research are documented (e.g., in a technical report). This includes a discussion of whether the experiment's objectives as outlined in the initial entries (**Section** 1.5.4.1) were achieved. This documentation becomes part of the QA records of the activity.

1.6 CHANGE CONTROL

All changes in scientific investigation planning documents go through the same review and approval process as specified in **Section** 1.2. The LLNL-YMP is responsible for evaluating the impacts of such changes on the associated Quality Assurance **controls.**

1.7 INTERFACE CONTROL

1.7.1 COORDINATION

Internal and external scientific investigation interfaces are identified and scientific investigation efforts are coordinated within the LLNL-YMP and between the LLNL-YMP and other High-level Nuclear Waste Program participating organizations. Interface controls include the assignment of responsibility and the establishment of procedures for the review, approval, release, distribution and revision of documents involving scientific investigation interfaces. Interfaces within the LLNL-YMP are coordinated according to procedures. Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, are coordinated among participating organizations in accordance with DOE Project Office procedures. Interfaces between the LLNL-YMP and its suppliers are controlled in accordance with procedures. Ongoing field or laboratory scientific investigations are identified to preclude inadvertent interruption and to assure operational compatibility. Such identification is clearly evident at the location at which the scientific investigation is being performed. Field investigations identify the location of the investigation.

1.7.2 TRANSMITTAL

The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces are documented.

1.8 VERIFICATION OF SCIENTIFIC INVESTIGATIONS

1.8.1 VERIFICATION PLANNING

Planning for verification activities is accomplished and documented via verification procedures, instructions, or checklists. Verification procedures, instructions, or checklists provide for the following:

- Identification of characteristics and activities to be verified.
- A description of the method of verification.
- Identification of the individuals or groups responsible for performing the verification.
- Acceptance and rejection criteria.
- Identification of required procedures, drawings, and specifications (including revisions).
- Recording identification of the verifier and the results of the verification.

1.8.2 VERIFICATION HOLD POINTS

Mandatory verification hold-points are established as necessary. When such hold points are established, work may not proceed without the specific consent of the responsible representative. These hold points are indicated in appropriate documents controlling the activity. Consent to waive any specified hold point is documented before work can be continued beyond the designated hold point.

1.8.3 PERSONNEL PERFORMING VERIFICATION

Scientific investigation verification is performed by any competent individual or individuals or group or groups other than those who performed the original investigation. This includes the following:

1.8.3.1

Individuals or groups from the originator's same organization.

1.8.3.2

Individuals or groups from other organizations contracted for this purpose.

1.8.3.3

The originator's supervisor providing all of the following requirements are met:

- **The supervisor is the only individual in the organization competent to perform verification.**
- **The supervisor did not establish the technical input used, specify a singular technical approach, or rule out certain technical considerations.**
- **The rationale for satisfying the two requirements above is documented and approved by the YMP Leader or designee. The QA manager concurs with the rationale.**

1.9 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

1.9.1 LOGISTICS OF SURVEILLANCE

The LLNL-YMP QA organization performs surveillances of all scientific investigations, as may be deemed appropriate for the purposes and the complexity of the work. The QA surveillance team for a scientific investigation consists of one or more qualified technical individuals and one or more QA personnel. The timing and the number of surveillances are determined by the QA surveillance team that is formed for this work. Surveillances are performed in accordance with the requirements specified in 033-YMP-R 18.

1.9.2 SURVEILLANCE TEAM

The technical member or members of the QA surveillance team are familiar with the plan for the scientific investigation.

1.10 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS

The LLNL-YMP is charged with developing implementing procedures for the technical review and approval of the results of scientific investigations. These procedures include the DOE Project Office in the review and approval cycle of the final report.

1.11 CLOSE-OUT VERIFICATION

The LLNL-YMP performs a close-out verification upon the completion of any scientific investigation to assure that the QA records for that investigation are adequate and complete. This is done because of the considerable period of time between the completion of work and use of the resulting information in the licensing process. Close-out verifications are performed by a team consisting of qualified technical personnel as well as QA personnel.

2.0 DESIGN CONTROL

2.1 GENERAL

2.1.1 DEFINITION

The design is defined, controlled, and verified. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analysis. The data collection activities result from scientific investigations and produce design input. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

It is the policy of the Yucca Mountain Project that a completed or final design of a facility or item evolves from a sequential order of design activities (or phases) wherein each phase becomes more detailed in nature than the preceding phase. It is recognized that the number and length of design phases required to produce a completed or final design of any particular item or facility varies, according to the timeliness and availability of pertinent information and the complexity of the item or facility. It is also recognized that YMP design activities progress at different rates and are dependent on and require interfaces with other Project participating organizations to produce a unified facility design.

2.1.2 QUALITY ASSURANCE CONTROLS

All design phases are assigned Quality Assurance **controls** prior to execution in accordance with the methods specified by the DOE Project Office.

2.1.3 QUALIFICATION OF PERSONNEL

Personnel performing design work are indoctrinated, trained, and qualified in accordance with the requirements of 033-YMP-R 2. Instructions, procedures and drawings for design work are in accordance with the requirements of 033-YMP-R 5.

2.1.4 PEER REVIEW

A peer review is conducted for design activities, including design output documents which involve use of untried or state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed. The peer review meets the requirements of **Section** 4.0.

2.2 DESIGN INPUT

2.2.1 IDENTIFICATION, REVIEW AND APPROVAL OF INPUT

Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, are identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements. The design input is specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

2.2.2 CHANGES TO DESIGN INPUT

Changes to approved design input, including the reason for the changes, are identified, documented, approved, and controlled by the responsible design organization.

2.2.3 CONSIDERATIONS FOR DESIGN INPUT

Considerations for design inputs as they apply to specific items or systems are contained in Appendix B of this document.

2.3 DESIGN ANALYSIS

2.3.1 DESIGN ANALYSIS DOCUMENTS

Design analyses are performed in a planned, controlled, and documented manner. Design analysis is performed and documented in sufficient detail as to purpose, method, assumptions, design input, references, and units such that a technically qualified person may review, understand, and 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, and date.

2.3.2 DOCUMENTATION OF DESIGN ANALYSES

Documentation of design analysis includes the following:

- Definition of the objective of the analysis.
- Definition of design input and their sources.
- A listing of applicable references.
- Results of literature searches or other background data.
- Identification of assumptions and indication of those which require verification as the design proceeds.

- 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.

- Signatures and dates of review and approval by appropriate personnel including QA Personnel. The purpose of the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.3.3 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application are documented and controlled as specified in **Section** 3.0 and Appendix H of this QAPP.

2.4 DESIGN VERIFICATION

2.4.1 IDENTIFICATION AND DOCUMENTATION

Design control measures are applied to verify the adequacy of design and verification is performed in a timely manner. The responsible design organization identifies and documents the verification method used, the results of the verification, and the verifier.

2.4.2 TIMING OF VERIFICATION

Verification of the adequacy of design are performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities. In those cases, where this timing can not be met, 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.

2.4.3 EXTENT OF VERIFICATION

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.

Where the design has been subjected to a verification process in accordance with **Section** 2.4, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, is verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features are considered. The original design and associated verification measures are adequately documented and referenced in the files of subsequent application of the design.

2.4.4 CHANGES TO VERIFIED DESIGNS

Changes to previously verified designs require verification including evaluation of the effects of those changes on the overall design.

2.4.5 PERSONNEL PERFORMING VERIFICATION

Design verification is performed in accordance with the requirements of **Section** 2.4.6 by any competent individual or individuals or group or groups other than those who performed the original design. This includes the following:

2.4.5.1

Individuals or groups from the originator's same organization.

2.4.5.2

Individuals or groups from other organizations contracted for this purpose.

2.4.5.3

The originator's supervisor providing all of the following requirements are met:

- The supervisor is the only individual in the organization competent to perform verification.
- The supervisor did not establish the design input used, specify a singular design approach, or rule out certain design considerations.
- The rationale for satisfying the two requirements above is documented and approved by the **YMP Leader or designee.** The QA manager concurs with this rationale.

2.4.6 METHODS OF DESIGN VERIFICATION

Design verification is accomplished by any one or a combination of the following: design reviews, alternate calculations, qualification testing, or peer review.

2.4.6.1 Design Reviews

Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. At a minimum, the items below are considered during the review and the results of such deliberations are documented.

- Were the design inputs correctly selected?
- Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- Was an appropriate design method used?
- Were the design inputs correctly incorporated into the design?
- Is the design output reasonable compared to design inputs?
- Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- Are computer programs used for analysis identified and verified in accordance with the methods specified in Paragraph 3.0 of this section?

2.4.6.2 Alternate Calculations

Alternate calculations are a form of analysis which is used to determine the adequacy of the original analysis. The use of alternate calculations includes a review of the appropriateness of assumptions, inputs and computer programs or other calculation method used.

2.4.6.3 Qualification Tests

Qualification tests that involve actual physical testing of systems, structures, or components are used to verify the adequacy of design. Where design adequacy is to be verified by qualification tests, the tests are identified. The test configuration is clearly defined and documented. Testing demonstrates adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily are considered in determining the most adverse 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 design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification is documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are performed on models or mockups, scaling laws are established and verified. The results of model test work are subject to error analysis, where applicable, prior to use in the final design work.

2.4.6.4 Peer Review

Peer review is an acceptable method of design verification when the design is beyond state-of-the-art and other methods of design verification are not feasible.

2.5 DESIGN CHANGE CONTROL

2.5.1 CHANGES TO APPROVED DESIGNS

Changes to approved designs, including field changes, are justified and subjected to design control measures commensurate with those applied to the original design and approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the DOE Project Office designates a new responsible organization. The designated organization has demonstrated competence in the specific design area of interest and has an adequate understanding of the requirements and intent of the original design. Errors and deficiencies in approved design and design information documents are documented, and action taken to assure that all errors and deficiencies are corrected. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure are reviewed and modified as necessary.

2.6 DESIGN INTERFACE CONTROL

2.6.1 IDENTIFICATION AND RESPONSIBILITY

Internal and external design interfaces are identified and controlled and design efforts are coordinated among and within responsible design organizations. Interface controls include the assignment of responsibility and the establishment of procedures among and within responsible design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES

Design information transmitted across interfaces is documented and controlled. Transmittals identify the status of the design information or the documents provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal is confirmed promptly by a controlled document.

2.7 DESIGN OUTPUT REQUIREMENTS

2.7.1 DESIGN OUTPUT DOCUMENTS

Design output documents:

2.7.1.1

Relate to the design input by documentation in sufficient detail to permit design verification.

2.7.1.2

Identify assemblies or components or both that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is 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 part is represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.7.1.3

Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. As a minimum, the review and approval cycle includes the participation of the technical and QA elements of both the responsible design organization and the DOE Project Office. The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.8 DESIGN DOCUMENTS AS QA RECORDS

Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification and records confirming interface control are collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of 033-YMP-R 17.

3.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

3.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL

For a geologic repository, computer software used to perform analysis in support of the license application is controlled to the same level of requirements as software used to perform direct design analysis. Auxiliary software used to support primary analysis software is controlled at a level commensurate with the complexity of that software.

Where commercial auxiliary software is used, all available documentation from the software supplier is obtained. It is recognized that source code is generally not available and controls are limited to unique version identification and user-related manuals.

Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the lifecycle model are contained in Appendix H to this QAPP.

3.1.1

The LLNL-YMP prepares a description of its software design, test and configuration management system and submit it to the next higher program organizational level for review and approval. The description:

- Provides criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.
- Indicates the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.
- Relates the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.
- Identifies the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
- Specifies the process to be used for verification and validation of the software developed or applied to geologic repository design analysis.
- Identifies the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

3.1.2

Software is placed under configuration management as each baseline element is approved. Software baseline elements are uniquely identified to assure positive control of all revisions; the identification of each code version is directly related to the associated documentation.

3.1.3

Changes to software are systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. Changes to computer software are subject to the same level of approval, verification, and validation as the original software.

3.1.4

Computer programs developed and/or modified are documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.

3.1.5

Testing of software, including new or modified software, is performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.

3.1.6

Verification and validation of computer software are performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated are identified and controlled. In all cases, the verification and validation of software is completed prior to relying on the software to support the license application.

3.1.7

Verification and validation procedures assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

3.1.8

Existing software is qualified for use. This qualification is based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. Software that has not been developed in accordance with this QAPP may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.

3.1.9

Methods for determining the applicability of requirements and managing interfaces involving the documentation, configuration management, change, qualification, verification, and validation of software, are described in each organization's software QA Plan and procedures.

3.2 DOCUMENTATION OF COMPUTER SOFTWARE

Documentation of scientific and engineering software includes the following, as a minimum:

- Software requirements specification;
- Software design and change documentation;
- Description of mathematical models and numerical methods;
- Software verification and validation documentation;
- User documentation;

- Code assessment and support;
- Continuing documentation and code listings; and
- Software summary.

This documentation is considered to be a QA Record and is subject to the requirements of 033-YMP-R 17. Appendix H to this QAPP provides detailed requirements for documentation of software used on the project.

3.3 SOFTWARE CONFIGURATION MANAGEMENT

An appropriate software configuration management program is instituted. Documentation of this program is provided to the Records Management System (RMS). The minimum requirements for this configuration management program are: (1) the inclusion of a unique identification, including software version numbers whenever feasible, in the output; (2) listings of the software; and (3) a brief chronology of the software versions, including descriptions of the changes made between versions.

4.0 PEER REVIEWS

A peer review process is instituted, when applicable, to provide adequate confidence in work being reviewed. Peer reviews meet the requirements of NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories." These requirements are contained in 033-YMP-R Appendix J.

5.0 TECHNICAL REVIEWS

When technical reviews are required they are conducted in accordance with procedures that contain specific criteria for the performance of the technical review.