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NUCLEAR WASTE MANAGEMENT PROGRAM

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No.: 8

Revision: 0

Date: December 15, 1988

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Subject: PREFACE

Approved: 12/19/88
LLNL-YMP Leader

The Quality Assurance Program Plan contains the requirements of the quality assurance program of the Lawrence Livermore National Laboratory's Yucca Mountain Project (LLNL-YMP). Implementing Procedures based on these requirements are maintained in the Quality Procedures Manual. Technical implementing procedures are maintained in the Technical Implementing Procedures Manual.

The QAPP, Quality Procedures Manual, and the Technical Implementing Procedures Manual collectively constitute the requirements and quality program procedures governing the LLNL-YMP.

Recommendations to improve the accuracy and completeness of these procedures are encouraged. It is only through a cooperative effort and commitment to quality by everybody that the quality assurance program can be effective.

It is the policy of the LLNL-YMP Leader to apply quality assurance methods to the extent necessary to assure that items and data produced in support of the YMP can be shown to be of adequate quality to be used in support of a DOE repository license application to the NRC.

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PDR WASTE
WM-11 PDC

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NUCLEAR WASTE MANAGEMENT PROGRAM

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033-YMP-R Appendix G	Requirements for Qualification of Existing Data not Generated Under A QA Program Meeting the Requirements of 10 CFR 60 Subpart G	12/15/88		0
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Subject: ORGANIZATION

Approved:

Approved by: [signature] 12/19/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 QUALITY ASSURANCE RESPONSIBILITIES

The LLNL-Yucca Mountain Project (LLNL-YMP) is responsible for establishing and executing a Quality Assurance Program Plan (QAPP). As appropriate the LLNL-YMP delegates to others, such as contractors, agents, or consultants, the work of establishing and executing the Quality Assurance (QA) program, or a portion thereof, but the LLNL-YMP retains complete responsibility. Any delegation for executing the QA Program Plan requirements is documented. The organizational structure, lines of communication, authority and duties of persons and organizations performing activities affecting quality are clearly established and delineated in writing. Activities affecting quality include both performing functions of attaining quality objectives and the QA functions. While the line organization is responsible for performing these activities properly, the QA organization verifies the proper performance of work through implementation of appropriate QA measures.

2.0 QA FUNCTIONS

The QA functions include assuring that an appropriate QA program is established, executed effectively, and verified by checking, auditing, surveillance and inspection, and assuring that activities affecting the quality functions are performed correctly. The persons and organizations performing QA functions have sufficient authority, access to work areas, and organizational freedom to identify quality problems; initiate, recommend, or provide solutions through designated channels; verify implementation of the solutions; and assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition occurs. This includes the ability to stop (or cause to be stopped) unsatisfactory work through established channels. Such persons or organizations have direct access to responsible management at a level where appropriate action can be effected and report to a management level at which the required authority and organizational freedom are provided, including sufficient independence from cost and schedule.

2.1 DEDICATED QA POSITIONS

The person responsible for directing and managing the overall LLNL-YMP QA program is identified and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This person has appropriate management and QA knowledge and experience, is at the same or a higher organization level as the highest line manager responsible for performing activities affecting quality, and is sufficiently independent from cost and schedule. Personnel in this position are responsible for approval of (1) QAPPs, changes thereto, and interpretations thereof and (2) implementing procedures and all changes thereto. This position has effective communication channels with other senior management positions. Personnel in this position have the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by the LLNL-YMP and its subordinate organizations. Full-time dedicated QA positions are established by the LLNL-YMP. The LLNL-YMP Quality Assurance Manager and personnel considered "full-time dedicated" are not assigned duties that prevent full attention to QA responsibilities or conflict with the reporting and resolution of QA issues and problems.

2.2 AUTHORITY

Authority for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and others is identified. This authority includes the ability of QA personnel to elevate the resolution of disputes to progressively higher organization levels through established channels to the DOE Project Office Quality Assurance Manager, if the dispute cannot be resolved within the LLNL-YMP.

2.3 ORGANIZATIONAL STRUCTURE

The organizational structure of the LLNL-YMP is depicted on organization charts appended to this Section. Figure 1.0.1 illustrates the organizational relationship of the Energy Program Leader, the LLNL-YMP Leader, the Quality Assurance Manager, and the Resource Planning and Control Manager. Figure 1.0.2 illustrates the organizational structure for the LLNL-YMP. The appendix documents the current staffing for the positions represented on these figures.

The Energy Program Leader delegates responsibility for meeting the YMP's scientific and quality assurance requirements to the LLNL-YMP Leader.

The LLNL-YMP Leader is responsible to the DOE Project Office Manager to assure that the Project activities are performed to a QAPP and that implementing procedures are consistent with the QAPP.

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

The LLNL-YMP Leader may at his discretion delegate responsibility for fulfilling technical assignments to Technical Area Leaders and administrative tasks to a Project Administrator.

Technical Area Leaders assign Task Leaders to carry out specific responsiblities. Task Leaders are assisted by Principal Investigators and technical staff.

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 LLNL-YMP Leader level.

The persons assigned QA functions have the required authority and organizational freedom to perform these functions.

3.0 QUALITY ASSURANCE PROGRAM PLAN

The Quality Assurance Program Plan (QAPP) applies to all items and activities affecting quality. The organizational structure and the responsibility of assignments are clearly established to assure that certain results, as described below, are obtained.

3.1 ACHIEVEMENT AND MAINTENANCE OF QUALITY

Quality is achieved and maintained by those who have been assigned responsibility for performing work.

3.2 VERIFICATION

Quality achievement is verified by persons or organizations not directly responsible for performing the work. Verification of conformance to established requirements (acceptance) is accomplished by individuals or groups within the QA organization unless specifically exempted elsewhere in this document.

4.0 MULTIPLE ORGANIZATIONS

If more than one organization is involved in the execution of activities affecting quality, then the responsibility and authority of the LLNL-YMP and each other organization is clearly established and documented.

4.1 DOCUMENTATION OF INTERFACES

External interfaces between the LLNL-YMP and other organizations and the internal interfaces between organizational units of the LLNL-YMP and changes thereto are documented. All interface responsibilities are defined and documented. Interfaces between the LLNL-YMP and the DOE Project Office and between the LLNL-YMP and other High-level Nuclear Waste Program participating organizations are described in the implementing procedures to the QAPP. From an overall standpoint, these interfaces are exchanges of technical requirements of work to be performed and liaison until completion of work. The DOE Project Office specifies the inter-participant implementing controls. The LLNL-YMP implementing procedures describe the methods of conducting inter-organizational interfaces.

The LLNL-YMP organizational structure for executing the QA programs is described in the LLNL-YMP QAPP. The LLNL-YMP Leader is responsible to the DOE Project Office Manager to assure that the Project activities are performed to a QAPP and implementing procedures that are consistent with the DOE Project Office's QAP.

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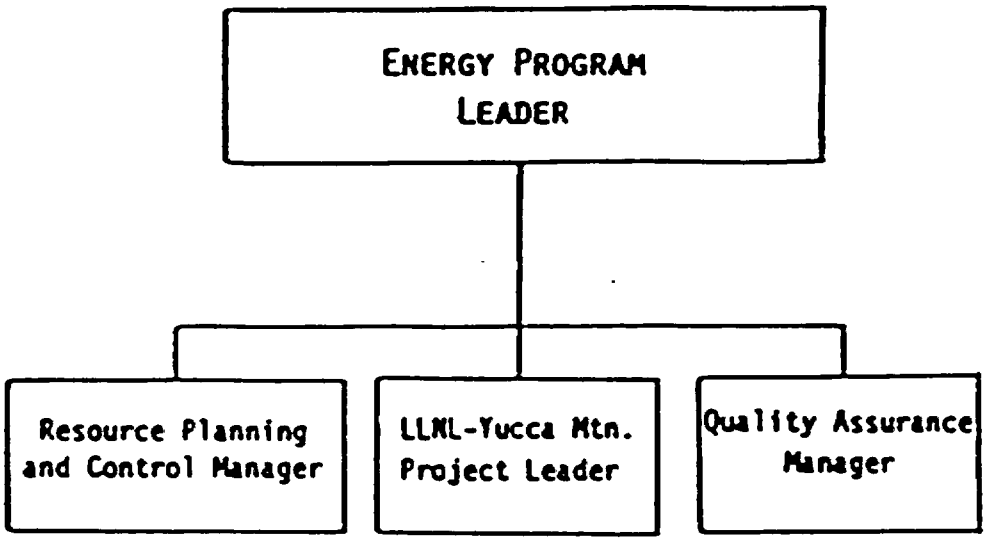

Figure 1.0.1

YUCCA MOUNTAIN PROJECT ORGANIZATION

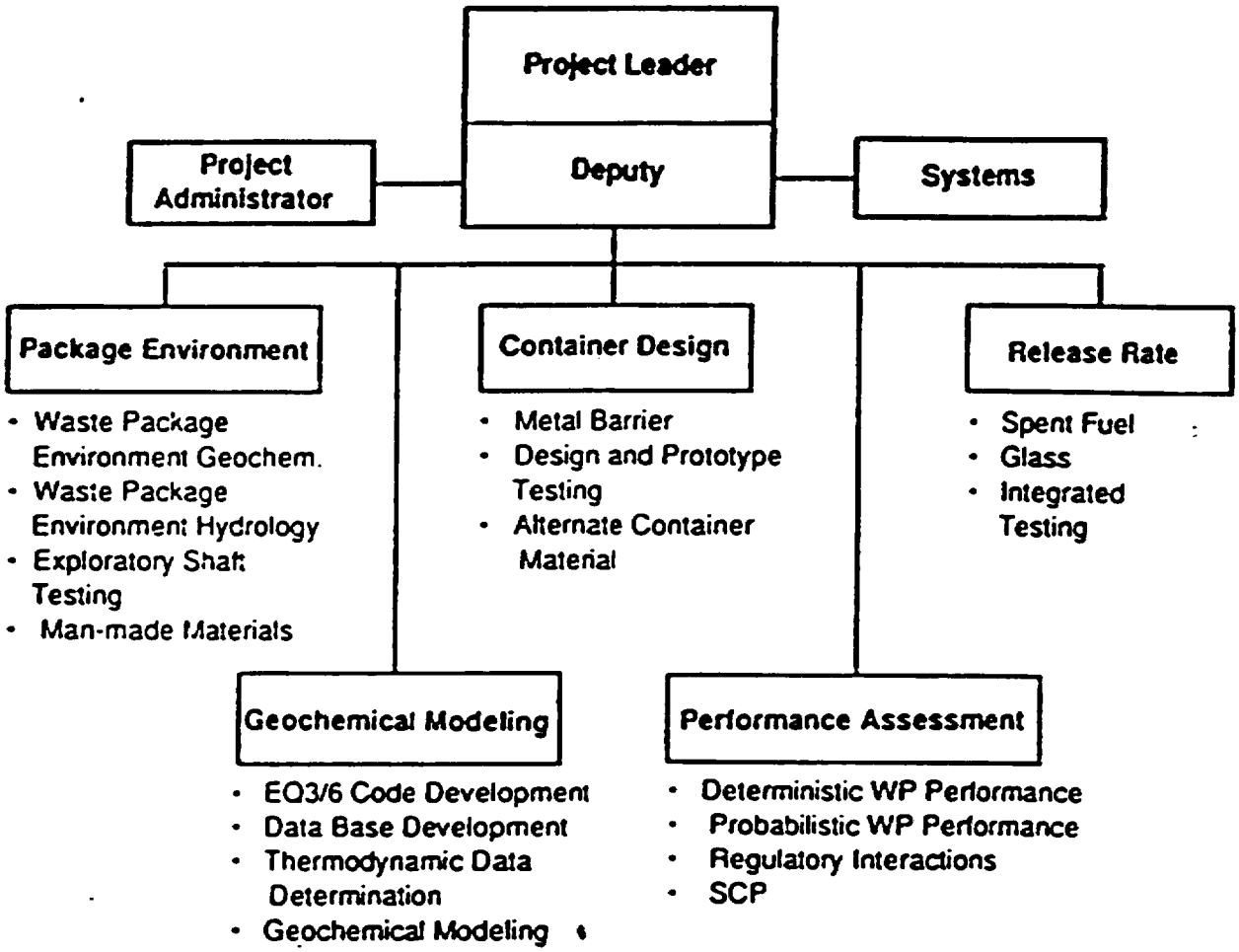

Figure 1.0.2

APPENDIX

Energy Program Leader	R. Schock
QA Manager	R. Schwartz, Acting
Resource, Planning and Control Manager	Vacant
<u>LLNL-YMP Leader</u>	L. Ballou, Acting
Deputy	D. Short
Systems	M. Revelli
Project Administrator	B. Bryan
<u>Package Environment</u>	D. Wilder, Acting
Geochemistry	W. Glassley
Hydrology	A. Tompson
Exploratory Shaft Testing	A. Ramirez, Acting
Other Materials	W. Bourcier, Acting
<u>Geochemical Modeling</u>	R. Aines
EQ3/6 Code Development	K. Jackson
Data Base Development	D. Olness
Thermochemical Data Determination	R. Silva
Geochemical Modeling	C. Bruton
<u>Container Design</u>	J. Kass
Metal Barrier	D. McCright
Alternate Container Material	E. Dalder
Design and Prototype Testing	T. Nelson
<u>Performance Assessment</u>	W. O'Connell
Deterministic WP Performance	D. Lappa
Regulatory Interactions	W. O'Connell, acting
SCP	D. Emerson
Probabilistic	W. O'Connell
<u>Release Rate</u>	H. Shaw
Spent Fuel	H. Shaw, Acting
Glass	R. Ryerson, acting
Integrated Testing	H. Shaw
<u>Quality Assurance</u>	R. Schwartz, Acting
Program Development	R. Schwartz, Acting
Audits and Surveillances	R. Oberle
Quality Engineering	Vacant

Subject: QUALITY ASSURANCE PROGRAM

Approved:

Approved by: 12/22/88 Date
Yucca Mountain Project Leader

Approved by: 12/22/88 Date
Quality Assurance Manager

1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM

The Quality Assurance (QA) Program for the LLNL-YMP consists of the LLNL-YMP Quality Assurance Program Plan (QAPP), quality procedures, and technical implementing procedures, and its subcontractors' QA Program Plans, quality procedures, and technical procedures. The LLNL-YMP submits this QAPP to the DOE Project Office for approval. Pending receipt of DOE Project Office approval, the QAPP and quality procedures may be issued by LLNL-YMP for interim use. When any QAPP or quality procedure is issued for interim use, the transmittal record is appropriately marked to indicate that it is for interim use. Approval of QA Plans by the DOE Project Office is documented.

The Quality Assurance Program Plan (QAPP) includes consideration of the technical aspects of the activities affecting quality and is generated by the LLNL-YMP QA organization with assistance from the LLNL-YMP technical staff. The QAPP provides instructions to implement and apply the QA requirements to the technical activities of the LLNL-YMP. The QAPP is planned, implemented, and maintained in accordance with the DOE Project Office QAPP and is consistent with and addresses all of the applicable requirements of the DOE Project Office QA Plans. Management above or outside of the QA organization regularly receives information as to the scope, status, adequacy, compliance, etc. of the QA Program.

Management performs readiness reviews, as deemed appropriate. Readiness reviews apply to major scheduled/planned activities which affect quality. Readiness reviews are used to verify that specified prerequisites and programmatic requirements are identified prior to starting a major activity.

The hierarchy of criteria applicable to the Yucca Mountain Project are shown in Figure 1. With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in the Figure and this QAPP exist, the requirements of this document prevail.

1.1 QA CRITERIA

The QA Criteria and specific requirements associated with those criteria are adapted to the LLNL-YMP activities through this QA plan. When a specific criteria is not applicable to LLNL-YMP activities, it is noted in the QAPP and recorded on the DOE Project Office's checklist with justification of its exception as required in Paragraph 1.2.

1.2 CONTENTS OF THE QAPP

The Quality Assurance Program of the LLNL-YMP includes the QAPP plus the implementing procedures required to provide and implement control over activities affecting quality. The control is consistent with the importance of the activity. Implementing procedures are developed by qualified personnel and are reviewed and approved by the LLNL-YMP QA organization prior to implementation to assure that the implementing procedures meet all the requirements of the LLNL-YMP QAPP.

The LLNL-YMP QAPP is submitted to the DOE Project Office for review and approval prior to implementation and includes a checklist based on the DOE Project Office QAPP which identifies how and where each requirement of the DOE Project Office QAPP is addressed.

1.3 QAPP VERIFICATION

Assurance that the QA requirements are adequately addressed and effectively implemented is provided by the DOE Project Office during the review and approval of the LLNL-YMP QAPP, monitoring and surveillance operations, and audits of activities. The LLNL-YMP also monitors the LLNL-YMP QAPP through internal audits, audits of subcontractors, and surveillance of operations to assess the adequacy of LLNL-YMP program and assure its effective implementation.

1.4 USE OF DATA NOT GENERATED UNDER QA CONTROLS

The QA program for the LLNL-YMP provides for the acceptance of data or data interpretations for use in licensing activities that were not generated under the controls of a QA program which meets the requirements of 10 CFR 60, Subpart G. These requirements are contained in Appendix G of this document. Once accepted, this data is classified as "primary data" for licensing purposes.

1.5 METHODOLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST

Items and activities to be placed on the Project Q-List are determined by the DOE Project Office. Requirements for the identification of items and activities to be included on the Q-list are contained in Appendix I to the LLNL-YMP QAPP.

1.6 APPROACH TO QA

The LLNL-YMP uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation and those that do not. The approach is designed to assure that each item or activity is assigned a QA level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. The LLNL-YMP or DOE Project Office identifies the appropriate quality assurance levels for all items and activities that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Once assigned, the QA level for a particular item or activity is applied by all LLNL-YMP personnel involved in the activity.

1.7 APPLICATION OF QA

A QAPP that complies with the requirements of the DOE Project Office QAP is established by the LLNL-YMP at the earliest practicable time consistent with the schedule for accomplishing the activities. The LLNL-YMP QAPP specifies that procedures required to implement the requirements are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official. The QAPP is applied throughout the life of the LLNL-YMP in accordance with the established policies, procedures, and instructions. The QAPP applies to all items and activities affecting quality. It also identifies other organizational entities participating in the LLNL-YMP and the designated functions of these organizations. The QAPP provides control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. The 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 the given activity are satisfied. The program takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. The program provides for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

The DOE Project Office and the LLNL-YMP regularly assess the status and adequacy of the QA Programs of the LLNL-YMP by means of overview, surveillance, and audit activities.

2.0 APPLICATION OF GRADED QUALITY ASSURANCE

2.1 SCOPE

2.1.1 EXTENT OF APPLICATION

The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. The preparation of administrative and management planning documents do not require QA level assignments, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA level assignments. The LLNL-YMP is charged with developing an implementing procedure for the application of graded QA. The procedure is in consonance with the QA requirements specified herein. It may be necessary to exempt certain LLNL-YMP items and activities from QA level assignment. Requests for exemptions are documented and contain sufficient justification to support the exemption request. Such exemptions are approved by the DOE Project Office Quality Assurance Manager.

2.1.2 PURPOSE OF A GRADED QA PROGRAM

The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Yucca Mountain Project consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. This is accomplished by deliberate quality planning and selective application of QA requirements on the item or activity performed, with varying degrees of QA applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY

This approach involves (1) identifying 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, or both, and (2) assuring that these items and activities are covered by a commensurate QA program. Alternatively, an item whose failure or malfunction would result only in operational inconvenience or negligible economic loss deserves only a quality inspection by the LLNL-YMP upon the delivery of the item. Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.

2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION

The graded approach set forth provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.

2.2 REQUIREMENTS

The requirements specified in this section are used to apply the graded quality philosophy to all YMP items and activities.

2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

The appropriate Quality Assurance Level for any item or activity is determined by the application of decision criteria as provided by the DOE Project Office. The basis for the selection of the Quality Assurance Level and assigned QA requirements are documented. The assigned Quality Assurance Levels and QA requirements are submitted to the DOE Project Office for review, resolution of comments, and approval prior to implementation or use. This review and approval is performed by the DOE Project Office Quality Assurance Manager and appropriate DOE Project Office Branch Chiefs.

2.2.2 SELECTION OF SPECIFIC QA LEVELS

This approach incorporates three quality assurance levels (QA level) of which one is assigned to each technical task that affects the quality of the LLNL-YMP. The definition, application, and assignment to each of the three QA levels are described in the following discussion.

2.2.2.1 <u>QA Level I</u> - are those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic 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. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of 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 completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

2.2.2.2 <u>QA Level II</u> - are those activities and items related to the systems, structures, and components requiring a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE Project Office concerns and the environment.

2.2.2.3 QA Level III - are those activities and items not classified as QA Levels I or II.

2.2.3 APPLICATION OF LEVELS

2.2.3.1 QA LEVEL I

QA Level I is the most stringent level of quality assurance. It is 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 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 byproduct material (waste) at the geologic repository. QA Level I control and documentation are applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent 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 assure 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:

- Where items and activities 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.

- 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 performance.

- Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.

- Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.

- 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.

- The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) is assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationalships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities are governed by the QA level assigned to the item.

2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation are applied to the LLNL-YMP 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 are 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 are appropriately controlled. Therefore, Quality Assurance Level II is applied to activities and items as follows:

- Where items and activities that 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.

- 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.

- Where items and activities could affect the retrievability of waste up to the time of repository closure.

- Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.

- The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, is assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment is made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities are governed by the QA Level assigned to the item.

- Where items and activities that, having failed, could result in a major cost overrun.

- 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 the DOE Project Office Administrative Procedures.

2.2.3.3 QA LEVEL III

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 a 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 LLNL-YMP QAPP may be used in the licensing process as background or corroborative information.

2.2.4 GENERAL

The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. 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 LLNL-YMP.

3.0 QA ACTIVITIES

3.1 OVERVIEW

The LLNL-YMP performs an overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. Overview includes the following as appropriate:

- The review and approval of subcontractor QAPPs.
- Surveillance of activities affecting quality to verify compliance with requirements.
- Performance of quality audits to verify the adequacy and compliance of QA programs.

3.2 REVIEW AND APPROVAL OF THE LLNL-YMP QA PROGRAM

The LLNL-YMP establishes procedures for the review of its subcontractor QA program documentation for adequacy, completeness and relevance. The procedures identify the types of documents to be submitted by the subcontractor for review and approval, assign project responsibility for review, and identify the methods for documenting review and approval action. Reviews of the subcontractor's QA program documentation may be recorded on checklists or other forms designated by the LLNL-YMP that specify the criteria for acceptability and indicate conformance or nonconformance.

4.0 MANAGEMENT ASSESSMENT

4.1 FREQUENCY OF MANAGEMENT ASSESSMENTS

Management assessments are conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) 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.

4.2 PERFORMANCE OF MANAGEMENT ASSESSMENTS

Management assessments are performed by the DOE Project Office and the LLNL-YMP. Procedures are developed for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are provided to the DOE Project Office and the DOE Project Office Quality Assurance Manager. The DOE Project Office makes appropriate submittals of management assessment reports to OCRWM. Management above or outside the QA organization is responsible for the management assessment activity.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 ESTABLISHMENT OF REQUIREMENTS

Requirements are established for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. The requirements establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) are certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.

5.1.1 POSITION DESCRIPTION

Minimum education and experience requirements are established and documented in position descriptions for each position involved in the performance of activities that affect quality.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience are verified. This verification is documented. The initial capabilities of an individual are based upon an evaluation of their education, experience, and training and are compared to those established for the position. Evaluations are documented by managers or supervisors responsible for the activities to be performed.

5.1.3 INDOCTRINATION

Prior to assigning personnel to perform activities affecting quality, the personnel are indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. Indoctrination is accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.

- QAPPs
- Implementing Procedures and Work Instructions (applicable to the individual's responsibilities).
- Regulations
- Project level Documents

5.1.4 TRAINING

Prior to assigning personnel to perform quality affecting activities, training is conducted, if needed, to gain the required proficiency. The training (in-depth instruction) includes the principles, techniques, and requirements of the activity. In-depth instruction is achieved through internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.

5.1.5 PROFICIENCY EVALUATION

After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality is evaluated and documented at least annually. Proficiency evaluations are performed in conjunction with periodic or day-to-day employee performance evaluations. Proficiency evaluations are performed by managers or supervisors who have responsibility for the activities being performed or verified.

5.1.6 RECORDS

Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations are retained as lifetime QA records. These records include, as a minimum, the items listed below.

5.1.6.1 Personnel Qualification Evaluation Records

Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.

5.1.6.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.

5.1.6.3 Training Records

Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.

5.1.6.4 Proficiency Evaluation Records

Records of proficiency evaluation include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

CRITERIA FOR QUALITY ASSURANCE

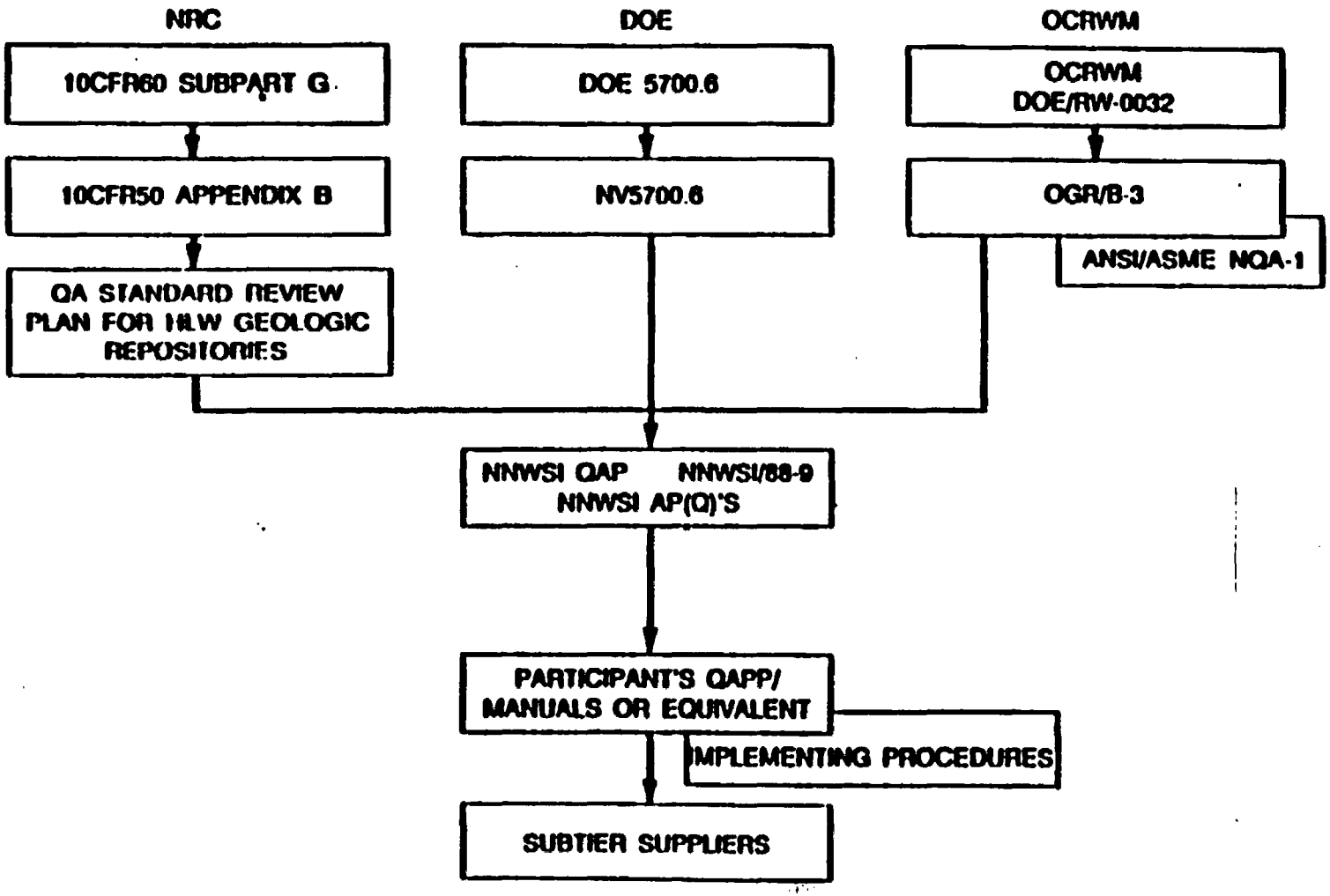

FIGURE 1

Approved by: 12/22/88 Date
Yucca Mountain Project Leader

Approved by: 12/22/88 Date
Quality Assurance Manager

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. The DOE Project Office conducts a technical, QA, and management review of scientific investigation planning documents and approves the document prior to implementation. Study plans are reviewed and approved by OCRWM prior to implementation. Such 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 the Quality Assurance Levels, or 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

The scientific investigation planning document contains a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. 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 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a scientific investigation planning document, as specified in Paragraph 1.1.1 is developed, the Quality Assurance Levels for all of the items and activities which are associated with that work, are assigned. It may be necessary in some cases to assign Quality Assurance Levels to the items and activities within a plan that was prepared earlier. Therefore, the Quality Assurance Level assignments are not a part of the planning documents themselves, even though they would normally accompany those planning documents and go through the same review and approval process.

1.2.2 CONFORMANCE

Scientific investigation planning documents are prepared and Quality Assurance Levels are assigned in accordance with the methods specified by the DOE Project Office.

1.3 REVIEW AND APPROVAL PROCESS

1.3.1 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.

1.3.2 DOE PROJECT OFFICE REVIEW

The DOE Project Office Quality Assurance Manager and the appropriate DOE Project Office Branch Chief review and approve the scientific investigation planning document prior to implementation. The DOE Project Office Quality Assurance Manager returns the planning document to the LLNL-YMP upon completion of the DOE Project Office review and approval cycle. Study plans are also reviewed and approved by OCRWM prior to implementation.

1.3.3 PEER REVIEW

A peer review of the scientific investigation planning document is conducted when deemed necessary by the DOE Project Office.

1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS

1.4.1 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.

1.4.2 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.

1.5 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application are documented and controlled as specified in Paragraph 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."

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

1.6.1 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 Paragraph 1.6.2. 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.

1.6.2 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.

- o Mandatory verification points.
- o 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.)
- o Methods of documenting or recording data and results, including precision and accuracy.
- o Methods of data reduction.
- o Provision for assuring that prerequisites have been met.
- o Special training or qualification requirements for personnel performing the scientific investigation.
- o Personnel responsibilities.

1.6.2.1

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

AND

1.6.2.2

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.

1.6.2.3

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.

1.6.2.4

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

1.6.3 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.

1.6.4 FORMAT FOR DOCUMENTATION

Documentation of scientific work (i.e., experiments and research) is performed using bound logbooks or notebooks to provide written record of the experiment or research.

1.6.4.1 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 objectivs. 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.

1.6.4.2 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 Paragraph 1.6.4.1.
- 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.

1.6.4.3 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.

1.6.4.4 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 (Pragraph 1.6.4.1) were achieved. This documentation becomes part of the QA records of the activity.

1.7 CHANGE CONTROL

All changes in scientific investigation planning documents go through the same review and approval process as specified in Paragraph 1.3. The LLNL-YMP is responsible for evaluating the impacts of such changes on the associated Quality Assurance level assignments.

1.8 INTERFACE CONTROL

1.8.1 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 wth 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 compatability. Such identification is clearly evident at the location at which the scientific investigation is being performed. Field investigations identify the location of the investigation.

1.8.2 TRANSMITTAL

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

1.9 VERIFICATION OF SCIENTIFIC INVESTIGATIONS

1.9.1 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.

1.9.2 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.

1.9.3 REPORTING INDEPENDENCE OF PERSONNEL

Verification is performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the actvity being verified. If these personnel are not part of the formal QA organization, they 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 these persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization overviews and monitors the verification activity.

1.10 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

1.10.1 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.

1.10.2 SURVEILLANCE TEAM

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

1.11 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.

1.12 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 LEVEL ASSIGNMENT

All design phases are assigned a Quality Assurance Level 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 Paragraph 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.

- o Definition of design input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data.
- o Identification of assumptions and indication of those which require verification as the design proceeds.
- o 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.
- o 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 Paragraph 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 Paragraph 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 Paragraph 2.4.6 by any competent, certified individual or individuals or certified 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 management superior to the supervisor. 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 <u>Design Reviews</u>

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.

- o Were the design inputs correctly selected?
- o 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?
- o Was an appropriate design method used?
- o Were the design inputs correctly incorporated into the design?
- o Is the design output reasonable compared to design inputs?
- o Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- o 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.

Subject: PROCUREMENT DOCUMENT CONTROL

Approved:

Approved by: [signature] 12/20/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/8 Date
Quality Assurance Manager

1.0 REQUIREMENTS

1.1 MEASURES TO ASSURE ADEQUATE QUALITY

Measures are established to assure that applicable regulatory requirements, design or site investigation bases, and other requirements that are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services utilized for the LLNL-YMP. To the extent necessary, procurement documents require sub-tier contractors to provide a Quality Assurance (QA) program that is consistent with the pertinent provisions of the LLNL-YMP QAPP as required for the specified Quality Assurance Level.

2.0 ADDITIONAL REQUIREMENTS FOR QA LEVEL I ACTIVITIES

2.1 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement include provisions for the items listed below, as deemed necessary by the LLNL-YMP:

2.1.1 SCOPE OF WORK

A statement of the scope of the work to be performed by the supplier is included in the procurement documents.

2.1.2 TECHNICAL REQUIREMENTS

Technical requirements are specified in the procurement documents. Where necessary, these requirements are specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents provide for identification of test, inspection, and acceptance requirements of the LLNL-YMP for monitoring and evaluating the supplier's performance.

2.1.3 QA REQUIREMENTS

2.1.3.1

Procurement documents require that the supplier have a documented QA program that implements either portions or all of the requirements of this document. Quality Assurance Program Plans (QAPPs) and documents of subcontractors for Quality Assurance Level I purchases are reviewed and approved by the LLNL-YMP. Those which do not adequately define QA requirements, as judged by the QA representative of the LLNL-YMP, are corrected prior to initiation of activities specified by the purchase order or contract. 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.

2.1.3.2

In developing QA requirements for test and other equipment, consideration is given to whether proper performance of that equipment can be determined during or after its use (i.e., whether failure or malfunction of the equipment can be detected).

2.1.4 RIGHTS OF ACCESS

At each tier of procurement, the procurement documents provide for access to the suppliers' facilities and records for inspection or audit by the LLNL-YMP, appropriate DOE Project Office personnel, or other DOE Project Office authorized representatives. DOE Project Office access to subtier contractor facilities is arranged through the LLNL-YMP.

2.1.5 DOCUMENTATION REQUIREMENTS

The procurement documents at all tiers identify the documentation required to be submitted to the LLNL-YMP. The time of submittal is established. If the LLNL-YMP require the supplier to maintain specific QA records, then the retention times and disposition requirements are specified in accordance with 033-YMP-R 17.

2.1.6 NONCONFORMANCE

The procurement documents prescribe the LLNL-YMP's requirements for reporting and approving disposition of nonconformances.

2.1.7 SPARE AND REPLACEMENT PARTS

The procurement documents require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality related data that are required for ordering these parts or assemblies. The technical and quality requirements are equal to or better than the original. If 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.

2.2 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents and changes thereto are made to assure that documents transmitted to the prospective supplier or suppliers include appropriate provisions to assure that items or services meet the specified requirements. The review is performed and documented prior to contract award. Procurement document reviews are performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. The review includes as a minimum, the cognizant technical organization and QA organization. The review by the QA organization assures that the following requirements are met:

- o QA requirements are correctly stated, inspectable, and controllable.
- o There are adequate acceptance and rejection criteria.
- o Procurement documents are prepared, reviewed, and approved in accordance with the QA requirements.

2.3 PROCUREMENT DOCUMENT CHANGES

Procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents. Changes that are made as a result of the bid evaluation or precontract negotiations are incorporated into the procurement documents. The review of such changes and their effects are completed and documented prior to contract award. Review of changes include the following considerations:

- o Appropriate content is included in procurement documents as required by Paragraph 2.1.
- o Additional or modified design or site investigation criteria is determined.
- o Analysis of exceptions or changes requested or specified by the supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.

2.4 DISTRIBUTION OF PROCUREMENT DOCUMENTS

The LLNL-YMP forwards to the DOE Project Office Quality Assurance Manager a copy of purchase documents, and changes thereto, as issued, when purchases involve Quality Assurance Level I items or services. Only those purchase documents which identify the vendor, describe the scope of work, and detail when work is to start are submitted to the DOE Project Office Quality Assurance Manager.

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NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. _____

No.: 033-YMP-R 5
Revision: 0
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Page: 1 of 1

Subject:

INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS

Approved:

Approved by: [signature] 12/20/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL

Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings, of a type appropriate to the circumstances except as noted in Paragraph 3.0. These documents include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities are satisfactorily accomplished. Instructions and procedures include a section which identifies the QA records which are generated during implementation of the document. If plans are used in lieu of procedures, then these plans include or reference appropriate acceptance criteria and identify the QA records which are generated. These documents, including drawings, are controlled as required in 033-YMP-R 6.

2.0 REVIEWS

Independent reviews of all instructions, procedures, plans and drawings are performed by the LLNL-YMP to assure technical adequacy and inclusion of appropriate quality requirements. If applicable, this review shall consider whether or not the activities are repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

Instructions are developed by the LLNL-YMP for the control of scientific notebooks, plans and the other documentation used in scientific investigations. (See 033-YMP-R 3.) When scientific notebooks are used to document scientific investigations, the requirements of 033-YMP-R 3, paragraph 1.6 shall prevail over the requirements of this Section. Scientific notebooks are collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of 033-YMP-R 17.

4.0 DISTRIBUTION

The LLNL-YMP provides the DOE Project Office Quality Assurance Manager with controlled distribution of all implementing procedures, plans and instructions used for QA Level I and II activities.

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NUCLEAR WASTE MANAGEMENT PROGRAM

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No.: 033-YMP-R 6
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Subject: DOCUMENT CONTROL

Approved:

Approved by: 12/21/88 Date
Yucca Mountain Project Leader

Approved by: 12/15/88 Date
Quality Assurance Manager

1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

1.1 METHODS

The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, are controlled through the implementation of methods that assure that only correct documents are used. Document control is applied to the following:

- o Documents containing or specifying quality requirements.
- o Documents that prescribe activities affecting quality.

The document control system is documented, and the QA organization provides the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.

1.2 IMPLEMENTATION

Implementation of document control provides for the following:

- o Identification of documents to be controlled.
- o Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
- o Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance.

- o A method for the removal or marking of obsolete or superseded documents to prevent inadvertent use.
- o A method for assuring that the correct and applicable documents are available at the location where they are to be used.
- o A master list or equivalent to identify the correct and updated revisions of documents.
- o Coordination of interface documents.

2.0 DOCUMENT CHANGES

2.1 MAJOR CHANGES

Changes to documents, other than those defined below as minor changes are considered as major changes and are reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organization has access to pertinent background data or information upon which to base their approval and, if applicable, specifically considers whether or not activities being changed are repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

2.2 MINOR CHANGES

Minor changes to documents, such as inconsequential editorial corrections, do not require that the reviewed documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision are clearly delineated.

3.0 DISTRIBUTION OF DOCUMENTS

3.1 DOCUMENT CONTROL SYSTEM

The document control system assures that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Paragraph 1.2. A master list or equivalent used to identify the correct, current and updated versions of documents are submitted to the DOE Project Office Quality Assurance Manager.

Subject: CONTROL OF PURCHASED ITEMS AND SERVICES

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

Measures are established to assure that purchased material, equipment, and services conform to the procurement documents. These measures include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery. 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 installation or use of such material and equipment. This documentary evidence is retained under the control of the DOE Project Office QA Records Management System (QARMS) and is sufficient to identify the specific requirements, such as codes, standards, or specifications, that are met by the purchased material and equipment. Specific requirements for the control of purchased items and services are listed below.

1.1 PROCUREMENT PLANNING

1.1.1 GENERAL

Procurement activities are planned and documented to assure a systematic approach to the procurement process. Procurement planning results in the documented identification of procurement methods and organizational responsibilities. LLNL-YMP Quality Assurance (QA) organization participation is provided for evaluation and selection of suppliers, verification of suppliers' activities and receiving inspections. Planning determines the following:

- What is to be accomplished.
- Who is to accomplish it.
- How it is to be accomplished.
- When it is to be accomplished.

1.1.2 PROCUREMENT TIMING

To assure interface compatibility and a uniform approach to the procurement process, planning is accomplished as early as practicable and no later than at the start of those procurement activities that are required to be controlled.

1.1.3 PROCUREMENT METHODS

Planning results in the documented identification of the methods to be used in procurement activities, the sequence of actions and milestones that indicate the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning provides for the integration of the following:

- Procurement document preparation, review, and change control.
- Selection of procurement sources.
- LLNL-YMP control of supplier performance.
- Verification (surveillance, inspection, or audit) activities by the LLNL-YMP, including notification for hold-and-witness points.
- Control of nonconformances.
- Corrective action.
- Acceptance of item or service.
- QA records.

1.2 SOURCE EVALUATION AND SELECTION

1.2.1 SELECTION OF SUPPLIERS

The selection of suppliers is based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of contract.

1.2.2 SOURCE EVALUATION AND SELECTION MEASURES

Procurement source evaluation and selection measures are implemented by the LLNL-YMP and provide for identification of LLNL-YMP's responsibilities for determining supplier capability.

1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES

Measures for evaluation and selection of procurement sources, and the results thereof, are documented and include one or more of the following items:

- Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history reflects current capability.

- Supplier's current quality assurance records supported by documented qualitative and quantitative information that can be objectively evaluated.

- Supplier's technical and quality capability as determined by a direct evaluation of their facilities and personnel and the implementation of their QA program.

1.3 BID EVALUATION

1.3.1 EXTENT OF CONFORMANCE

Bid evaluation determines the extent of conformance to the procurement documents. This evaluation is performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

- Technical considerations.

- QA requirements.

- Supplier's personnel.

- Supplier's production capabilities.

- Supplier's past performance.

- Alternates.

- Exceptions.

1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS

Before the award of the contract, the LLNL-YMP resolves or obtains commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation.

1.4 SUPPLIER PERFORMANCE EVALUATION

1.4.1 INTERFACE MEASURES

The LLNL-YMP establishes measures to interface with the supplier. The measures include the following:

- Documentation of the understanding between the LLNL-YMP and supplier of the provisions and specifications of the procurement documents.

- Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements.

- Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements.

- o Identifying and processing necessary change information. Measures to control changes in procurement documents are established, implemented and documented in accordance with the requirements of the LLNL-YMP QAPP.

- o Establishing methods of document information exchange between the LLNL-YMP and supplier.

1.4.2 VERIFICATION MEASURES

1.4.2.1 Extent of Verification

The LLNL-YMP establishes measures to verify supplier's performance, as deemed necessary by the LLNL-YMP. The measures establish the extent of source surveillance and inspection activities.

NOTE: When the LLNL-YMP utilizes another Yucca Mountain Project participating organization, the LLNL-YMP organization initiates a request to the DOE Project Office to conduct a surveillance of the organization performing the work. The surveillance is conducted to determine that the item or activity is being produced or performed in accordance with the LLNL-YMP requirements. These surveillances may utilize LLNL-YMP personnel as technical advisors at the DOE Project Office's discretion.

The extent of verification activities, including planning, are a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Verification activities are accomplished by qualified personnel assigned to check, inspect, audit, or witness the suppliers' activities. These verification activities are conducted as early as practicable. However, LLNL-YMP verification activities do not relieve the supplier of their responsibilities for verification of quality achievement.

1.4.2.2 Record of Verification Activities

Activities performed to verify conformance to requirements of procurement documents are recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions are documented. These completed documents are considered QA records and are controlled in accordance with 033-YMP-R 17. The LLNL-YMP assures that this documentation is evaluated to determine the supplier's QA program effectiveness.

1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS

Documents that are generated by suppliers are controlled, handled, and approved in accordance with documented procedures. Means are implemented to assure that the submittal of these documents 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.

1.6 ACCEPTANCE OF ITEM OR SERVICE

1.6.1 METHODS FOR ACCEPTANCE

Methods are established for the acceptance of an item or service being furnished by the supplier. Prior to offering the item or service for acceptance, the supplier verifies that the item or service being furnished complies with the procurement requirements. Methods used to accept an item or related service from a supplier are either a supplier certificate of conformance, a source verification, a receiving inspection or post-installation test at the facility site, or a combination thereof. Requirements applicable to these methods of acceptance are listed below.

1.6.1.1 Certificate of Conformance

When a certificate of conformance is used, the following minimum criteria are met:

- The certificate identifies the purchased material or equipment, such as by the purchase order number.
- The certificate identifies the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This is accomplished by including a list of the specific requirements or by providing at the point of receipt, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- 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 LLNL-YMP or 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 LLNL-YMP or supplier's QA program.
- Means are provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification is conducted by the LLNL-YMP at intervals commensurate with the supplier's past quality performance.

1.6.1.2 Source Verification

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.

Source verification is implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance is furnished to the receiving destination of the item, to the LLNL-YMP, and to the supplier.

1.6.1.3 Receiving Inspection

When receiving inspection is used, purchased items are inspected as necessary to verify their conformance to specified requirements, by taking into account source verification and audit documentation and the demonstrated quality performance of the supplier. Receiving inspections are performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspections are coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to the receiving inspection. Receiving inspections associated with engineered items are planned, performed, and documented in accordance with the requirements specified in 033-YMP-R 10, Para. 2.1, 4.0, 4.1, 6.1, 9.0 and 9.1. Personnel selected for receipt inspection activities have the experience or training commensurate with the scope, complexity, or special nature of the activities. When required, personnel are indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.

1.6.1.4 Post-Installation Testing

When post-installation testing is used, post-installation test requirements and acceptance documentation are established mutually by both the LLNL-YMP and the supplier.

1.7 ACCEPTANCE OF SERVICES ONLY

1.7.1 PROCUREMENT OF SERVICES ONLY

In certain cases involving procurement of services only, such as third party inspections, engineering, and consulting; and installation, repair, overhaul, or maintenance work, the LLNL-YMP accepts the service by any or any combination of the following methods:

- Technical verification of data produced.
- Surveillance, audit, or both, with regard to the activity.
- Review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.

1.8 CONTROL OF SUPPLIER NONCONFORMANCES

1.8.1 METHODS

The LLNL-YMP and supplier establish and document methods for disposition of items and services that do not meet procurement document requirements. These methods include the following provisions:

1.8.1.1 Evaluation

Provisions for evaluation of nonconforming items.

1.8.1.2 Submittal

Provisions are established for submittal of nonconformance notice by the supplier to the LLNL-YMP. These submittals include supplier recommended disposition (e.g., use as-is or repair) and technical justification. Nonconformances to the procurement requirements or LLNL-YMP approved documents, which consist of one or more of the items listed below are submitted to the LLNL-YMP. Approval of the recommended disposition is in accordance with documented procedures.

- Technical or material requirement is violated.
- Requirement in supplier documents, which has been approved by the LLNL-YMP, is violated.
- Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- 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.

1.8.1.3 Disposition

Provisions for LLNL-YMP disposition of supplier recommendation.

1.8.1.4 Verification

Provisions for verification of the implementation of the disposition.

1.8.1.5 Records Maintenance

Provisions for maintenance of records of nonconformances that are submitted by the supplier.

2.0 COMMERCIAL-GRADE ITEMS

2.1 ALTERNATIVES

If a design requires commercial-grade items, then the following requirements are an acceptable alternative to other requirements of this section, except as noted in Paragraph 2.1.2 below and the requirements of 033-YMP-R 4. If a scientific investigation requires use of commercial-grade items, these items are controlled by the use of the following requirements (except Paragraph 2.1.1) and 033-YMP-R 4.

2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS

Where the commercial-grade item is to be used as an integral part of the designed facility, it is identified in an approved design or design out-put document. An alternate commercial-grade item may be supplied if the cognizant organization provides verification that the alternate commercial-grade item will perform the intended function and meet the requirements applicable to both the replaced item and its application.

2.1.2 SOURCE EVALUATION AND SELECTION

Source evaluation and selection is in accordance with Paragraph 1.2, if it is determined necessary by the LLNL-YMP based on the complexity of the item and importance to safety.

2.1.3 PURCHASE ORDER

Commercial-grade items are identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).

2.1.4 RECEIPT OF COMMERCIAL-GRADE ITEM

After receipt of a commercial-grade item, the LLNL-YMP determines that the following conditions have been met:

- Damage was not sustained during shipment.
- The item received was the item ordered.
- Inspection, testing, or both, is accomplished by the LLNL-YMP, in accordance with written procedures, to assure conformance with the manufacturer's published requirements. If applicable, acceptance of the item is accomplished via the calibration program in accordance with the requirements of 033-YMP-R 12.
- Documentation, as applicable to the item, was received and is acceptable.

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NUCLEAR WASTE MANAGEMENT PROGRAM

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Subject: IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA

Approved:

Approved by: [signature] 12/20/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/8 Date
Quality Assurance Manager

INTRODUCTION

This section provides the requirements for the identification and control of items, samples and data and consists of three separate parts. The requirements for items are stated in part A; in part B for samples; and, part C for data resulting from scientific investigations. Part A applies to activities related to the engineered items and does not apply to scientific investigations. Parts B and C apply to scientific investigation activities and do not apply to engineered items.

PART A - IDENTIFICATION AND CONTROL OF ITEMS

1.0 IDENTIFICATION

Items are identified to assure that only correct and accepted items are used or installed. The identification is verified prior to installation or use. Identification is maintained either on the item, its containers, or in documents traceable to the item from receipt until installed.

1.1 GENERAL

Items of production (batch, lot, component, part) are identified from the initial receipt and fabrication of the items up to and including installation and use. This identification relates an item to an applicable design or other pertinent specifying document.

1.1.1 Physical identification is used to the maximum extent possible. Where physical identification on the item is either impracticable of insufficient, physical separation, procedural control, or other appropriate means are employed.

1.1.2 Identification markings, when used, are applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided and are not obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

1.1.3 When specified by codes, standards or specification that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records) the program is designed to provide such identification and traceability control.

1.1.4 Where specified, items having limited calendar or operating life or cycles are identified and controlled to preclude use of items whose shelf life or operating life has expired.

2.0 CONTROL

Provisions are made for the control of item identification consistent with the planned duration and condition of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identification on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing facility records.

PART B - IDENTIFICATION AND CONTROL OF SAMPLES

Procedures are developed and implemented to assure that samples are identified and controlled in a manner consistent with their intended use. Such procedures define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation and the generation of records.

1.0 IDENTIFICATION

Physical identification is used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods are described and used. All identification methods provide methods whereby identification of samples are traceable to the appropriate documentation such as drawings, specifications, drilling logs, test records, inspection documents, and nonconformance reports.

1.1 GENERAL

Samples are identified by placing the identification directly on the sample, on their container or on records traceable thereto. If it is impractical to place the identification on the sample, methods are described and implemented 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.

1.1.1 Procedures are developed and implemented to assure that sample collection methods, techniques and related equipment produce the intended sample. Sample handling methods are developed, documented and utilized to assure that all samples meet the technical objectives dictated by the scientific investigation, for which the samples are collected.

1.1.2 Storage methodology is 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 defined by the personnel responsible for the activity using the samples and depends on the sensitivity of the sample to storage conditions.

1.1.3 Transportation methods are described and effected by procedures prescribing appropriate containers, handling and any other environmental or safety considerations for the sample(s). Where multiple organizations are involved, appropriate procedures define responsibilities and documentation methods to be used.

1.1.4 Controls are developed and implemented to assure that sample identification is verified and maintained when handled, transported or transferred from one organization's responsibility to another.

1.1.5 Measures are taken to maintain sample identification while in storage. These measures are consistent with the planned duration and conditions of storage and describe actions to be taken where samples have a maximum life expectancy while in storage. Physical segregation of samples to preclude mixing with like samples is used to the maximum degree practical.

1.1.6 Where samples are controlled by more than one organization, procedures describing the organizational responsibilities are developed and implemented.

1.1.7 The DOE Project Office decides the ultimate curation of all types of samples including liquids, gases and solids. The DOE Project Office will, as a minimum, address the transportation, handling, storage, retrievability of samples and the generation and retention of records. All records generated as a result of testing of samples are handled in accordance with 033-YMP-R 17.

PART C - IDENTIFICATION AND CONTROL OF DATA

1.0 IDENTIFICATION

Data generated from a LLNL-YMP 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 such data appear.

1.1 GENERAL

The identification of LLNL-YMP data includes a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the Quality Assurance Level assigned to the activity which produced the data.

1.1.1 Control measures are established and implemented to assure that LLNL-YMP data are properly identified. These measures include verification of the identification of such data prior to release for use.

1.1.2 Where data are the results of the efforts of more than one organization, procedures describing the organizational responsibilities for that data are developed and implemented. The documentation resulting from the scientific investigation involving more than one organization are annotated to show which organization produced what portion of the data.

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NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. _____

No.: 033-YMP-R 9
Revision: 0
Date: December 15, 1988
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Subject: CONTROL OF PROCESSES

Approved:

Approved by: [signature] 12/19/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

The requirements of this section apply to engineered items and scientific investigations for process control. The requirements for special processes apply to engineered items only. Measures are established to assure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination are accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

2.0 PROCESS CONTROL

2.1 METHOD

All processes are controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means assure that process parameters are controlled and that specified environmental conditions are maintained.

2.2 IDENTIFICATION OF SPECIAL PROCESSES

2.2.1 RESPONSIBILITY

Personnel designated responsibility for activities identify which portions of the activities involve the use of special processes. A special process is a process in which the results are highly dependent on either the control of the process or the operator's skill, or both, and in which the specified quality cannot be readily determined by inspection or testing of the item.

2.2.2 QUALIFICATION REQUIREMENTS

The necessary requirements for qualifications of personnel, procedures, or equipment are specified or referenced in the procedures or instructions either for processes that are not covered by existing codes and standards or for processes where the quality requirements for an item or test exceed those of existing codes or standards.

2.2.3 CONDITIONS

Conditions necessary for accomplishment of the special process are included in procedures or instructions. These conditions include proper equipment, controlled parameters of the special process and calibration requirements.

2.2.4 APPLICABLE CODES AND STANDARDS

The requirements of applicable codes and standards, including acceptance criteria for the special process are specified or referenced in the procedures of instructions.

2.3 QUALIFICATION OF SPECIAL PROCESS PROCEDURES

2.3.1 PROGRAM FOR QUALIFICATION

Procedures are qualified in accordance with applicable codes, standards or other specifications. The program for qualification of procedures is specified in documents prepared by the cognizant technical organization. The responsible QA organization provides appropriate reviews to assure compliance with these requirements.

2.4 QUALIFICATION OF PERSONNEL PERFORMING SPECIAL PROCESSES

2.4.1 TRAINING, QUALIFICATION, AND CERTIFICATION

Personnel are trained, qualified, and certified in accordance with written procedures. The training and qualification, and certification are the responsibility of the LLNL-YMP. These procedures are reviewed by the Quality Assurance (QA) organization for compliance with requirements.

2.4.2 PROCEDURE

Qualification utilizes the actual working procedure, to the extent possible.

2.4.3 PERSONNEL QUALIFICATION REQUIREMENTS

Qualification of personnel incorporates the personnel qualification requirements of the applicable codes, standards, or specifications.

2.5 SPECIAL PROCESS EQUIPMENT

Special process equipment is checked out, qualified, and certified in accordance with specified requirements. These requirements implement the requirements of applicable codes, standards, and specifications. Equipment checkout, qualification, and certification are the responsibility of the LLNL-YMP. The QA organization reviews the procedures for qualification of equipment for compliance with requirements.

2.6 SPECIAL PROCESS RECORDS

Records are maintained for the currently qualified personnel, procedures, and equipment of each special process and the requirements for maintenance of these records are specified. Special process verification methods and criteria are documented and retained.

Subject: INSPECTION

Approved:

Approved by: [signature] 12/20/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

Measures are established by the responsible technical management to provide inspections required to verify conformance of an engineered item to specified requirements. These measures provide for: (1) inspections to be performed in accordance with written procedures by qualified personnel who did not perform the work being evaluated; (2) criteria for determining when inspections are required or how and when inspections are to be performed; (3) sampling methodology, if used; (4) the identification of mandatory hold points; and (5) identification of inspections requiring special expertise. The results of all inspection activities are documented by the inspecting organization. The requirements of this section apply to engineered items and do not apply to scientific investigation activities.

2.0 PERSONNEL

2.1 REPORTING INDEPENDENCE OF PERSONNEL

Inspections are performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being inspected. If these personnel are not part of the formal QA organization, they 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 the persons who perform the inspection activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization overviews and monitors the inspection activity.

2.2 QUALIFICATION

Each person who verifies conformance of work activities for purposes of acceptance is qualified to perform the assigned inspections or tests. The qualification of personnel performing inspection and test activities are certified in writing. Personnel selected to perform inspection and test activities have the experience or training commensurate with the scope, complexity, or special nature of the activities. Personnel are indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are employed.

3.0 INSPECTION HOLD POINTS

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

4.0 INSPECTION PLANNING

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

- Identification of characteristics and activities to be inspected.
- A description of the method of inspection.
- Identification of the individuals or groups responsible for performing the inspection operation.
- Acceptance and rejection criteria.
- Identification of required procedures, drawings, and specifications and revisions.
- Recording inspector or data recorder and the results of the inspection operation.
- Specifying necessary measuring and test equipment including accuracy requirements.

4.1 SAMPLING

When sampling is used to verify acceptability of a group of items, the sampling procedures is based on recognized standard practices.

5.0 IN-PROCESS INSPECTION

Inspection of items in-process or under construction are performed for work activities where necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel is provided.

5.1 COMBINED INSPECTION AND MONITORING

Where a combination of inspection and process monitoring methods is used, it is performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. Both inspection and process monitoring are provided when other techniques cannot provide adequate control.

5.2 CONTROLS

Where required, controls are established and documented for the coordination and sequencing of activities at established inspection points during successive stages of the conducted process or construction.

6.0 FINAL INSPECTION

Final inspection includes a records review of the results and resolution of nonconformance identified by prior inspections. The final inspection is planned to reach a conclusion regarding conformance of the item to specified requirements.

6.1 INSPECTION REQUIREMENTS

Completed items are inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the item's quality and conformance to specified requirements. If not previously examined, then quality records are examined for adequacy and completeness.

6.2 ACCEPTANCE

The item's acceptance is documented and approved by identified authorized personnel.

6.3 MODIFICATIONS, REPAIRS, OR REPLACEMENTS

Modifications, repairs, or replacements of items performed subsequent to final inspection require reinspection or retests, as appropriate, to verify acceptability.

7.0 IN-SERVICE INSPECTION

Required in-service inspection of structures, systems, or components is planned and executed by or for the organization responsible for operation.

7.1 METHODS

Inspection methods are established and executed to verify that the characteristics of an item continue to 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.

8.0 QUALIFICATION REQUIREMENTS

Appendix C of this document defines the requirements for the qualification of inspection and test personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptance. Appendix D defines the requirements for qualification of nondestructive examination personnel.

9.0 RECORDS

The following are the requirements for inspection records which are retained in accordance with 033-YMP-R 17.

9.1 INSPECTION RECORDS

As a minimum, inspection records identify the following:

- Item or activity.
- The date of the inspection.
- Name of individual performing the inspection.
- Name or names of personnel contacted during the inspection.
- A description of the type of observation (method of inspection).
- Inspection criteria including identification of drawing, specification, etc. (and applicable revision).
- Equipment used during the inspection.
- Evidence as to the acceptability of the results.
- Acceptance statement.
- References to information on action taken in connection with conditions adverse to quality, nonconformances and/or actions taken to resolve any discrepancies.

9.2 PERSONNEL QUALIFICATION RECORDS

Records of personnel qualification are established and maintained. The actual examinations used to qualify personnel are retained as part of the record files.

Subject: TEST CONTROL

Approved:

Approved by: 12/19/88 Date
Yucca Mountain Project Leader

Approved by: 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL DISCUSSION

Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service are planned and executed. Characteristics to be tested and test methods to be employed are specified. The test procedures are implemented by trained and appropriately qualified personnel. The requirements of this section apply to engineered items and do not apply to scientific investigation activities.

2.0 TEST REQUIREMENTS

Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, are provided or approved by the LLNL-YMP, unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests are controlled. Test requirements and acceptance or rejection criteria are based upon specified requirements contained in applicable design or other pertinent technical documents.

3.0 TEST PROCEDURES

3.1 TEST INSTRUCTIONS, PROCEDURES AND DRAWINGS

Instructions, procedures, and drawings for tests are prepared in accordance with the requirements of 033-YMP-R 5. Test procedures or instructions contain criteria for determining when a test is required and how the test is performed.

3.2 TEST PREREQUISITES

Test procedures include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites include the following, as applicable: (1) calibrated instrumentation, (2) appropriate equipment, (3) completeness of item to be tested, (4) trained or appropriately qualified personnel, (5) condition of test equipment and the item to be tested, (6) suitable and controlled environmental conditions, and (7) provisions for data acquisition and storage.

3.3 REVIEW OF PROCEDURES

Test plans and procedures used for qualification tests are reviewed in accordance with the verification requirements defined in Paragraph 2.4 of 033-YMP-R 3. They prescribe mandatory inspection hold points (as required), methods of documenting test data and results, and methods of data analysis.

3.4 POTENTIAL SOURCES OF ERROR

The potential sources of uncertainty and error in test procedures, which must be controlled and measured to assure that tests are well controlled, are identified.

3.5 ALTERNATIVES

In lieu of specifically prepared written test procedures, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, are used. Such documents include adequate instructions to assure the required quality of work.

4.0 TEST RESULTS

Test results are documented and their conformance with acceptance criteria evaluated by a responsible authority to assure that test requirements have been satisfied.

5.0 TEST RECORDS

Test records, as a minimum, identify the following:

- Item tested.
- Date of test.
- Tester or data recorder identification.
- Type of observation.
- Results and acceptability.
- Action taken in connection with any deviations noted.
- Person evaluating results.

University of California Lawrence Livermore National Laboratory NUCLEAR WASTE MANAGEMENT PROGRAM CONTROLLED COPY NO. _____	No.: 033-YMP-R 12 Revision: 0 Date: December 15, 1988 Page: 1 of 2
Subject: CONTROL OF MEASURING AND TEST EQUIPMENT	Approved:

Approved by: [signature] 12/22/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/22/88 Date
Quality Assurance Manager

1.0 GENERAL

1.1 MAINTAINING ACCURACY OF EQUIPMENT

Measures are established to assure that tools, gages, instruments, and other measuring and test equipment used in activities that affect quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

1.2 SCOPE OF CONTROL PROGRAM

The Quality Assurance Program Plan (QAPP) defines the scope and methodology of the program for the control of measuring and test equipment. This includes all measuring and test equipment or systems 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.

1.3 DESCRIPTION OF RESPONSIBILITIES

Responsibilities for the effective establishment, implementation and assurance of the calibration program are described.

2.0 PURPOSE OF EQUIPMENT

Measuring and test equipment are devices or systems 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.

Specific requirements for control of measuring and test equipment are listed below:

2.1 SELECTION

Selection of measuring and test equipment is controlled to assure that such equipment is of proper type, range, and accuracy to accomplish the function of determining conformance to specified requirements. The type, range, accuracy and tolerance of a measuring device are specified in test and inspection procedures. Each device has a unique identification number. This number is recorded on the data sheet, log, etc., along with the measurement taken, to assure traceability to the measurement of the device that was used to take the measurement.

2.2 CALIBRATION

Measuring and test equipment is calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and is calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration is documented. Calibration standards have equal or greater accuracy than equipment being calibrated. Calibration standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.

2.3 CONTROL

The method and interval of calibration for each item is defined, based on the type of equipment, stability, characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. Measuring and test equipment is labeled, tagged, or otherwise documented in a fashion which indicates the due date of the next calibration and to provide traceability to calibration data. If measuring and test equipment is found to be out of calibration, an evaluation is made and documented of the validity of previous results obtained and of the acceptability of items previously inspected, tested or data gathered since the last calibration. Devices that are out of calibration are tagged or segregated and are not used until they have been recalibrated. If any measuring or test equipment is found to be out of calibration consistently then it is repaired or replaced. Calibration is performed when the accuracy of equipment is suspect.

2.4 COMMERCIAL DEVICES

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

2.5 HANDLING AND STORAGE

Measuring and test equipment are handled properly and stored to maintain accuracy.

2.6 RECORDS

Records are maintained and equipment is marked suitably to indicate calibration status. Calibration records identify the calibration procedure (including revision) utilized to perform the calibration.

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NUCLEAR WASTE MANAGEMENT PROGRAM

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Subject: HANDLING, SHIPPING, AND STORAGE

Approved:

Approved by: [signature] 12/20/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

Measures are established to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Handling, storage, and shipping of items is conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity. Specific requirements are listed below.

1.1 SPECIAL EQUIPMENT AND PROTECTIVE ENVIRONMENTS

When required for particular items, special equipment (e.g., containers, shock absorbers, and accelerometers) and special protective environments (e.g., an inert gas atmosphere, specific moisture content levels, and temperature levels) are specified and provided, and their existence verified.

1.2 SPECIFIC PROCEDURES.

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific procedures for handling, storage, packaging, shipping, and preservation are used.

1.3 INSPECTION AND TESTING OR SPECIAL TOOLS AND EQUIPMENT

Special handling tools and equipment are utilized and controlled as necessary to assure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are maintained adequately.

1.4 OPERATORS OF SPECIAL EQUIPMENT

Operators of special handling and lifting equipment are experienced or trained to use the equipment.

1.5 MARKING AND LABELING

Instructions for marking and labeling for packaging, shipment, handling, and storage of items are established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

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Subject: INSPECTION, TEST, AND OPERATING STATUS

Approved:

Approved by: [signature] 12/19/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 INDICATION OF STATUS

The requirements of this section apply to engineered items and do not apply to scientific investigations. The status of inspection and test activities are 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. Status indicators provide for indicating the operating status of systems and components of the facility, such as by tagging valves and switches, to prevent inadvertent operation.

2.0 METHODS OF INDICATING STATUS

Status is maintained through indicators, such as physical location and tags, markings, travelers, stamps, inspections records, or other suitable means. Procedures describing status indicators and their use contain current actual examples of each type indicator.

3.0 APPLICATION AND REMOVAL OF STATUS INDICATORS

The authority for application and removal of status indicating tags, markings, labels, and stamps is specified in procedures governing inspection, test, and operating status.

Subject: CONTROL OF NONCONFORMING ITEMS

Approved:

Approved by: [signature] 12/19/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

Measures are established to control items that do not conform to requirements to prevent their inadvertent installation or use. These measures include documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All personnel involved in LLNL-YMP activities are responsible for reporting nonconformances in accordance with established nonconformance control procedures. These procedures are consistent with the minimum requirements listed below.

1.1 IDENTIFICATION

1.1.1 METHOD OF IDENTIFICATION

Identification of nonconforming items are made by marking, tagging, or other methods that do not adversely affect the end use of the item. The identification is legible, easily recognizable, and contains the nonconformance report number. The nonconformance report number is a sequential number preceded by the organizational acronym (e.g., LLNL-1, etc). If tags are used, they are securely attached to avoid loss during handling.

1.1.2 EXCEPTIONS

If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, is identified.

1.1.3 CONDITIONAL RELEASE

Work on the nonconforming item is stopped until completion of the action specified in the Nonconformance Report (NCR) disposition. If only a specific portion of the item is in nonconformance, then that specific area is identified and work may proceed on the remaining areas.

If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the approval of the DOE Project Office is obtained before such continuance. Requests for conditional releases on nonconforming items include documented justification that the following conditions are met:

- The nonconforming item can be removed or corrected at a later date without damage to, or contamination of the associated permanent facility equipment or structure.
- The nonconforming item remains accessible for inspection.
- The nonconforming item is evaluated and limitation(s) for use of the equipment or system is established.
- Traceability and identification of the nonconforming item are maintained.

1.2 LOGGING

1.2.1 NONCONFORMANCE CONTROL LOG

The LLNL-YMP maintains a nonconformance control log to track nonconforming items. This log contains the following information:

- The nonconformance report number.
- A brief description of the nonconforming condition.
- Identification of the person or organization responsible for determining and carrying out the nonconformance disposition.
- The status of each nonconformance report (open or closed).

1.3 SEGREGATION

1.3.1 HOLD AREA

When practical, nonconforming items are segregated by placing them in a clearly identified and designated hold area until they are dispositioned properly.

1.3.2 ALTERNATIVE

When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of a nonconforming item.

1.4 DISPOSITION

1.4.1 NONCONFORMANCE CHARACTERISTICS

Nonconforming characteristics are reviewed and recommended dispositions of nonconforming items are proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item is controlled pending an evaluation and an approved disposition by authorized personnel. Distribution of nonconformance documentation is made to all affected organizations.

1.4.2 RESPONSIBILITY AND AUTHORITY

The responsibility and authority for the evaluation, disposition, and close-out of nonconforming items is defined and documented. Those personnel assigned signature approval of the disposition are identified. Quality Assurance (QA) responsibilities relating to nonconformances are described.

1.4.3 PERSONNEL

Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to pertinent background information.

1.4.4 DISPOSITIONING OF NCR

The person or organization assigned the responsibility of dispositioning the NCR assures the following:

- Nonconformance documentation adequately identifies and describes the nonconformance.
- Appropriate justification for the disposition is documented. In the case of use-as-is or repair dispositions, technical justification is required. The as-built records, if such records are required, reflect the accepted deviation.
- The disposition references any approved design documents, procedures, plans, work orders, etc., used for the correction of the nonconforming condition.
- The technical details for correction of the nonconforming condition are adequate for the recommended disposition.
- If continuance is requested, justification for the activity to continue is documented and approved by the appropriate DOE Project Office Branch Chief and the DOE Project Office Quality Assurance Manager.
- The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.
- If a change to reflect the as-built condition is appropriate, then the disposition addresses action to change the existing design documents, test plans or procedures, reports, etc. Any documents changed are cross-referenced on the NCR.
- Disposition identifies and documents the correction as repair, rework, use-as-is, or reject/scrap.
- Disposition identifies the people or organization responsible to implement the disposition.

1.4.5 DOE PROJECT OFFICE APPROVAL

In those cases where the proposed disposition is "repair", the DOE Project Office approves the proposed disposition prior to implementation. In the case of a proposed disposition of "use-as-is", the NCR is forwarded to the DOE Project Office for approval after all actions necessary to support the technical justification of the disposition is completed. The appropriate DOE Project Office Branch Chief and the DOE Project Office Quality Assurance Manager approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.

1.4.6 CORRECTIVE ACTION

The action taken to correct the nonconforming item is verified and documented. Repaired or reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition establishes alternate acceptance criteria.

1.4.7 INTERFACES

Internal interfaces between LLNL-YMP units and external interfaces between LLNL-YMP and other High-level Nuclear Waste Program participating organizations are clearly described.

2.0 REPETITIVE NONCONFORMANCES

When repetitive or recurring nonconforming conditions are identified, an evaluation is made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action is beyond the scope of the action taken for the disposition on the existing NCRs and is processed in accordance with corrective action procedures prescribed by the LLNL-YMP.

3.0 TRENDING

Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances. Results are reported to upper management for review and assessment.

4.0 DISTRIBUTION OF DOCUMENTS

Copies of nonconformance reports for items are sent to the DOE Project Office Quality Assurance Manager upon issuance and upon closure. The original nonconformance reports are sent to the DOE Project Office for approval as required by Paragraph 1.4.5.

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NUCLEAR WASTE MANAGEMENT PROGRAM

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Subject: CORRECTIVE ACTION

Approved:

Approved by: 12/19/88 Date
Yucca Mountain Project Leader

Approved by: 12/15/ Date
Quality Assurance Manager

1.0 GENERAL

A corrective action system is defined to assure that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical.

1.1 SIGNIFICANT ADVERSE CONDITIONS

For significant conditions adverse to quality the identification, cause, and corrective action taken to preclude recurrence are documented and reported to immediate management and upper levels of management for review and assessment. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality or an unusual occurrence exists, the LLNL-YMP assures that:

- Immediate actions are taken to remedy the specific conditions.
- Causative factors are determined.
- Controls are reviewed, implemented, monitored, and revised, if necessary.
- Affected managers at all levels are notified of adverse conditions and of lessons learned to improve conditions or avoid similar occurrences.

1.2 FOLLOW-UP ACTION

The QA organization documents concurrence of the adequacy of proposed corrective actions to assure that QA requirements are satisfied. Follow-up action is taken by the QA organization to verify proper implementation of this corrective action and to close out the corrective action. Those responsible for implementing the corrective action assure that the corrective action is completed in a timely manner.

1.3 CORRECTIVE ACTION

Corrective action reports are periodically analyzed by the QA organization to show quality trends. Results are reported to upper management for review and assessment.

2.0 DISTRIBUTION OF DOCUMENTS

Copies of corrective action reports are sent to the DOE Project Office Quality Assurance Manager by the LLNL-YMP upon issuance and closure.

Subject: QUALITY ASSURANCE RECORDS

Approved:

Approved by: [signature] 12/19/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

Records that furnish documentary evidence of quality are specified, prepared, and maintained in accordance with the requirements of this Section. This includes the requirements that all documents be legible, identifiable, and retrievable.

1.1 DEFINITION

A document or other item is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below. The term records, used throughout this Section is to be interpreted as Quality Assurance Records. Quality Assurance Records include (1) individual documents that have been executed, completed, and approved and furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents, such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; (5) magnetic media; and (6) other materials that provide data and document quality, regardless of the physical form or characteristic. A completed record is a document that will either receive no more entries or whose revision would normally consist of the reissue of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document. Records are distributed, handled and controlled in accordance with written procedures. All records, including superseded records, are retained.

1.2 ESTABLISHING A RECORD SYSTEM

A record system or systems is established by the LLNL-YMP at the earliest practicable time consistent with the schedule for accomplishing work activities.

1.2.1 RECORDS MANAGEMENT

The record system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation prepared in accordance with 033-YMP-R 5.

Consistent with applicable regulatory requirements, the DOE Project Office establishes requirements concerning record types and retention including duration, location, and assigned responsibility.

1.2.2 MINIMUM RECORDS

Sufficient records are specified, prepared, and maintained to furnish documented evidence of activities that affect quality. The records include at least the following: operating logs, the results of reviews (i.e., data, analysis), inspections, tests, audits, monitoring of work performance, and materials analyses. Also, the records include closely related data such as qualifications of personnel, procedures, and equipment. A list of typical QA records is contained in Appendix E.

1.2.3 CONTROL OF RECORDS

Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition of QA records are established and documented.

1.3 PRESERVATION OF RECORDS

The procedure that defines the implementation of the record system for the LLNL-YMP identifies measures to be implemented for the preservation and safe-keeping of the records before storage and for the prevention of delays between record completion and storage at the DOE Project Office Record Center.

1.4 RETENTION CLASSIFICATION

For purposes of record retention, all LLNL-YMP records are classified as lifetime records and are retained for the life of the LLNL-YMP.

2.0 GENERATION OF RECORDS

2.1 RECORDS SPECIFICATION

The applicable design specifications, procurement documents, implementing procedures, operational procedures, or other documents specify the records to be generated, supplied, or maintained by the LLNL-YMP.

2.1.1 QUALITY OF RECORDS

Documents that are designated to become records are legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished.

2.1.2 COMPLETION OF RECORDS

Documents that are designated to become records are completed in accordance with the methods specified by the DOE Project Office.

3.0 VALIDATION OF RECORDS

3.1 METHODS OF VALIDATION

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 are originals or reproduced copies. Authentication may take the form of a statement by the responsible individual. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual.

3.2 AUTHENTICATION LIST

The LLNL-YMP maintains a list containing the signatures and initials of the personnel authorized to authenticate records.

4.0 RECEIPT OF RECORDS

4.1 RECEIPT CONTROL

The LLNL-YMP designates a person as responsible for receiving the records. The designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage in accordance with approved procedures. The receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process. As a minimum, the receipt control system includes the following:

- A method for designating the required records.
- A method for identifying the records received.
- Procedures for receipt and inspection of incoming records.
- A method for submittal of completed records to the storage facility without unnecessary delay.

4.2 PROTECTION OF RECORDS

The individual responsible for receiving records provides protection from damage, deterioration, or loss during the time that the records are in their possession.

5.0 RECORDS IDENTIFICATION

5.1 IDENTIFICATION DESIGNATION

Records or indexing systems, or both provide sufficient information to permit identification between the record and the items or activities to which it applies. Records are clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, task number, preparing organization, author, date, title, subject, etc.). The identification number or other designation is not repeated. The DOE Project Office or its designee reviews and approves the records identification system of the LLNL-YMP to assure consistency.

5.2 INDEXING SYSTEM

The records are indexed and the indexing system or systems include, as a minimum, the location of the record within the records system or systems.

6.0 PERMANENT STORAGE FACILITY

Records are controlled from the time they are complete until the time they are stored in a permanent storage facility. Temporary storage, preservation, safe keeping, and retrievability of completed records are in accordance with the requirements applicable to the permanent storage of records. The use of dual storage facilities is an acceptable alternative to a single fire-rated, environmentally controlled facility.

6.1 STORAGE LOCATION

The records are stored in a predetermined location or locations that meet the requirements of applicable standards, codes, and regulatory agencies.

6.2 STORAGE PROCEDURE

Before the records are stored, a written storage procedure is prepared and responsibility assigned for enforcing the requirements of that procedure. As a minimum, this procedure includes the following:

- A description of the storage facility.
- The filing system to be used.
- The method for verifying that the records received are legible and are in agreement with the transmittal document.

- The method of verifying that the records are those designated (see Paragraph 4.1).
- The rules governing access to and control of the files.
- The method for maintaining control of and accountability for records removed from the storage facility.
- A method for filing supplemental information (see Paragraph 9.0).

7.0 PRESERVATION

Records are stored in a manner approved by the LLNL-YMP. In order to preclude deterioration of the records, the following requirements apply:

- Provisions are made in the storage arrangement 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.
- Provisions are made for special processed records (e.g., radiographs, photographs, negatives, microfilm, magnetic material, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

8.0 SAFEKEEPING

8.1 MEASURES TO PRECLUDE ENTRY

Measures are established to preclude the entry of unauthorized personnel in the storage area. These measures guard against larceny and vandalism.

8.2 REPLACEMENT, RESTORATION, OR SUBSTITUTION

Measures are taken to provide for replacement, restoration, or substitution of lost or damaged records. These measures are accomplished within 90 days following determination that either a record has been lost or a record has been damaged to a degree that it is no longer complete or legible.

9.0 CORRECTED INFORMATION IN RECORDS

9.1 METHOD

Records are corrected in accordance with written procedures that provide for appropriate review or approval by the LLNL-YMP.

9.2 IDENTIFICATION

The correction includes the date and the identification of the person authorized to issue such correction and does not obliterate the corrected data.

10.0 STORAGE FACILITY

The following requirements apply to both permanent and temporary record storage facilities.

10.1 CONSTRUCTION AND MAINTENANCE OF FACILITY

Records are stored in facilities constructed and maintained in a manner that minimizes the risk of damage or destruction from natural disasters, such as winds, floods, or fires; environmental conditions such as high and low temperatures and humidity; and infestation of insects, mold, or rodents.

10.2 METHODS

The two satisfactory methods of providing storage facilities are (1) single and (2) dual; these are detailed in the following sections.

10.2.1 SINGLE FACILITY

Design and construction of a single record storage facility meet the following criteria:

- Reinforced concrete, concrete block, masonry, or equal construction.
- A floor and roof with drainage control and if a floor drain is provided, then a check valve (or equivalent device) is included.
- Doors, structures and frames, and hardware that are designed to comply with the requirements of a minimum two-hour fire rating.
- Sealant applied over walls as a moisture or condensate barrier.
- Surface sealant placed on the floor to provide a hard wearing surface to minimize concrete dusting.
- Foundation sealant and provisions for drainage.
- Forced-air circulation with a filtration system.
- A fire protection system.
- Only those penetrations used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed. All such penetrations are sealed or dampered to comply with the minimum two-hour fire protection rating.
- The construction details are reviewed for adequacy of protection of contents by a person who is competent in the technical fields of fire protection and fire extinguishing.
- If the facility is located within a building or structure, then the environment and construction of that building can provide a portion or all of these criteria.

10.2.2 ALTERNATE SINGLE FACILITIES

The following are acceptable alternatives to the criteria for a single facility:

- o Two-hour fire rated vault that meets National Fire Protection Association (NFPA) 232-1975.
- o Two-hour fire rated Class B file containers that meet the requirements of NFPA 232-1975.
- o Two-hour fire rated file room that meets the requirements of NFPA 232-1975 with the following additional provisions.
  - An early-warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station.
  - Records storage in fully enclosed metal cabinets.
  - Adequate access and aisle ways.
  - Work that is not associated directly with record storage or retrieval is prohibited in the file room.
  - Smoking, eating, or drinking are prohibited in the file room.
  - Two-hour fire rated dampers or doors in all boundary penetrations.

10.2.3 DUAL FACILITIES

If storage at dual facilities for each record is provided, then the facilities are at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Neither facility is required to satisfy the requirements of Paragraph 10.2.1 or 10.2.2 but meet the other requirements of this document.

11.0 RETRIEVAL

11.1 PROVISIONS

Storage systems provide for retrieval of information in accordance with planned retrieval times based upon the record type. Final reports contain a listing, by unique number or other designation, that enables prompt retrieval of all documents used to compile or evaluate the report. This listing includes as a minimum, all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and test plans. All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc. are retrievable from the Records Management System (RMS).

11.2 PERSONNEL

A list is maintained that designates those personnel who have access to the files.

11.3 ACCESSIBILITY

Records maintained by the LLNL-YMP at LLNL or other location (on an interim or other basis) is accessible to the DOE Project Office or its designated alternate.

12.0 DISPOSITION

12.1 ACCESSIBILITY AT VARIOUS LOCATIONS

Records accumulated at various locations, prior to transfer, are accessible to the DOE Project Office either directly or through the LLNL-YMP.

12.2 CUSTODIAN

The custodian inventories the submittals, acknowledges receipt, and processes records in accordance with this document or the procedures implementing this document.

12.3 REQUIREMENTS OF REGULATORY AGENCIES

Various regulatory agencies have requirements concerning records that are within the scope of this document. The most stringent requirements are used to determine final dispositions.

University of California
Lawrence Livermore National Laboratory

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. _____

No.: 033-YMP-R 18
Revision: 0
Date: December 15, 1988
Page: 1 of 5

Subject: AUDITS

Approved:

Approved by: [signature] 12/19/88 Date
Yucca Mountain Project Leader

Approved by: [signature] 12/15/88 Date
Quality Assurance Manager

1.0 GENERAL REQUIREMENTS

All LLNL-YMP activities are subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall Quality Assurance (QA) program and to determine their effectiveness. A system of planned, periodic audits to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records is established to assure that the QA program is effective and properly implemented. The audits are performed in accordance with written procedures using checklists by appropriately trained personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented, reported to, and reviewed by responsible management. Tracking systems are instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies, nonconformances, and potential quality problems identified during the audit are documented and monitored until verification of effective corrective action is made. The audited organization describes in a formal report the corrective action taken to address findings, and submits the report to the auditing organization and responsible management.

Follow-up action, including verification of corrective action or reaudit of specific areas, are performed.

1.1 PROJECT AUDITS

Internal audits of the LLNL-YMP are conducted by the LLNL-YMP QA Manager. External audits of LLNL-YMP subcontractors are conducted by the LLNL-YMP QA Manager. Audits of the LLNL-YMP may also by conducted by the DOE Project Office.

1.1.1 DOE PROJECT OFFICE AUDITS

The DOE Project Office QA Department develops a schedule defining the DOE Project Office audits planned for each fiscal year. This schedule is approved and issued by the DOE Project Office as an annual planning document. As a minimum the DOE Project Office audits the LLNL-YMP annually. The audits cover the entire scope of the LLNL-YMP QAPP. Additional audits are conducted when a unique need arises or when an audit is requested by the LLNL-YMP. The LLNL-YMP is audited to verify the effectiveness and adequacy of implementation of all elements of the LLNL-YMP QAPP and the DOE Project Office QA Plan.

These audits eliminate the need for LLNL-YMP to conduct audits of other High-level Nuclear Waste Program participating organizations. Representatives of the LLNL-YMP may be invited to participate in a DOE Project Office audit when the audited activities are of mutual interest. Copies of audit documents for the DOE Project Office audits are sent to the audited organization.

1.1.2 LLNL-YMP AUDITS

The LLNL-YMP conducts internal (covering the entire LLNL-YMP QAPP, on an annual basis) and direct subcontractor (external) audits of activities under its control. These audits are scheduled, planned, conducted, and reported as described in the LLNL-YMP QAPP. External and internal audit schedules, dates, and changes thereto, are sent to the DOE Project Office Quality Assurance Manager. Audit schedules identify the date of the audit, the activities to be audited, and the requirements to which the activities will be audited.

1.2 SCHEDULING

Internal and external QA audits, are scheduled in a manner that provides coverage and coordination with ongoing QA program activities. Audits are scheduled at a frequency commensurate with the status and importance of the activity and are initiated early enough to assure effective QA. The LLNL-YMP performs or arranges for annual evaluations of suppliers. This evaluation is documented and takes into account, where applicable, (1) review of supplier 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.

1.2.1 INTERNAL AUDITS

Applicable elements of the LLNL-YMP QAPP are audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of the audit is established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA program.

1.2.2 EXTERNAL AUDITS

Elements of an external organization's (a subcontractor's) QA program are audited at least annually or once during the life of the activity, whichever is the shorter period, with the following exception: If the activity is less than four months in duration, an audit is not required to be performed unless an audit is necessary due to the complexity or importance of the activity being performed. The justification for not performing audits of vendors whose activities are less than four months in duration is documented and approved by the LLNL-YMP Quality Assurance Manager. A copy of the documented justification is provided to the DOE Project Office Quality Assurance Manager.

1.2.3 JOINT AUDITS

If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit satisfies the needs of all of the purchasers, and the audit

report is distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

1.3 PREPARATION

Preparation for an audit includes the items listed below.

1.3.1 AUDIT PLAN

The LLNL-YMP develops and documents an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklist.

1.3.2 PERSONNEL

The LLNL-YMP selects and assigns auditors who are independent of any direct responsibility for the performance of the activities that they are to audit. If the audit is to be an internal one, then the personnel who have direct responsibility for performing the activities to be audited are not involved in the selection of the audit team. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA audit personnel.

1.3.3 SELECTION OF AUDIT TEAM

An audit team is identified before the beginning of each audit. This team contains one or more auditors and has an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses. The audit team leader identifies the technical specialists, if any, to participate in the audit and includes this information in the audit plan. Audit team members selected to participate in audits for technical purposes have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit teams are employed when activities to be audited involve more than a single technical area. The audit team leader assures that the audit team is prepared before the audit begins.

1.4 PERFORMANCE

Audits are performed in accordance with written procedures using checklists as early in the life of the activity as practical and are continued at intervals consistent with the schedule for accomplishing the activity. Elements selected for audit are evaluated against specified requirements including a review of corrective actions taken on deficiencies in the area being audited that were identified during previous audits. Objective evidence is examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively. The audit results are documented by audit personnel and are reviewed by management having responsibility for the area audited. Conditions that require prompt corrective action are reported immediately to the management of the audited organization. Audit findings are reviewed with the audited organizations at a closing meeting.

1.5 REPORTING

The audit report is signed by the audit team leader and issued within 30 calendar days. This report includes the following information, as appropriate:

- o Description of the audit scope.
- o Identification of the auditors.
- o Identification of persons contacted during audit activities.
- o Summary of audit results, including a statement of the effectiveness of the QA program elements that were audited.
- o Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

1.6 RESPONSE

Management of the audited organization or activity investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and, within thirty calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. The adequacy of audit responses are evaluated by or for the auditing organization.

1.7 FOLLOW-UP ACTION

Follow-up action is taken to determine whether or not corrective action has been accomplished as scheduled and is verified by the auditing organization. An analysis of audit results is performed by the QA organization to identify quality trends. The results of the analysis are reported to responsible management for review, assessment, and appropriate action.

1.8 RECORDS

1.8.1 AUDITS

As a minimum, audit records include the following:

- o Identification of the organization(s), activities, or items audited and the individual(s) contacted during the audit(s).
- o Description of any deficiencies, nonconformances, and potential quality problems identified.
- o Audit plans, audit reports, written replies, and the record of completion of corrective action, and close-out of the audit.

1.8.2 PERSONNEL RECORDS

Records of personnel qualifications for Auditors and Lead Auditors performing audits are established and maintained by the LLNL-YMP. Records for each Lead Auditor are maintained and updated annually.

2.0 SURVEILLANCES

The LLNL-YMP audit program is supplemented by independent surveillance activities. The purpose of a surveillance is to monitor or observe items or activities to verify conformance to specified requirements. These surveillances are conducted by the LLNL-YMP and are scheduled or implemented on a random basis.

Measures for the surveillance of site investigation activities are established and executed in accordance with procedures prepared by the LLNL-YMP. Surveillances are scheduled and conducted based on the activity's relative impact or importance, or both, to the LLNL-YMP. All deficiencies, nonconformances, and potential quality problems identified during surveillances are documented and monitored until verification of effective corrective action is made. Specific requirements applicable to surveillance activities are as follows:

2.1 PLANNING

Surveillances are performed to written checklists or surveillance plans whenever practical. The documentation identifies characteristics, methods, and acceptance criteria, provides for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance. The specification of acceptance criteria related to surveillances may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements."

2.2 REPORTING INDEPENDENCE

Surveillance personnel do not report directly to the immediate supervisors who are responsible for the work being surveilled.

2.3 RECORDS

As a minimum, surveillance records identify the following:

- Item or activity.
- Date of surveillance.
- Name of individual performing the surveillance.
- Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.
- Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances are handled in accordance with the requirements of 033-YMP-R 15 or R 16, as applicable.
- Surveillance criteria.
- Equipment used during the surveillance.
- Results.
- Acceptance statement.

Subject: APPENDIX A - "TERMS AND DEFINITIONS"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

ACCEPTANCE CRITERIA: Specified limits defined in codes, standards, or other requirement documents placed on characteristics of an item, process, or service.

ACCESSIBLE ENVIRONMENT: (1) the atmosphere; (2) the land surface; (3) surface water; (4) oceans; and (5) the portion of the lithosphere that is outside the controlled areas.

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The LLNL-YMP QAPP applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation. The QA Level I requirements of this QAPP apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-list nor do they require QA level assignment. However, activities related to natural barriers important to waste isolation are identified and listed on a Q-list. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. Examples are site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.

ACTIVITY: Any time consuming effort (operation, task, function, or service) which influences or affects the achievement or verification of the objectives of the DOE Project Office as depicted in the WBS Dictionary.

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

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. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

AUTHENTICATION (QA RECORDS): Authentication is the act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by one of the following methods: (1) a stamped, initialed, or signed, and dated document; (2) a statement by the responsible individual or organization; or (3) issuing a document which is clearly identified as a statement by the reporting individual or organization. A document cannot become a Quality Assurance (QA) record until it has been authenticated.

AUXILIARY SOFTWARE: (1) Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format, or plotting of data in support of primary analysis software. (2) A stream of commands or sequence of streams of commands executed to utilize system maintained software in which the system maintained software generates reportable results. Auxiliary software does not generate primary data.

BARRIER: Any material or structure that prevents or substantially delays the movements of water or radionuclides.

BASELINE: As used for computer software: (1) The stage of computer software at a completed and reviewed phase of the software lifecycle; (2) Approved documentation generated within or as a result of completing a phase of the software life cycle.

CERTIFICATE OF CONFORMANCE: A document signed by an authorized individual that certifies the degree to which items or services meet specified requirements.

CERTIFICATION: The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

CHARACTERISTIC: Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

COMMERCIAL GRADE ITEM: An item satisfying all of the following requirements:

1) The item is not subject to design or specification requirements that are unique to Mined Geologic Disposal Systems;

2) The item is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description, i.e., catalog.

3) The item is used in applications other than Mined Geologic Disposal Systems.

COMPUTER MODEL VALIDATION: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing code results to (1) physical data, or (2) a verified or validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for code validation if it is the only available means for validating a code.

COMPUTER CODE VERIFICATION: Assurance that a computer code correctly performs the operations specified in a numerical model (NUREG-0856). Usually accomplished by comparing code results to (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).

CONDITION ADVERSE TO QUALITY: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability.

CONFIGURATION MANAGEMENT: As used for computer software: (1) A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration.

CONSEQUENCE ANALYSIS: A method by which the consequences of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

CONTAINMENT: The confinement of radioactive waste within a designated boundary.

CONTAINMENT, PERIOD OF: Known as the period during the first several hundred years following permanent closure of the geologic repository in which radiation and thermal levels are high and the uncertainties of assuring repository performance are great. During this time, special emphasis is placed upon the ability to contain the wastes by waste packages within an engineered barrier system.

CONTRACTOR: An organization under contract to provide supplies, construction, or services.

CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that extend horizontally no more than 5 kilometers in any direction from the outer boundary of the underground facility and the underlying subsurface, which is an area that has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure. The controlled area is also known as the site.

CONVERSION REPORT: A written description of all modifications made to the original code or an externally available existing code after it is acquired.

CORRECTIVE ACTION: Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition.

CORROBORATIVE DATA: Existing data used to support or substantiate other existing data.

CREDIBLE EVENT OR CREDIBLE ACCIDENT: An event or accident scenario which needs to be considered in the design of a geologic repository.

DESIGN: The act of developing designs for construction or of analyzing the performance or repository engineered structures, systems, components, and natural barriers. Design documentation includes, but is not limited to, drawings, specifications, test plans, design reports, test reports, system design descriptions, configuration status listings, design manuals, and manuals describing computer programs used for design or performance analysis.

DESIGN INPUT: Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based.

DESIGN OUTPUT: Documents, such as drawings, specifications, and others that define technical requirements of structures, systems, and components.

DESIGN PROCESS: Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

DEVIATION: A departure from specified requirements.

DISPOSITION: The action taken to resolve a nonconforming condition and to restore acceptable conditions.

DOCUMENT: Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Appendix.

DOE: The U.S. Department of Energy or its duly authorized representatives.

ENGINEERED BARRIER SYSTEM: The waste package and the underground facility.

ENGINEERED ITEM: Any structure, system, or component identified in design documents as being a functional part of the completed facility.

EXISTING DATA: Data developed prior to the implementation of a 10 CFR 60, Subpart G QA 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.).

EXTERNAL AUDIT: An audit of those portions of another organization's QA program that is neither under the direct control nor within the organizational structure for the auditing organization.

FINAL DESIGN: Approved design output documents and approved changes thereto.

FUNCTIONAL CHARACTERISTICS: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the OGR Program or other Federal regulatory documents.

GEOLOGIC REPOSITORY: A system that is either intended to be used for or may be used for the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the geologic repository operations area and the portion of the geologic setting that provides isolation of the radioactive waste.

GEOLOGIC REPOSITORY OPERATIONS AREA: A high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, in which waste handling activities are conducted.

IMPORTANT TO SAFETY: As it applies to structures, systems, and components, those engineered structures, systems, and components that are essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure.

IMPORTANT TO WASTE ISOLATION: The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment, (i.e for achieving the postclosure performance objectives in 10CFR60, Subpart E).

INDOCTRINATION: Instruction provided to personnel for familiarization with programmatic and work-oriented documents applicable to the assigned activity.

INSPECTOR: A person who performs inspection activities to verify whether or not an item or activity conforms to specified requirements.

INSPECTION: Examination of measurement to verify whether an item or activity conforms to specified requirements.

INTERNAL AUDIT: An audit of those portions of an organization's QA program that is retained under its direct control and within its organizational structure.

ISOLATION: Inhibiting the transport of radioactive materials so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

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.

LIFETIME RECORDS: Quality Assurance Records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All LLNL-YMP QA Records are classified as Lifetime Records.

MATERIAL: A term that includes items plus any hardware or geologic samples either used in or resulting from research and development or site investigations on the LLNL-YMP. Hardware and geologic specimens include but are not limited to test apparatus or equipment, special nuclear material cores, geologic samples, water and gas samples, etc.

MEASURING AND TEST EQUIPMENT: Devices or systems used to calibrate, measure, gage, test, or inspect, in order to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

NONCONFORMANCE: A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

NON-MECHANISTIC FAILURES: Postulated failures which are not based on previously observed models or mechanisms but which are assumed to provide conservatism in safety assessments.

NTS: Nevada Test Site

NTS SUPPORT CONTRACTOR: Organizations that are directly under contract to DOE/NV for activities at the NTS and other locations.

OBJECTIVE EVIDENCE: Any documented statement of fact, other information, or record, either quantitative or qualitative, that pertains to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

OPERATIONS, PERIOD OF: Includes the time during which emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing of shafts.

OVERVIEW: An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

OWNER: The person, group, company, agency, or corporation that has or will have title to the repository.

PARTICIPATING ORGANIZATION: This term applies to the following: (1) the government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in High-level Nuclear Waste Program activities.

PEER: A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject 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, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the <u>adequacy</u> of work. In contrast to peer review, the term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

PEER REVIEW GROUP: A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

PEER REVIEW REPORT: A documented in-depth report of the proceeding and findings of a peer review.

PERFORMANCE ALLOCATION: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components.

PERFORMANCE ASSESSMENT: The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to determine compliance with the numerical criteria associated with 10 CFR Part 60.

PERMANENT CLOSURE: The sealing of shafts and boreholes. Permanent closure represents the end of active human intervention with respect to the engineered barrier system.

PERFORMANCE CONFIRMATION: The program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

PRINCIPAL INVESTIGATOR (PI): The individual who has the technical responsibility for a particular technical task. This responsibility includes, but is not limited to, planning and cost control, the day-to-day technical direction and control of the item or activity, and the assembly of a support team to accomplish the item or activity. This term may be synonymous with task leader or project engineer.

PROCEDURE: A document that specifies or describes the way in which an activity is to be performed.

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60 in accordance with the DOE Project Office Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with YMP Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the YMP Project QA Program."

PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means by which to acquire possession or ownership of items, or right to the use of services by payment.

PURCHASER: The organization responsible for the establishment of procurement requirements and for the issuance or administration, or both, of procurement documents.

Q-LIST: A list of geologic repository engineered structures, systems, and components that have been determined to be important to safety, and engineered barriers important to waste isolation that must be covered under the QA requirements of 10 CFR 60, Subpart G.

QUALIFICATION (of DATA): A formal process intended to provide a desired level of confidence that data are suitable for their intended use.

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.

QUALIFICATION TESTING: Demonstration that an item meets design requirements

QUALIFIED DATA: Data initially collected under a 10CFR60, Subpart G quality assurance program or existing data qualified in accordance with Appendix G of this QAPP.

QUALIFIED PROCEDURE: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

QUALITY ACTIVITIES LIST: A list of those major activities conducted during site characterizaion, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the 10 CFR 60, Subpart G Quality Assurance program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

QUALITY ASSURANCE: All those planned and systematic actions that are necessary to provide adequate confidence that the geologic repository and its subsystems or subcomponents will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means by which to control the quality of the material, structure, component, or system to predetermined requirements.

QUALITY ASSURANCE RECORD: An individual document or other item 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) documents prepared and maintained to demonstrate implementation of Quality Assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents 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 document quality regardless of the physical form or characteristic.

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 document (or documentation), and that is signed and dated by the originator and, as applicable, by approval personnel.

QUALITY ASSURANCE LEVEL I: Those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic 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. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of 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 completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

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

QUALITY ASSURANCE LEVEL III: Those activities and items not classified as QA Levels I or II.

QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document that describes the organization's Quality Assurance Program, the applicable QA requirements, and the instructions to implement and apply the QA requirements to activities.

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

RADIOACTIVE WASTE: High-Level Waste (HLW) and other radioactive materials that are received for emplacement in a geologic repository.

READINESS REVIEW: An independent, systematic documented review to determine and inform management of the readiness to advance from one phase, process, or activity into another. Readiness Reviews are used to coordinate many elements and provide attention to detail, to assure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of the project.

RECEIVING: Taking delivery of an item at a designated location.

RELIABILITY ANALYSIS: An analysis that estimates the reliability of a system or component.

REPAIR: The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

REPOSITORY: See Geologic Repository Operations Area.

RETRIEVAL: The act of intentionally removing radioactive waste from the underground location at which the waste had been emplaced previously for disposal.

REWORK: The process by which a nonconforming item or activity is made to conform to the original requirements by completion or correction utilizing existing approved procedures.

RIGHT OF ACCESS: The right of a purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or Quality Assurance audit.

SCENARIO: An account or sequence of a projected course of action or event.

SCIENTIFIC INVESTIGATION: Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural barriers or the man-made aspects of the geologic repository, including the overall design of the facilities and the waste package. This will include, but will not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository.

SCIENTIFIC NOTEBOOK: A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods, or both. These notebooks may be used in lieu of a technical procedure.

SERVICE: The performance of activities that include but are not limited to site characterization, design, fabrication, investigation, inspection, nondestructive examination, repair, or installation.

SITE: Location of the controlled area.

SITE CHARACTERIZATION: The program of exploration and research both in the laboratory and in the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the procedures under 10 CFR Part 60. Site characterization includes borings, surface excavations, excavation or exploratory shafts, limited subsurface lateral excavations and borings, and in situ testing at depth as needed to determine the suitability of the site for a geologic repository. It does not include preliminary borings and geophysical testing needed to decide whether or not site characterization should be undertaken.

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.

SUPPLIER: Any individual or organization under contract to provide items or services to the DOE Project Office, LLNL-YMP, or to other High-level Nuclear Waste Program participating organizations for support of project activities.

SURVEILLANCE: The act of monitoring or observing to verify whether or not an item or activity conforms to specified requirements.

TECHNICAL PROJECT OFFICER (TPO): The individual within each DOE Project Office's participating organization who has been assigned overall responsibility for the organization's scope of work as detailed in the Work Breakdown Structure (WBS) Dictionary.

TECHNICAL REVIEW: A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluation of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

TESTING: An element of verification that is used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

TRACEABILITY: The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

TRAINING: In-depth instruction provided to personnel to develop and demonstrate initial proficiency in the application of selected requirements, methods, and procedures, and to adapt to changes in technology, methods, or job responsibilities.

UNDERGROUND FACILITY: The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.

UNRESTRICTED AREA: Any area, access to which is not controlled for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

USE-AS-IS: A disposition that is permitted for a nonconforming item or service when it can be established that the item is satisfactory for its intended use.

VALIDATION (QA RECORDS): Validation is the act of reviewing a document or document package to ensure it is complete, authenticated, reproducible, and microfilmable.

VERIFICATION: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether or not items, processes, services, or documents conform to specified requirements.

WAIVER: Documented authorization to depart from specified requirements.

YMP PROJECT PARTICIPANTS: An all inclusive term used to describe (generically) the various organizations involved in the YMP Project. This term includes the YMPO, Participating Organizations, and NTS Support Contractors. These organizations are required to have a YMPO approved Quality Assurance Program Plan (QAPP) for the conduct of their activities.

YMP PROJECT PERSONNEL: All U.S. Department of Energy Participating Organizations, and NTS Support Contractor personnel involved in YMP Project activities.

YMP PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic quality assurance requirements that are applicable to the YMP Project.

YMP WORK BREAKDOWN STRUCTURE (WBS) DICTIONARY: A controlled document which establishes a product oriented framework for organizing and defining work to be accomplished.

YUCCA MOUNTAIN PROJECT OFFICE (YMPO): The organization to which the U.S. Department of Energy, Nevada Operations Office (DOE/NV), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors.

WASTE PACKAGE: The waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

University of California
Lawrence Livermore National Laboratory

NUCLEAR WASTE MANAGEMENT PROGRAM

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Page: 1 of 3

Subject: Appendix B - "DESIGN INPUTS"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

Design inputs include many characteristics and functions of an item or system. These inputs vary depending on the application; however, it is desirable to consider at least the following listed inputs as they apply to specific items or systems of the repository:

1. Basic functions of each structure, system, and component.

2. Performance requirements such as capacity rating and system output.

3. Codes, standards, and regulatory requirements including the applicable issue, agenda, or both.

4. Design conditions such as pressure, temperature, fluid chemistry, and voltage.

5. Loads such as seismic, wind, thermal, and dynamic.

6. Environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure.

7. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components.

8. Material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance.

9. Mechanical requirements such as vibration, stress, shock, and reaction forces.

10. Structural requirements covering such items as equipment foundations and pipe supports.

11. Hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities.

12. Chemistry requirements such as provisions for sampling and limitations on water chemistry.

13. Electrical requirements such as source of power, voltage, raceway requirements, electrical insulation, and motor requirements.

14. Layout and arrangement requirements.

15. Operational requirements under various conditions such as repository startup, normal repository operation, repository emergency operation, special or infrequent operation, system abnormal or emergency operation, repository decontamination, decommissioning, and dismantling.

16. Instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance. Other requirements such as the type of instrument, installed spares, range of measurement, and location of indication are included.

17. Access and administrative control requirements for repository security.

18. Redundancy, diversity, and separation requirements of structures, systems, and components.

19. Failure effects requirements of structures, systems, and components including a definition of those events and accidents that they must be designed to withstand.

20. Test requirements including pre-operational and subsequent periodic in-service tests and the conditions under which they will be performed.

21. Accessibility, maintenance, repair, and in-service inspection requirements for the repository including the conditions under which these will be performed.

22. Personnel requirements and limitations including the qualification and number of personnel available for repository operation, maintenance, testing, and inspection, and radiation exposures to the public and repository personnel.

23. Transportability requirements such as size and shipping weight, limitation, and Interstate Commerce Commission regulations.

24. Fire protection or resistance requirements.

25. Handling, storage, cleaning, and shipping requirements.

26. Other requirements to prevent undue risk to the health and safety of the public.

27. Materials, processes, parts, and equipment suitable for application.

28. Safety requirements for preventing injury to personnel including such items as radiation safety that restrict the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems.

29. Quality control and Quality Assurance requirements.

30. Reliability requirements of structures, systems, and components, including their interactions, which may impair functions that are important to safety.

31. Interface requirements between repository equipment and operation and maintenance personnel.

32. Requirements for criticality control and accountability of nuclear materials.

Subject:
APPENDIX C - "REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

1.0 GENERAL

The following are the requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. The requirements for the qualification of personnel performing nondestructive examination are specified in Appendix D.

2.0 FUNCTIONAL QUALIFICATIONS

Three levels of qualification are utilized depending on the complexity of the functions involved. The requirements for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional activities.

2.1 LEVEL I PERSONNEL CAPABILITIES

A Level I person is capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in user's written procedures.

2.2 LEVEL II PERSONNEL CAPABILITIES

A Level II person has all of the capabilities of a Level I person for the inspection or test category or class in question. Additionally, a Level II person has demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results.

2.3 LEVEL III PERSONNEL CAPABILITIES

A Level III person has all of the capabilities of a Level II person for the inspection, test category or class in question. In addition, the individual is capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this section.

3.0 EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience requirements are considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspection or test activity provide reasonable assurance that a person can competently perform a particular task. Other factors which demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency are documented.

3.1 LEVEL I EDUCATION AND EXPERIENCE REQUIREMENTS

- Two years of related experience in equivalent inspection or testing activities; or
- High school graduation and six months of related experience in equivalent inspection or testing activities; or
- Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.

3.2 LEVEL II EDUCATION AND EXPERIENCE REQUIREMENTS

- One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or
- High school graduation plus three years of related experience in equivalent inspection or testing activities; or
- Completion of college work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities; or
- Graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities.

3.3 LEVEL III EDUCATION AND EXPERIENCE REQUIREMENTS

- Six years satisfactory performance as a Level II in the corresponding inspection or test category or class; or
- High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection of testing activities with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with relevant Quality Assurance aspects of a nuclear facility; or

- Completion of college level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities, or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

- Graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear or comparable facility.

4.0 CERTIFICATION

4.1 QUALIFICATION REQUIREMENTS

The LLNL-YMP designates those inspection and test activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel. Further, the responsible organization establishes written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the established requirements are permitted to perform inspection and test activities. If a single inspection or test requires implementation by a team or a group, then personnel who do not meet the requirements of this section may be used in data-taking assignments or in repository or equipment operation, provided they are supervised or overseen by a qualified individual.

4.2 PERSONNEL SELECTION

Personnel selected to perform inspection and test activities have the experience or training commensurate with the scope, complexity, or special nature of the activities.

4.3 INDOCTRINATION

Provisions are made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, elements of the Quality Assurance Program Plan, and procedures that are to be employed.

4.4 TRAINING

The need for a formal training program are determined, and such training activities are conducted as required to qualify personnel who perform inspection and tests. On-the-job training is included also in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests. Training is provided with regard to those changes to the QAPP and implementing procedures that affect previous training.

4.5 DETERMINATION OF INITIAL CAPABILITY

The capabilities of a candidate for certification is initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration in accordance with the organization's personnel qualification procedure.

4.6 EVALUATION OF PERFORMANCE

The job performance of inspection and test personnel is reevaluated at periodic intervals not to exceed three years. Reevaluation includes evidence of continued satisfactory performance or redetermination of capability. If during this evaluation, or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with qualification requirements specified for the job, then that person is removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of one year is reevaluated and a redetermination of their capability made in accordance with the organization qualification procedure.

4.7 CERTIFICATION OF QUALIFICATION

The qualification of personnel is certified in writing in an appropriate form, including the following information:

- Employer's name.
- Identification of person being certified.
- Activities certified to perform.
- Basis used for certification that includes such factors as:
  - Education, experience, and training (when necessary).
  - Test results (where applicable).
  - Results of capability demonstration.
- Results of periodic evaluation.
- Results of physical examinations (when required).
- Signature of employer's designated representative who is responsible for such certification.
- Dates of certification and certification expiration.

4.8 PHYSICAL

The LLNL-YMP identifies any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.

Subject:
APPENDIX D - "REQUIREMENTS FOR THE QUALIFICATIONS OF NON-DESTRUCTIVE EXAMINATION PERSONNEL"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

This Appendix provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak-testing (LT), which is hereinafter referred to as nondestructive examination (NDE), to verify conformance to specified requirements.

1.0 CERTIFICATION

1.1 APPLICABLE DOCUMENTS

The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 edition, and its applicable supplements applies as requirements to NDE personnel covered by this section.

1.2 PROGRAM

The responsible organization establishes written procedures for the control and administration of NDE personnel training, examination, and certification.

1.3 CERTIFICATE OF QUALIFICATION

The qualification of personnel is certified in writing in an appropriate form, including the following information:

- o Employer's name.
- o Identification of person being certified.
- o Activities certified to perform.
- o Basis used for certification that includes such factors as;
  - Education, experience, and training (when necessary).
  - Test results (where applicable).
  - Results of capability demonstration.

- Results of periodic evaluation.
- Results of physical examinations (when required).
- Signature of employer's designated representative who is responsible for such certification.
- Dates of certification and certification expiration.

1.4 PHYSICAL

The LLNL-YMP identifies any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.

Subject: APPENDIX E - "LIST OF TYPICAL QA RECORDS"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

The following is a list of typical QA records. The LLNL-YMP retention period is defined as lifetime. (1) QA records will be submitted to the DOE Project Office Records Center by the LLNL-YMP.

1.0 SITE CHARACTERIZATION

- Surveys of the underground facility excavations, shafts, and boreholes referenced to readily identifiable surface features.
- Description of the materials encountered.
- Geologic maps and geologic cross section.
- Locations and amounts of seepage.
- Instrument locations, readings, analysis, and reports for in situ testing.
- Technical specifications.
- Sample extraction location maps.
- Site Characterization Report.
- Environmental Assessment.
- Peer review documentation.
- Test plans and procedures, and results thereof.
- Data reduction, evaluations, analyses, and reports for:
  - Geomorphology.
  - Stratigraphy.
  - Tectonics.

- Seismicity.
- Geoengineering.
- Hydrology.
- Geochemistry.
- Climatology and Meteorology.

o Environmental Impact Statement.

o Environmental Report.

2.0 DESIGN RECORDS

o Applicable codes and standards used in design.

o Design drawings.

o Design calculations and records of checks.

o Approved design change requests.

o Design deviations.

o Design reports.

o Design verification data.

o Design specifications and amendments.

o Safety analysis report.

o Stress reports for code items.

o Systems descriptions.

o Systems process and instrumentation diagrams.

o Technical analysis, evaluations, and reports.

3.0 PROCUREMENT RECORDS

o Procurement specifications.

o Purchase order including amendments.

4.0 MANUFACTURING RECORDS

o Applicable code data reports.

o As-built drawings and records (Note: As-built drawings and records shall correctly identify the installed condition of the item. The type of as-built drawings and records to be maintained shall be specified).

- o Certificate of compliance.
- o Eddy-current examination final results.
- o Electrical control verification tests results.
- o Ferrite test results.
- o Heat treatment records.
- o Liquid penetrant examination final results.
- o Location of weld filler material.
- o Magnetic particle examination final results.
- o Major defect repair records.
- o Material properties records.
- o Nonconformance reports.
- o Performance test procedure and results records.
- o Pipe and fitting location report.
- o Pressure test (hyrostatic or pneumatic).
- o Radiographs (for in-service inspection applications).
- o Radiograph review records.
- o Ultrasonic examination final results.
- o Welding procedures.

5.0 INSTALLATION AND CONSTRUCTION RECORDS

5.1 RECEIVING AND STORAGE - NONCONFORMANCE REPORTS

5.2 CIVIL

- o Concrete cylinder test reports and charts.
- o Concrete design mix reports.
- o Concrete placement records.
- o Inspection reports for channel pressure tests.
- o Material property reports on containment liner and accessories.
- o Material property reports on metal containment shell and accessories.

- o Material property reports on reinforcing steel.
- o Material property reports on reinforcing steel splice sleeve material.
- o Procedure for waste package vessel pressure proof test and leak rate tests and results.
- o Reports of high strength bolt torque testing.
- o Location and description of structural support systems.
- o Details, methods of emplacement, and location of seals used.

5.3 WELDING

- o Ferrite test results.
- o Heat treatment records.
- o Liquid penetrant test final results.
- o Material property records.
- o Magnetic particle test final results.
- o Major weld repair procedures and results.
- o Radiographs (for in-service inspection application).
- o Radiograph review records.
- o Weld location diagrams.
- o Weld procedures.

5.4 MECHANICAL

- o Cleaning procedures and results.
- o Code data reports.
- o Installed lifting and handling equipment procedures, inspection, and test data.
- o Lubrication procedures.
- o Material properties records.
- o Pipe and fitting location reports.
- o Pipe hanger and restraint data.
- o Pressure test results (hydrostatic or pneumatic).
- o Safety valve response test procedures.

5.5 ELECTRICAL AND INSTRUMENTATION AND CONTROL

- o Cable pulling tension data.
- o Cable separation data.
- o Cable splicing procedures.
- o Cable terminating procedures.
- o Certified cable test reports.
- o Relay test procedures.
- o Voltage breakdown test results.

5.6 GENERAL

- o As-built drawings and records.
- o Final inspection reports and releases.
- o Nonconformance reports.
- o Specifications and drawings.
- o Details of equipment, methods, progress, and sequence of work.
- o Construction problems.
- o Anomalous conditions encountered.

6.0 PRE-OPERATIONAL AND START-UP TEST RECORDS

- o Automatic emergency power source transfer procedures and results.
- o Final system adjustment data.
- o Pressure test results (hydrostatic or pneumatic).
- o Instrument alternating current (AC) systems and inverters test procedures and reports.
- o Offside power source energizing procedures and test reports.
- o Onsite emergency power source energizing procedure and test reports.
- o Pre-operational test procedures and results.

7.0 OPERATION RECORDS

- Records and drawing changes that identify repository design modifications made to systems and equipment described in the Final Safety Analysis Reports.
- Radioactive waste inventory, emplacement location, and transfer records.
- Offside environmental monitoring survey records.
- Waste shipment records.
- Repository radiation and contamination survey results.
- Radiation exposure records for individuals entering radiation control areas.
- Records of gaseous and liquid radioactive material released to the environment.
- Records of transient or operational cycles for those repository components designed for a limited number of transients or cycles.
- Training and qualification records for members of the repository operating staff.
- In-service inspection records.
- Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments.
- Meeting minutes of the Repository Nuclear Safety Committee and licensee nuclear review board.
- Surveillance activities, inspections, and calibrations required by the technical documents.
- Records of repository tests and experiments.
- Changes made to Operating Procedures.
- Sealed source leak-test results.
- Records of annual physical inventory of all sealed source material.
- Logs of repository operation.
- Records and logs of maintenance activities, inspection, repair, and replacement of principal items of structures, systems, and components.
- Operational, shift supervisor, and control-room logs.
- Licensee event reports.
- Fire protection records.

- Nonconformance reports.
- Repository equipment operations instructions.
- Security plan and procedures.
- Emergency plan and procedures.
- Quality Assurance and Quality Control Manuals.
- Records of activities required by the security plan and procedures.
- Applicable records noted in other section of this appendix for any modification or new construction applicable to structures, systems, or components.
- Evaluation of results of reportable safety concerns as required by regulations.
- Annual environmental operating report.
- Annual repository operating report.
- Location and description of dewatering systems.

Subject:
APPENDIX F - "REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

1.0 GENERAL

This Appendix provides requirements for the qualification of Lead Auditors. A Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. This Appendix also provides amplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training.

1.1 QUALIFICATION OF AUDITORS

The LLNL-YMP establishes the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of Quality Assurance programs. Personnel selected for Quality Assurance auditing assignments have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors either have or are given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions is developed by one or more of the methods listed below.

1.1.1 ORIENTATION

Orientation to provide a working knowledge and understanding of this document and the auditing organization's procedures for implementing audits and reporting results.

1.1.2 TRAINING PROGRAMS

Training programs to provide general and specialized training in audit performance. General training includes fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training includes methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing audit findings.

1.1.3 ON-THE-JOB-TRAINING

On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training includes planning, performing, reporting, and follow-up action involved in conductings audits.

1.2. QUALIFICATION OF LEAD AUDITORS

An individual meets the requirements listed below before being designated a Lead Auditor.

1.2.1 COMMUNICATIONS SKILLS

The prospective Lead Auditor has the capability to communicate effectively, both orally and in writing. These skills are attested to in writing by the Lead Auditor's employer.

1.2.2 TRAINING

Prospective Lead Auditors have training to the extent necessary to assure their competence in auditing skills. Training in the following areas is given based upon management evaluation of the particular needs of each prospective Lead Auditor:

- Knowledge and understanding of this document, 10 CFR Part 60, and other nuclear and/or DOE related codes, standards, regulations, and regulatory guides, as applicable to the LLNL-YMP.
- General structure of Quality Assurance programs and applicable elements as defined in this document.
- Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- 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.
- On-the-job training to include applicable elements of the audit program.

1.2.3 AUDIT PARTICIPATION

The prospective Lead Auditor has participated in a minimum of five Quality Assurance audits within a period of time not to exceed three years prior to the date of qualification. One of the audits is a nuclear Quality Assurance audit made within the year prior to qualification.

1.2.4 EXAMINATION

The prospective Lead Auditor passes an examination that evaluates his comprehension of and ability to apply the body of knowledge identified in Paragraph 1.2.2 above. The test may be oral, written, practical, or any combination of the three types. If any portion of the examination is oral, written documentation of the oral examination questions/content is maintained. The development and administration of the examination is in accordance with Paragraph 1.4 of this section.

1.3 MAINTENANCE OF QUALIFICATION

1.3.1 MAINTENANCE OF PROFICIENCY

Lead Auditors maintain their proficiency through regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; and participation in training programs. Based on annual assessment, management extends the qualification, requires retraining, or requires requalification. These evaluations are documented.

1.3.2 REQUALIFICATION

Lead Auditors who fail to maintain their proficiency for a period of two years or more require requalification. Requalification includes retraining in accordance with the requirements of Paragraph 1.2.2 of this section, reexamination in accordance with Paragraph 1.4.2, and participation as an Auditor in at least one nuclear Quality Assurance audit.

1.4 ADMINISTRATION

1.4.1 ORGANIZATIONAL RESPONSIBILITY

Training of auditors is the responsibility of the LLNL-YMP. The responsible auditing organization selects and assigns personnel who are independent of any direct responsibility for the performance of the activities that they will audit. The Lead Auditor, prior to commencing the audit, concurs that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

1.4.2 QUALIFICATION EXAMINATION

The development and administration of the examination for a Lead Auditor required by Paragraph 1.2.4 is the responsibility of the LLNL-YMP. The employer may delegate this activity to an independent certifying agency, but retains responsibility for conformance to this document of the examination and its administration. Integrity of the examination is maintained by the LLNL-YMP or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type or types and content of the examination or examinations is retained by the LLNL-YMP.

1.5 CERTIFICATION OF QUALIFICATION

Each Lead Auditor is certified by the LLNL-YMP as being qualified to lead audits. As a minimum, this certification shall document the following:

- Employer's name.
- Lead Auditor's name.
- Date of certification or recertification.
- Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.).
- Signature of LLNL-YMP designated representative who is responsible for such certification.

Subject: APPENDIX G - "REQUIREMENTS FOR QUALIFICATION OF EXISTING DATA NOT GENERATED UNDER A QA PROGRAM MEETING THEREQUIREMENTS OF 10 CFR 60, SUBPART G"

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

1.0 GENERAL

This appendix provides requirements for the qualification of existing data, that will be needed to support a license application, which have not been initially generated under a QA Program meeting the requirements of 10CFR60, Subpart G.

2.0 METHODS FOR QUALIFICATION OF EXISTING DATA

2.1 Four methods or combinations of methods are acceptable for the process of qualifying existing data:

a. The execution of the peer review process in accordance with the requirements of Appendix J of this QAPP.

b. The use of corroborating data which is defined as existing data used to support or substantiate other existing data. Inferences drawn to corroborate the existing data are 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 reviews for qualification.

c. The use of confirmatory testing which is defined as testing conducted under a 10CFR60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic mechanical) of an existing data base. One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. The amount of confirmatory testing required is dealt with on a case-by-case basis in the documented reviews for qualification.

d. Demonstrating that the existing data was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.

3.0 SELECTION AND DOCUMENTATION OF QUALIFICATION METHODOLOGY

3.1 When the methods indicated in Sections 2.1b, 2.1c, and 2.1d are utilized to qualify existing data, a technical review is conducted to support the quality of the data. Additional confidence/credibility can be achieved when a combination of methods is used.

3.2 Documentation of the decision process provides an auditable trail of all factors used in arriving at the choice of the qualification method(s), and the decision as to the qualification of the existing data. The level of confidence in the existing data is commensurate with the intended use of the data. Attributes which are considered in the qualification process are:

A. Qualifications of personnel or organizations generating the data are comparable to qualifications requirements of personnel generating similar data under the LLNL-YMP QAPP.

B. The technical adequacy of equipment and procedures used to collect and analyze the data.

C. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).

D. The environmental conditions under which the data were obtained if germane to the quality of data.

E. The quality and reliability of the measurement control program under which the data were generated.

F. The extent to which conditions under which the data were generated may partially meet Subpart G.

G. Prior uses of the data and associated verification processes.

H. Prior peer or other professional reviews of the data and their results.

I. Extent and reliability of the documentation associated with the data.

J. Extent and quality of corroborating data or confirmatory testing results.

K. The degree to which independent audits of the process that generated the data were conducted.

L. The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.

M. Replication of test results

Note: Additional guidance related to this subject can be found in NUREG-1298 "QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES" (February, 1988).

Subject: APPENDIX H - REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE APPLICATION

Approved:

Approved by: 12/22/88 Date
Yucca Mountain Project Leader

Approved by: 12/22/88 Date
Quality Assurance Manager

1.0 OBJECTIVES

The purpose of this appendix is to establish requirements for the development, management, control, and documentation of software used to support the Yucca Mountain Project (YMP). The software requirements are intended to ensure software quality and to provide part of the basis on which YMP will evaluate the soundness of the software used.

This appendix supplements 033-YMP-R 3 of this QAPP and is used in conjunction with that section as applicable.

2.0 APPLICABILITY

The requirements set forth in this appendix apply to computer software used to produce or manipulate data that is used directly in site-characterization and performance assessment analyses and in the design, analysis, and operation of repository structures, systems, and components.

Written procedures are established that assure the requirements of this appendix are implemented in a consistent and systematic manner. The extent to which these requirements apply are defined in the software QA plan and is related to the nature, complexity, and importance of the software applications.

3.0 TERMS AND DEFINITIONS

Terms and definitions used in this appendix for software are defined below:

Baseline: As used for computer software: (1) The stage of computer software at a completed and reviewed phase of the software lifecycle; (2) Approved documentation generated within or as a result of completing a phase of the software life cycle.

Computer Code: A set of computer instructions for performing the operations specified in a numerical model.

Configuration Management: As used for computer software: (1) A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration.

Computer Code Verification: Assurance that a computer code correctly performs the operating specified in a numerical model (NUREG-0856). Usually accomplished by comparing code results to (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).

Discrepancy: Condition adverse to quality; reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances.

Life Cycle: See software development life cycle.

Model: A representation of a physical system, based on scientific principles and laws, that transforms a set of input information or data into another set of output information or data.

Model Validation: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing code results to (1) physical data, or (2) a verified and validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for model validation if it is the only available means for validating a model.

Numerical Method: A procedure for solving a problem primarily using numerical methods.

Numerical Model: A representation of a process or system using numerical methods.

Software: A set of computer operations specified in any programming language that can be translated unambiguously into machine language. (Operations specified in machine language are also software).

Software-development Life Cycle: A method of project planning and documentation for the development of a software product. Life cycle allows optimal traceability regarding the goals, restrictions, decisions made, and current progress of a code.

4.0 SOFTWARE VERIFICATION AND MODEL VALIDATION

Software verification and model validation activities are performed as described in the software QA plan.

4.1 SOFTWARE VERIFICATION

Verification plans employ methods such as inspections, analyses, demonstrations, and tests to assure that the software adequately and correctly performs all intended functions and that the software does not perform any function that, either by itself or in combination with other functions, can degrade the entire system.

Verification activities are performed according to written procedures relative to specific hardware configurations. The amount of verification activity is determined by the type and complexity of the software. The results of verification are documented in accordance with Section 6.0 and reviewed in accordance with Section 7.0 of this appendix.

4.2 MODEL VALIDATION

Model validation activities are performed according to written procedures to demonstrate that models embodied in computer software are correct representations of the process or system for which they are intended. This is accomplished by comparing software results against verified and traceable data obtained form laboratory experiments, field experiments or observations, or in-situ testing. Specific sets of data used in the validation process are identified, and justification is documented for their use. When data are not available from the sources mentioned above, alternative approaches may be used and are documented. Alternative approaches may include peer review and comparisons with the results of similar analyses performed with verified software. The results of the model validation are documented according to Section 6.0 and reviewed according to Section 7.0.

5.0 SOFTWARE CONFIGURATION MANAGEMENT

Software configuration management system is established to assure positive identification of software and control of all software baseline changes.

5.1 CONFIGURATION IDENTIFICATION

Software configuration baseline items are identified at the appropriate phase of each software lifecycle. Approved changes to a baseline are added to the baseline as updates. A baseline plus updates specify the most recent software configuration. A labeling system for configuration items is implemented that:

- Uniquely identifies each software configuration item or version identifier.
- Identifies changes to software configuration items by revision identifiers.
- Facilitates placement of the software configuration item in a relationship with other configuration item.

5.2 CONFIGURATION CHANGE CONTROL

Changes to software configuration items are formally controlled and documented. This documentation contains a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baseline and software configuration items. Assurance is provided that only authorized changes are made to software baselines and software configuration items.

5.3 CONFIGURATION STATUS ACCOUNTING

The information that is needed to manage software configuration items is recorded and reported. The information includes the approved configuration identification, the status of formal proposals for changes to software configuration items, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.

6.0 DOCUMENTATION

Documentation is required as defined by the software QA plan. The following is acceptable documentation of computer software used on the Yucca Mountain Project. Additional documentation may also be identified in the software QA plan.

6.1 SOFTWARE LIFE CYCLE DOCUMENTATION

6.1.1 SOFTWARE LIFECYCLE REQUIREMENTS SPECIFICATION

Software requirements documentation outlines the requirements that the software must fulfill. A specific capability of software is called a requirement only if its achievement can be verified by a prescribed method. The requirements address the following as applicable to the software application:

- Functionally - the functions the software are to perform.
- Performance - the time-related issues of software operation such as speed, recovery time, response time, etc.
- Design constraints imposed on implementation - any element that will restrict design options.
- Attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.
- External Interface - interactions with other participants, hardware, and other software.

6.1.2 SOFTWARE LIFECYCLE DESIGN DOCUMENTATION

Software design documentation addresses the following as applicable to the software application:

- o A description of the major components of the software design as they relate to the requirements of the software requirements specification.
- o A technical description of the software with respect to control flow, data flow, control logic, and data structure.
- o The description of the allowable and tolerable ranges for inputs and outputs.
- o The design described in a manner that is easily traceable to the software requirements.
- o A description of life cycle verification activities.

6.1.3 SOFTWARE LIFECYCLE IMPLEMENTATION DOCUMENTATION

Software implementation documentation addresses the following as applicable:

- o Source code listing.
- o Revised requirements documents.
- o Revised design documents.

Any design changes made to the requirements and design phase document are assessed as to the impact to the design. The revised requirements and design phase documents are reviewed at the same review level as the original documents.

6.1.4 SOFTWARE LIFECYCLE TESTING DOCUMENTATION

Life cycle testing activities are documented. Software testing documentation includes a plan that describes the tasks and criteria for accomplishing the verification of the software in this phase. The documentation also specifies the hardware and system software configuration(s) for which the software is designed. In those cases where testing is used to ensure that requirements were met in the software design, test documentation provides traceability from requirements to design as implemented in the code. This documentation also includes a report on the results of the execution of the life cycle verification activities. This report includes the results of all reviews, audits and tests, and a summary of the status of the software.

6.2 MANDATORY DOCUMENTATION

The following mandatory documentation (consistent with NUREG-0856) is provided to meet the requirements of Section 3.2 of this QAPP, as applicable:

- o Software Summary
- o Mathematical and Numerical Models

- o User's Manual
- o Code Assessment and Support
- o Continuing Documentation and Code Listing

7.0 REVIEWS

Documentation produced during software development, acquisition, implementation, testing, and use is subject to appropriate reviews as described in the software QA plan.

7.1 SOFTWARE LIFE CYCLE REVIEWS

Reviews of software life cycle activities are performed for each life cycle phase completed. The procedures used for reviews identify the reviewers and their responsibilities.

The documentation for all reviews contains a record of review comments and the personnel responsible for comment resolution. After review comments are resolved, the approved documents are updated and placed under configuration management.

The following reviews are performed as applicable:

7.1.1 SOFTWARE LIFECYCLE REQUIREMENTS REVIEW

The review of software requirements is performed at the completion of the software requirements documentation. This review assures that the requirements are complete, verifiable and consistent. The review assures that there is sufficient detail available to facilitate definition of the software design or acquisition.

7.1.2 SOFTWARE LIFECYCLE DESIGN REVIEW

The software design review is held at the completion of the software design documentation. This review evaluates the technical adequacy of the design approach and assures that the design satisfies all the requirements in the requirements documentation. The complexity of the software design may require the performance of multiple design reviews.

7.1.3 SOFTWARE LIFECYCLE IMPLEMENTATION REVIEW

The software implementation review is an evaluation of the completed software lifecycle requirements, design, and implementation processes.

7.1.4 SOFTWARE LIFECYCLE TESTING REVIEW

The software testing review is an evaluation of the adequacy of completed software lifecycle verification activities.

7.2 MANDATORY REVIEWS

Mandatory documents (consistent with Section 6.2 of this appendix) are reviewed and documented in accordance with review procedures established in the software QA plan.

The adequacy of verification activities is reviewed. Also the adequacy of model-validation activities is reviewed.

8.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

Formal procedures are established for software discrepancy reporting and corrective action. This discrepancy reporting system is integrated with the configuration management system to assure formal processing of discrepancy resolutions.

Software discrepancy procedures assures that, as a minimum:

- Defects are documented and evaluated for possible corrective action.
- Defects are assessed for impact on previous applications.
- Corrections are reviewed and approved before changes to software configuration items are entered into baselines.
- Preventive and corrective actions provide for appropriate notification of organizations to which controlled copies have been distributed.

9.0 MEDIA CONTROL AND SECURITY

Physical media containing the images of software are physically protected to prevent their inadvertent damage, degradation, or loss.

10.0 SOFTWARE ACQUISITION, PROCUREMENT, AND TRANSFER

Procedures are established for controlling the acquisition or procurement of computer software from an outside organization and for the transfer of computer software to an outside organization.

Software requests by participating organizations includes appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QA plan. Requirements not satisfied at the time when the software is received, are completed by the organization in the appropriate phase of the applicable software life cycle. For those requirements that are not satisfied, the reasons are documented for distribution to the users.

Configuration management requirements apply to acquired or procured software using the product originally received as the initial baseline. Configuration management records document any conversions, modifications, configuration changes, or additional software required to make the software functional.

11.0 SOFTWARE QUALITY ASSURANCE PLAN

A software QA plan is prepared that describes the software development, acquisition and applications undertaken. Individual software QA plans may additionally be prepared for specific software products. The software QA plan identifies the:

- o Organizational responsibilities for the management and control of software.
- o Software products to which the software QA plan applies.
- o Criteria for meeting the requirements set forth in this appendix to the applicable software.
- o Software life-cycle model used.
- o Required documentation.
- o Software configuration-management system.
- o Verification and validation methodologies.
- o Discrepancy reporting and corrective actions.
- o Software review procedures.

Software lifecycle management is a requirement, and the software QA Plan presents the specific software lifecycle controls. A generic lifecycle that presents the conceptual lifecycle management steps is presented in Section 11.1.

11.1 SOFTWARE LIFECYCLE

A software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner is implemented. The relative emphasis placed on the phases of the software life cycle will depend on the nature, complexity, importance, and intended applications of the software.

The following lifecycle elements apply as appropriate for the specific lifecycle model defined, interpreted, and described in the software QA plan.

11.1.1 LIFECYCLE REQUIREMENTS PHASE

During this phase, requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the completed software are specified, documented, and reviewed. These requirements include the following characteristics:

- o A format and language that is understood by the programming organization and the user.
- o Enough detail to allow for objective verification.

- Adequate definition to provide for the response of the software to the identified input data.

- The information necessary to design the software without prescribing the software design itself.

11.1.2 LIFECYCLE DESIGN PHASE

During the design phase, a software design based on the requirements is specified, documented, and systematically reviewed. The design specifies the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation.

Verification activities during this phase consist of, but are not limited to:

- The planning for design-based test cases.

- The review and analysis of the software design.

- The verification of the software design.

11.1.3 LIFECYCLE IMPLEMENTATION PHASE

During this phase, the design is translated into a programming language and the implemented software is debugged. Only minor, if any, design issues are resolved at this phase.

Verification activities during this phase consist of:

The possible modification of test cases necessary due to design changes made during coding.

The examination of source code listings to assure adherence to coding standards and conventions.

11.1.4 LIFECYCLE TESTING PHASE

The testing phase consists of verification activities. Software verification will be essentially completed during this phase. The verification activities will include:

- Execution of the test cases and evaluation of the results.

- Evaluation of the completed software to assure adherence to the requirements.

- The preparation of a report describing the results of software verification.

Model validation is conducted in accordance with Section 4.2 of this appendix. Because model validation is application dependent, model validation may not be completed at this stage.

11.1.5 LIFECYCLE INSTALLATION AND CHECKOUT PHASE

During this phase, the software may become part of a system incorporating other software components, the hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.

Testing activities during this phase consist of the execution of test cases for installation and integration. Test cases from earlier phases are used for installation testing.

11.1.6 LIFECYCLE OPERATIONS AND MAINTENANCE PHASE

During the operations and maintenance phase, the software has been approved for operational use. Maintenance activity consists of identification of latent errors and notification of users. Further activities may consist of maintenance of the software to remove latent errors (corrective maintenance), response to new or revised requirements (perfective maintenance), or adaptation of the software to changes in the software environment (adaptive maintenance). Software modifications are approved, documented, tested, and controlled in accordance with software configuration management requirements.

12.0 SOFTWARE APPLICATIONS

Procedures are established for controlling the application of software that perform technical calculations in support of site-characterization and performance assessment analyses and for the design, analysis, and operation of repository structures, system, and components. These software applications are reviewed and approved to assure that the software selected is applicable to the problem being solved and that input data assumptions are valid and traceable.

Procedures are established for documenting software applications that perform technical calculations to ensure that these applications and the results of these applications can be independently reproduced.

Procedures are established for reviewing these applications to provide reasonable assurance that the software used is appropriate for the intended application and that the results produced are accurate. Documentation appropriate for a given application or analysis includes the computer code, the input data, the assumptions or approximations employed to develop the input data, and appropriate user documentation for performing the application or analysis.

Subject: APPENDIX I - REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS AND ACTIVITIES SUBJECT TO QUALITY ASSURANCE REQUIREMENTS

Approved:

Approved by: _____ 12/22/88 Date
Yucca Mountain Project Leader

Approved by: _____ Date
Quality Assurance Manager

1.0 GENERAL

This Appendix provides requirements for the identification of items important to safety and the identification of items and activities important to waste isolation. These items and activities are subject to the highest quality assurance level (QA Level I) of this QAPP and are listed on a "Q-List".

2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste. In order to obtain a license for receipt and possession of radioactive material at the geologic repository, it must be demonstrated that the repository system will function as required to protect health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and long-term isolation of waste following permanent closure of the geologic repository. The QA Level I requirements of this QAPP specify the QA Program for these items and related activities important to safety and/or waste isolation to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

2.1 QUALITY ASSURANCE CRITERIA FOR THE Q-LIST AND QUALITY ACTIVITIES LIST

The QA Level I requirements of this QAPP apply to items and activities important to saftey and/or waste isolation. As derived form 10 CFR Part 60 (60.152), this QA program is based on the 18 criteria of 10 CFR Part 50 Appendix B. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria are supplemented as necessary to meet the specific requirements of the repository program. In addition to the QA Level I requirements of this QAPP items important to safety and the waste package are subject to the design criteria of 10 CFR 60.131(b) and 60.135 respectively.

2.2 CRITERIA FOR NON-Q-LIST ITEMS

Certain items that are not important to safety and/or waste isolation are also addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements. While these items are not subject to the QA Level I requirements of this QAPP, QA Level II requirements are applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), Paragraph 5.1(b)

2.3 DATA NOT COLLECTED UNDER A 10 CFR 60 SUBPART G QA PROGRAM

All data collection, interpretations, analyses, and other work to be used to support findings important to safety and/or waste isolation in the licensing process are technically and procedurally defensible. "Existing data" are qualified in accordance with the requirements of Appendix G of this QAPP. In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10CFR 60 Subpart G QA Program. Supporting documentation of these materials (e.g. the technical specifications and QA records) are reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they are "qualified" for use to assure they will perform their intended function.

3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY

Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems and components are on the Q-list as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designate function.

3.1 Probabilistic Risk Analysis (PRA) is used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the HLW program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions are used. Conservative assumptions include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

3.2 Operator actions or errors which could initiate accidents are identified in PRAs or other analysis. These are controlled to minimize the probability of occurrence. Other activities which are subject to QA Level I requirements, such as designing, inspecting, and purchasing will not be identified in PRAs but are controlled in accordance with QA Level I requirements.

3.3 PRAs utilize the following techniques:

3.3.1 System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques which may be used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

An event-tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events is compiled to assure that the event trees properly depict all important sequences.

A fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident is examined to determine how failures of components within that system could cause the failure of the entire system.

If failure of a mitigating system could contribute to an off-site dose, individual components within the mitigating system are reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

3.3.2 Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the HLW facility. The energy, magnitude, and timing of radiological releases resulting form various accidents are considered in this analysis.

3.3.3 Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

Additional guidance related to the assessment of pre-closure accidents can be found in NUREG 1318, (April, 1988), paragraph 5.2(a).

3.4 REDUNDANCY

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system does not comprise or prevent the associated safety function from being performed. For the high-level waste repository, 10 CFR 60 [60.131(b) (5) (ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety are also on the Q-list.

3.5 USE OF PREVIOUSLY ESTABLISHED GUIDELINES AND STANDARDS

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program.

For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the Q-list. While some of these guidelines and standards may not be directly applicable to a geologic repository, they are considered to the extent practicable, to eliminate the need to develop new approaches.

3.6 RETRIEVAL

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations are conducted at that time, to identify Q-list items.

4.0 IDENTIFICATION OF ITEMS AND ACTIVITIES IMPORTANT TO WASTE ISOLATION

The term "important to waste isolation" refers to engineered natural barriers that will be relied on to meet the containment and isolation performance objectives of 10 CFR 60 Subpart E. Four of the performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:

- ground water travel time
- waste package containment period
- maximum yearly release rate from the engineered barrier system
- the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the EPA standard in 40 CFR Part 191).

The items and activities important to waste isolation include:

- Components of the engineered barrier system relied on to meet the performance objectives.
- Elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives.
- Activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers.
- Activities in the preclosure phase that could effect post-closure performance.

The broad performance objectives for waste isolation provide some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments are conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60.

The initial allocation of performance will provide a basis for determining what site characterization testing will be needed. The initial allocations of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities are controlled in accordance with the QA Level I requirements of this QAPP. However, there may be cases where it is known that data are not needed for performance requirements of this QAPP and therefore would not have to be performed in scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed in accordance with the QA Level I requirements of this QAPP.

Note: Additional guidance related to this subject can be found in NUREG-1318, "TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS" (April, 1988).

Subject:

APPENDIX J - REQUIRMENTS FOR PEER REVIEW

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

1.0 GENERAL

This appendix provides the requirements regarding the applicability of peer reviews, the structure of peer review groups, acceptability of peers, and the conduct and documentation of peer reviews.

2.0 APPLICABILITY OF PEER REVIEW

2.1 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.

2.2 In general, the following conditions are indicative of situations in which a peer review is considered:

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--such as, data may not have been collected in conformance with an established QA program.

2.3 A peer review is 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.

3.0 STRUCTURE OF PEER REVIEW GROUP

The number of peers comprising a peer review group varies commensurate with the following:

A. The complexity of the work to be reviewed.

B. Its importance to establishing that safety or waste isolation performance goals are met.

C. The number of technical disciplines involved.

D. The degree to which uncertainties in the data or technical approach exist.

E. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

3.2 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.

4.0 ACCEPTABILITY OF PEERS

4.1 The technical qualification of the peer reviewers, in their review areas, is at least equivalent 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.

4.2 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. funding 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.

5.0 PEER REVIEW PROCESS

5.1 Since the peer review process may vary from case to case, a peer review plan is prepared prior to initiating a peer review. The peer review plan describes the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce a peer review report.

5.2 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 application.

f. Accuracy of calculations.

g. Adequacy of requirements and criteria.

h. Validity of conclusions.

Documentation is prepared to indicate the results of meetings, deliberations and activities of the peer review process.

6.0 PEER REVIEW REPORT

6.1 A report documenting the results of the peer review is prepared and issued under the direction of the peer review group chairperson and is signed by each peer review group member. The peer review report includes the following:

a. A clear description of the work or issue that was peer reviewed.

b. Conclusions reached by the peer review process.

c. Individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate.

d. Listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

Note: Additional guidance related to his subject can be found in NUREG-1297, "PEER REVIEW FOR HIGH LEVEL NUCLEAR WASTE REPOSITORIES" (FEBRUARY, 1988).

Subject: APPENDIX K - FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLAN

Approved:

Approved by: 12/20/88 Date
Yucca Mountain Project Leader

Approved by: 12/16/88 Date
Quality Assurance Manager

1.0 PURPOSE AND OBJECTIVES OF STUDIES

1.1 Describe the information that will be obtained in the study. Briefly discuss how this information will be used; and

1.2 Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

2.0 RATIONAL FOR SELECTED STUDY

2.1 Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and

2.2 Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference if available, reports which evaluate alternatives considered.

2.3 Describe the constraints that exist for the study, and explain how these contraints affect selection of test methods and analytical approaches. Factors to be considered include:

a) Potential impacts on the site from testing;

b) Whether the study needs to simulate repository conditions;

c) Required accuracy and precision of parameters to be measured with test instrumentation;

d) Limits of analytical methods that will use the information from the tests;

e) Capability of analytical methods to support the study;

f) Time required versus time available to complete the study;

g) The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;

h) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and

i) Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information).

3.0 DESCRIPTION OF TESTS AND ANALYSES

3.1 Since studies are comprised of tests and analyses, provide for each type of test:

a) Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESF elements, repository layout, stratigraphic units, depth, and test location);

b) Summarize the test methods. Reference any standard procedures (e.g., ASTM, APT) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level I. Reference the applicable specific QA requirements that will be applied to the test;

c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;

d) Indicate the range of expected results of the test and the basis for those expected results;

e) List the equipment required for the test and describe briefly any such equipment that is special;

f) Describe techniques to be used for data reduction and analysis of the results;

g) Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;

h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and

i) Relationship of the test to the set performance goals and confidence levels.

3.2 For each type of analysis:

a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

b) Describe the methods of analysis including any analytical expressions and numerical models that will be employed;

c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA Level I. Reference the applicable QA requirements.

d) Identify the data input requirements of the analysis;

e) Describe the expected output and accuracy of this analysis; and

f) Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

4.0 APPLICATION OF RESULTS

4.1 Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies);

4.2 For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;

4.3 For design uses, refer to, or describe where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineering barriers, and shafts and borehole seals); and

4.4 For characterization uses, refer to, or describe where the information from the study described above will be used in planning other characterization activities.

5.0 SCHEDULE AND MILESTONES

5.1 Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;

5.2 Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study, and

5.3 Dates for activities or milestones including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5 of the SCP.