LOS ALAMOS NATIONAL LABORATORY QUALITY ASSURANCE PROGRAM PLAN FOR THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT

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Los Alamos National Laboratory is committed to the highest standards of technical excellence. Well-planned programs for maintaining and improving quality are essential elements of this commitment. This Quality Assurance Program Plan has been prepared as an explicit statement of this commitment as it applies to our work in support of the Yucca Mountain Site Characterization Project. Each person working in support of the Project shall be indoctrinated in the requirements of this Plan; activities shall be planned, implemented, and maintained as it requires; and all work shall follow its implementing procedures.

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ACRONYMS

AP	—	Administrative Procedure
DOE	—	Department of Energy
DP	—	Detailed Technical Procedure
EES	—	Earth and Environmental Sciences Division
HLW	—	High-Level Waste
LANL	—	Los Alamos National Laboratory
NBS	—	National Bureau of Standards
NCR	—	Nonconformance Report
NRC	—	Nuclear Regulatory Commission
OCRWM	—	Office of Civilian Radioactive Waste Management
PI	—	Principal Investigator
PMP	—	Project Management Plan
PQM	—	Project Quality Manager
PRA	—	Probabilistic Risk Assessment
QA	—	Quality Assurance
QADD	—	Quality Assurance Division Director
QAL	—	Quality Assurance Liaison
QALA	—	Quality Assurance Level Assignment
QAO	—	Quality Assurance Officer
QAP	—	Quality Assurance Plan
QAPL	—	Quality Assurance Project Leader
QAPP	—	Quality Assurance Program Plan
QAS	—	Quality Assurance Support
QP	—	Quality Implementing Procedure
RPC	—	Records Processing Center
SQAP	—	Software Quality Assurance Plan
TPO	—	Technical Project Officer
WBS	—	Work Breakdown Structure
YMP	—	Yucca Mountain Site Characterization Project (formerly NNWSI)

1.0 ORGANIZATION

1.1 Management

Management responsibility for the Yucca Mountain Site Characterization Project (YMP) at Los Alamos National Labaoratory (LANL) is assigned to group EES-13. The Project Office uses a Work Breakdown Structure (WBS) to describe and relate the work of the Project. Individual WBS elements are assigned to the Project participants, which include LANL. EES-13 plans and manages the LANL efforts required to support work assignments made by the Project Office. The EES-13 Group Leader shall be YMP Technical Project Officer (TPO). Any delegation of this responsibility by the EES-13 Group Leader shall be in writing.

1.2 Quality Assurance Program

A Quality Assurance (QA) Program shall be established and shall be described in a Quality Assurance Program Plan (QAPP). Major changes may be made to the QAPP. However, these changes shall be subject to the Project Office's approval. Implementation of the requirements of the QAPP shall be accomplished through quality implementing procedures (QPs). The QPs shall ensure that standard practice and objective evidence (records) attesting to compliance with the requirements result from their use.

1.3 Quality Assurance Organization

The overall LANL YMP organization is described in Figure 1-1. Duties and responsibilities of all personnel shall be described in position descriptions prepared by supervisors. The position description shall also document the minimum education and experience required for each position. QA responsibilities follow.

1.3.1 Technical Project Officer

The TPO shall be responsible for the development of the overall quality program. The TPO shall approve the QAPP, QPs, implementing technical and administrative procedures, and technical information products.

1.3.2 Project Leaders

The Project Leaders are responsible for understanding and implementing the LANL YMP QA Program in their areas of responsibility, as applicable, on a day-to-day basis. This shall include developing quality, technical, or administrative procedures as appropriate; participating in audits and surveillances; reviewing and approving technical information products in accordance with the appropriate procedures; and ensuring that support staff is trained to the appropriate QP and technical or administrative procedures.

1.3.3 Coordinators

Coordinators are responsible for understanding and implementing the LANL YMP QA Program in their areas of responsibility, as applicable, on a day-to-day basis. This shall include developing quality, technical, or administrative procedures as appropriate; participating in audits and surveillances; and ensuring that support staff is trained to the appropriate QP and technical or administrative procedures.

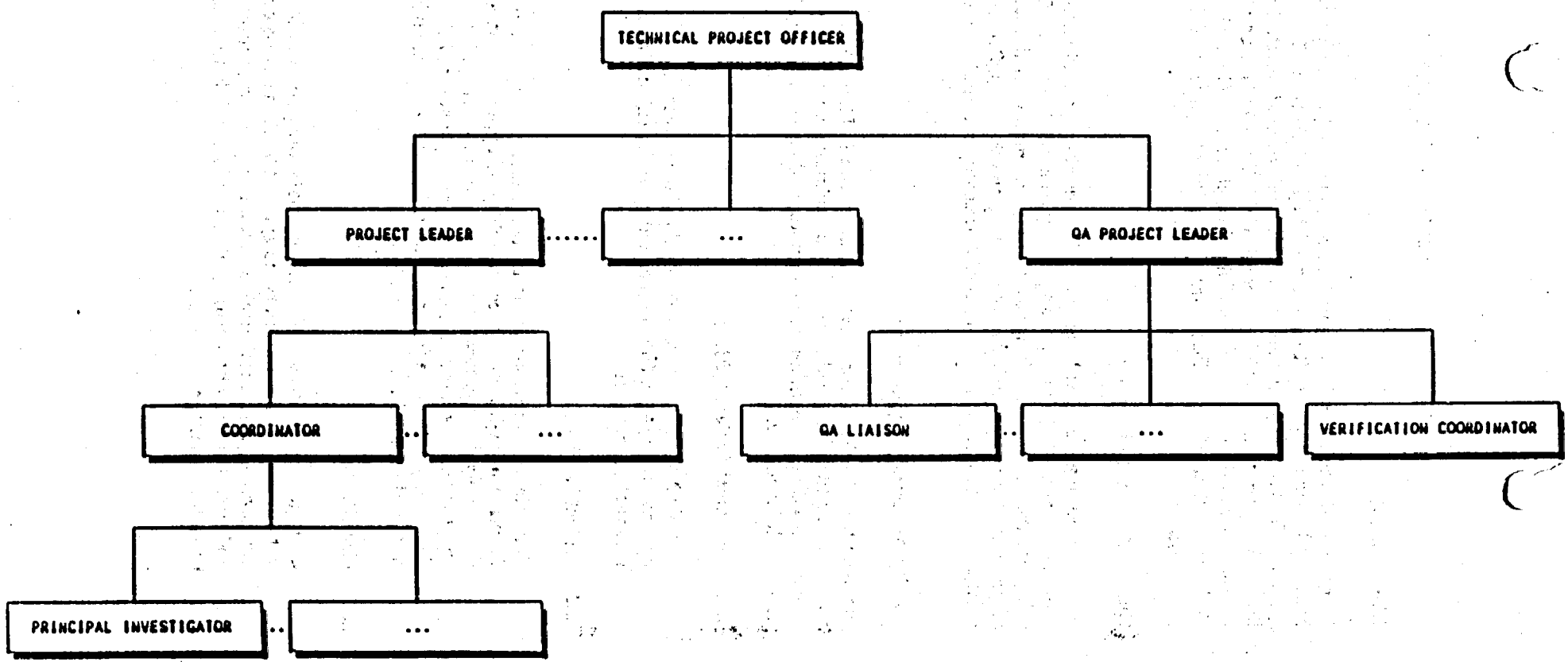

Figure 1-1. YMP Organization at LANL.

1.3.4 Principal Investigators

Principal Investigators (PIs) are responsible for understanding and implementing the LANL YMP QA Program for scientific investigation activities, as applicable, on a day-to-day basis. This shall include developing quality and technical procedures; participating in audits and surveillances; and ensuring that support staff is trained to the appropriate QPs and technical procedures.

1.3.5 Dedicated Quality Assurance Positions

The following positions are assigned QA responsibilities only.

1.3.5.1 Quality Assurance Project Leader

Responsibility for the development of a Quality Assurance Program Plan (QAPP) and implementation of the QAPP shall be assigned to an EES-13 staff member who shall be titled QA Project Leader (QAPL). The QAPL shall approve the QAPP and the QPs. The QAPL shall report administratively to the TPO. Verification of the overall quality program shall be assigned to a subcontractor. The verification subcontractor shall report to the QAPL. The verification subcontractor shall survey and audit the YMP work at LANL. The verification subcontractor shall review the QPs proposed by LANL. Additional duties in connection with administration of the QA Program may be assigned to a subcontractor at the discretion of the QAPL. Such assignments shall be documented.

The QAPL is authorized to resolve disputes regarding the interpretation of quality requirements or their applicability. Disputes that cannot be satisfactorily resolved by the QAPL shall be decided by the TPO. Decisions by the TPO may be appealed by the QAPL to the LANL Quality Assurance Officer (QAO) or the YMP QA Division Director (QADD). QA-related decisions by the LANL QAO or the YMP QADD are final.

1.3.5.2 Quality Assurance Liaison

LANL organizational units (divisions or groups) and subcontractors with twelve or more full-time-equivalent employees assigned to the YMP shall employ a Quality Assurance Liaison (QAL). Group EES-13 shall employ a QAL at-large who shall serve all smaller units. The QAL shall facilitate implementation of the quality assurance program within the unit. The QAL shall report programmatically to the QAPL. Personnel assigned as QALs shall not have other duties or responsibilities that prevent or conflict with those in connection with their QAL assignment. Additional duties and responsibilities as well as the education and experience required of personnel assigned as QALs shall be described in position descriptions prepared by the QAPL.

1.3.5.3 Verification Coordinator

The Verification Coordinator shall report directly to the QAPL. The Coordinator shall be part of the subcontractor verification organization and be fully responsible for directing the internal audit and survey program and ensuring that the assigned audit staff is trained to the appropriate LANL implementing procedures.

1.4 Achievement, Maintenance, and Verification of Quality

Quality shall be achieved and maintained by those performing the actual work, i.e., the line organizations. Quality achievement shall be verified by persons not directly responsible for performing

the work, i.e., the QA verification staff. Allegations of inadequate quality or disputes over quality requirement conformance shall be resolved in accordance with the LANL implementing procedure for quality conflict resolution.

1.5 Interface Between Participant Organizations

Interfaces are defined as exchanges or shared technical requirements of work and organizational liaison with ongoing work. When more than one participant organization is involved in activities affecting quality, the responsible line organization shall clearly define the interface in accordance with the LANL implementing procedure. This interface between LANL and other participants shall be through the TPO. All interfaces between LANL and the Project Office are through the TPO as defined in the implementing procedures.

For internal interfaces at LANL, this document describes the various duties and responsibilities of the overall LANL YMP organization to effectively manage the LANL YMP. No further action or implementation procedures are necessary. Interfaces between LANL and its subcontractors shall be defined in procurement documents resulting from the use of the procurement implementation procedures.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Basic Requirements of the LANL YMP Quality Assurance Program

LANL's QA Program consists of the LANL QAPP and QPs. The LANL QAPP and QPs will be prepared by the LANL YMP QA and technical staff to comply with the most current revision of the YMP Quality Assurance Plan (QAP). The QAPP will be submitted to the QADD for review prior to implementation. When the LANL QAPP is submitted to the Project Office for review, a checklist based on the YMP QAP is included. After the QAPP is reviewed by the QADD and after comments and revisions are resolved, the documents will be approved by the PQM; the approved QAPP will be issued. After internal LANL review, comment, and approval (pursuant to Section 6 of this QAPP), QPs will be issued for use.

Changes to the LANL YMP QAPP may be proposed by any LANL YMP staff by submitting the proposal, in writing, to the LANL YMP QAPL. Proposed changes will be evaluated by the QAPL, to ensure compliance with YMP quality requirements, and will either be approved or disapproved. Approved changes will be submitted to the TPO for review and either be approved or disapproved. Disapproved changes will be returned to the originator with a description of why the proposed change was disapproved. If the TPO approves the proposed change, the change will be submitted to the Project Office QADD for review. If the QADD approves the change, then the QAPP will be revised and redistributed.

Revisions to any portion of a section requires redistribution of that entire section, including the signature page, indicating approval of the revision; the title page, indicating the revision of the document; and the table of contents, indicating the revision of the section.

This QAPP complies with the requirements of the Project Office QAP. The LANL YMP and subcontractor activities shall be carried out in accordance with this QAPP and QPs, which shall be applied in a way that is consistent with the importance of the activity.

As part of the QA Program, management above or outside of the QA organization shall regularly receive information as to the scope, status, adequacy, compliance, etc., of the QA Program. Readiness reviews, as appropriate, shall be performed and shall apply to major scheduled and/or planned activities that could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified before a major activity is started.

This QAPP applies to LANL QA Level I and II activities associated with the YMP, including nuclide migration studies; geochemistry; mineralogy; petrology studies; and planning for the exploratory shaft construction, technical direction, and testing program. LANL also provides assistance in accordance with this QAPP to other Project organizations in areas of specialized expertise as directed by the Project Office.

The activities covered by this QAPP shall be delineated in the LANL YMP WBS, which is maintained at the TPO's office. The QAPP includes the following basic provisions for activities affecting quality.

- Activities affecting quality shall be planned and documented to ensure a systematic approach. Planning results in the documented identification of methods and organizational responsibilities. Planning shall begin as early as practicable and shall be completed no later than the start of those activities.
- Activities affecting quality shall be accomplished under controlled conditions, which include the use of appropriate equipment, the maintenance of environmental conditions suitable for accomplishing the activity, the use of formal procedures for the given activity, and the assurance that all prerequisites for the given activity have been satisfied.

- Procedures for activities affecting quality shall specify any equipment and technical skills necessary to achieve the required quality for that activity.
- Procedures for activities affecting quality shall specify the means to verify quality by peer reviews (Project Office directed), technical review, survey and audit, or a combination of these.
- All LANL YMP personnel performing activities affecting quality shall be indoctrinated and/or trained in both technical and QA requirements of their assigned task. QA auditors are trained and qualified in accordance with YMP requirements. The certification of YMP personnel shall be documented.
- LANL YMP management shall assess the adequacy and implementation of this QAPP regularly and shall formally report the results on an annual basis to the Project Manager and PQM.
- LANL participants are responsible for interfaces with other major YMP participants as specified in the WBS and outlined in Section 1 of this QAPP.

2.1.1 Verification of the Quality Assurance Program Plan

The QAPL or his appointee shall conduct internal audits of all phases of the application of this QAPP for all LANL YMP activities affecting quality. These internal audits shall assess the continuing implementation, effectiveness, compliance, and adequacy of the QA Program. LANL shall prepare a QP for the review of suppliers' QA Programs. The procedure shall make provisions for the assignments of responsibility for review and approval of the supplier QA Program. The procedure shall identify documents for review and approval and the documentation of results. Reviews shall be recorded on checklists that specify the criteria and that indicate conformance or nonconformance.

2.1.2 Use of Data Not Generated under Quality Assurance Controls

For use in licensing activities, the QA Program for the LANL YMP provides some data or data interpretations that were not generated under a program that meets the requirements of 10 CFR 60, Subpart G. Specific methods for acceptance of this information will be in YMP AP-5.9Q, "Acceptance of Data and Data Interpretations Not Developed under the Yucca Mountain Site Characterization Project QA Program." Once accepted, these data shall be classified as "primary data" for licensing purposes. A LANL QP shall be prepared to implement these requirements (see also Appendix G).

2.1.3 Approach to Quality Assurance

The YMP uses a graded approach to QA that recognizes the differences between items and activities that may or may not have an effect on radiological health, safety, and waste isolation. The graded approach is designed to ensure that each item or activity is assigned a QA level consistent with its potential impact on, or importance to, radiological health and safety; waste isolation; nonradiological health and safety; achievement of Department of Energy (DOE) mission objectives; NRC licensing requirements; and operability and maintainability of the repository, including its costs and schedules. The assignment is accomplished by deliberate planning and selective application of QA requirements on the items or activities to be performed. The degrees of QA to be applied depend on the item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations. LANL or the Project Office shall identify QA levels for all items and activities affecting quality that are associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. QA levels assigned by LANL are subject to Project Office approval before work begins on the item or activity.

2.2 Application of Graded Quality Assurance

LANL YMP activities will be graded in accordance with the Project Office guidance, and the resulting grading reports will be submitted to the Project Office for review and approval. Graded activities will be those defined in the YMP controlled documents YMP/90-55, Q-List; YMP/90-56, Quality Activities List; and YMP-90-57, Project Requirements List. Grading for activities at lower WBS levels will be conducted in accordance with a LANL QP. The resulting grading report will be submitted to the Project Office for their information.

2.3 Quality Assurance Activities

LANL shall perform an overview of the QA activities of all organizations, including LANL subcontractors and suppliers of services. The overview shall include a review of the existing QA Program before a contract is awarded; method for documenting review and approval action; and a survey(s) and/or audit(s) to verify the adequacy of, and compliance with, the QA Program during the contract period.

Following LANL's QPs for procurement, the statement of work may require, if appropriate, that the supplier or subcontractor have or create a QA Program equivalent to the LANL QAPP or, at the supplier's option, use the QAPP. These procedures shall identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action.

2.4 Management Assessment

Management assessments shall be conducted at least annually to verify that the QA Program is being effectively implemented; that the system and management controls established to achieve and ensure quality are effective; that the resources and personnel provided to the QA Program are adequate; and that personnel are trained to the QA requirements of the program. These assessments shall be performed and reported in accordance with LANL QPs, which shall include the minimum requirements for planning, organizing, performing, and documenting the results.

The assessment procedure shall specify that results be analyzed for quality trends and that reports and recommendations be tracked. Management outside or above the QA organization shall be responsible for the management assessment activity. Copies of the LANL management assessment report shall be transmitted to the YMP Project Manager and PQM.

2.5 Personnel Indoctrination and Training Procedures

LANL shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. Position descriptions shall establish minimum personnel qualifications and the necessary indoctrination or training or both before a person starts work on activities that affect quality. In addition, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, Appendix F) shall be certified in accordance with those codes and standards.

2.5.1 Position Descriptions and Evaluation of Personnel Qualifications

For the YMP, LANL requires position descriptions that specify and generally describe the activities performed for each YMP personnel position. Requirements for formal education and experience shall be stated in these YMP position descriptions for personnel performing and verifying activities that affect quality. The relevant education, experience, and training of personnel shall be verified. The initial capabilities of an individual shall be based on an

evaluation of his education, experience, and training and compared to those established for the position. The YMP personnel proficiency evaluations shall be performed and documented at least annually by managers or supervisors responsible for the activities performed. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations.

2.5.2 Indoctrination

Personnel assigned to perform activities affecting quality shall first be indoctrinated to the purpose, scope, methods of implementation, and applicability of the following documents (including revisions and changes) as they relate to the work to be accomplished:

- QAPPs,
- implementing procedures and work instructions (applicable to the individual's responsibilities),
- regulations, and
- Project-level documents.

Indoctrination may be effected through the use of a mandatory reading list, classroom presentations, video presentation, or other instructional methods.

2.5.3 Training

Before being assigned activities affecting quality (i.e., assignments where it is deemed necessary to develop and demonstrate initial proficiency), personnel shall undergo training to gain the required proficiency. This training shall encompass the principles, techniques, and requirements of the activity. Such training may include classroom sessions, workshops, on-the-job training, or other instructional methods.

2.5.4 Training and Certification for Auditor

Requirements for training and certification of auditors, lead auditors, and technical observers are addressed in Appendix F of this QAPP.

2.5.5 Records

YMP personnel files shall contain the indoctrination and training records, position descriptions, annual certification forms, initial qualification evaluations for work on the LANL YMP, and supervisors' documentation of the annual YMP proficiency evaluations. These documents shall be retained as QA records.

Records of these activities will include the objective and content of the training or indoctrination dates the name of the instructor, attendees, results of any YMP proficiency evaluations, the initial evaluation, and any other applicable information and shall be maintained as lifetime QA records. The evaluation documents for the proficiency of YMP personnel shall include the name of the employee, the name of the evaluator, evaluation results, date, and activities covered by the evaluation.

The evaluation documents for the qualification of YMP personnel shall include the verification and evaluation of employee education, experience, and training as compared with those required for the position.

3.0 SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

3.1 Scientific Investigation Control

3.1.1 Preparation of Scientific Investigation Planning Documents

Scientific investigations affecting quality shall be planned and documented to ensure a systematic approach. Before the start of any scientific investigation, the responsible PI shall develop a scientific investigation planning document for that investigation that outlines the work to be performed and delineates the instructions for complying with the requirements of the defined scope of work. Scientific investigations categorized as site characterization activities, as defined in the Nuclear Waste Policy Act (as amended), shall use study plans as the scientific investigation planning document. The requirements for the format and content of study plans are included in Appendix K of this QAPP. QA level assignments (QALAs) will be made in accordance with administrative procedures (APs).

At a minimum, the scientific investigation planning document shall include or reference the following:

- a description of the work to be performed, with the scope and proposed methodology clearly defined;
- a discussion of the purpose for the work;
- identification of who is to perform the work;
- instructions on how to perform the work (i.e., using the applicable technical procedures or scientific notebooks); and
- schedule requirements.

The description of the work to be performed in the scientific investigation shall include references to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, planning documents for higher-level scientific investigations, or WBS items for which the work is performed. The study plan will be the controlling document, will describe the scope of work, and will identify the controls to be used. The description shall identify the known factors and concerns that are important for the planning or the performance of the scientific investigation. Any previous work used in support of the scientific investigation shall be described, including identification of the QA levels or QA controls under which that work was performed. Note: This requirement does not apply to study plans. The scientific investigation planning document shall be attached to documents containing a level of detail that will enable an independent reviewer to determine that the appropriate QA level has been applied to the investigation. LANL scientific investigation planning documents that are approved and in place with approved QALAs will remain in place and active until they are superseded or withdrawn by LANL or the Project Office.

3.1.2 Quality Assurance Level Assignment

Once a scientific investigation planning document has been developed, the associated QALA for each of the activities and built-to-order items in that plan shall be prepared. It may be necessary in some cases to assign QA levels to the supporting activities and built-to-order items in previously prepared plans. Therefore, the QALA is not itself a part of the plans, even though it normally accompanies those plans and goes through the same review and approval process.

3.1.3 Review and Approval of Scientific Investigation Planning Documents

The organization that develops a scientific investigation planning document shall conduct a technical review of it to ensure that

- fabrications, installations, modifications, inspections, experiments, and tests have been incorporated;
- the scientific investigation can be conducted as specified;
- time, resources, and training are sufficient to accomplish the work in accordance with the specified sequential progression of operations; and
- the overall measures to be employed preserve the quality of the work.

The technical review shall be performed by any qualified individual other than those who developed the original scientific investigation planning document. The originator's immediate supervisor may perform the review if the supervisor is the only other technically qualified individual and if the need is documented and approved in advance by the QAPL. The results of the technical review and the resolutions of any comments by the reviewers shall be documented and shall become part of the QA records as prescribed in the QP for document review.

The scientific investigation planning document shall be reviewed pursuant to LANL procedures. The TPO or his designee shall then forward the scientific investigation planning document to the Project Office for review and approval by the appropriate branch chief. The scientific investigation planning document will be returned to the TPO upon completion of the Project Office review and approval cycle. Study plans shall also be reviewed and approved by OCRWM prior to implementation. A peer review of the scientific investigation planning document shall be conducted if the Project Office deems it necessary. In the event that any completed research reports or activities are required to have a peer review, they will be referred to the Project Office by the TPO.

All changes in the scientific investigation planning document shall go through this same review and approval process. If modified work is not within the scope of the study plan or the scientific investigation planning documents and

- is not repeatable or
- could potentially impact the waste isolation capability of the site or
- could interfere with other site characterization activities,

then approval shall be obtained from an appropriately qualified reviewer. The PI is responsible for evaluating the effects of such changes on the associated QALAs. Minor changes in the scientific investigation planning document limited to inconsequential editorial corrections need not go through the same review and approval process as a technical change must. However, minor changes shall be reviewed and approved by the appropriate Project Leader and concurred with by the QAPL before issue. A file of the minor changes made in scientific investigation planning documents shall be maintained in the appropriate Resident File.

3.1.4 Scientific Investigation Data Interpretation and Analysis Documents

Interpretation and analysis shall be performed in a planned, controlled, and documented manner that shall provide details that will be sufficient for a technically qualified individual to review, understand, and verify the analysis without recourse to the originator. Documentation shall include purpose, method, assumptions, input, references, and qualitative and quantitative units. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer, and date.

Documentation of interpretation and analysis shall include or reference the following:

- a definition of the objective;
- a definition of input and 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; and
- signatures and dates of review and approval by appropriate personnel.

3.1.5 Use of Computer Programs

Computer programs used to support a license application shall be subject to the requirements of LANL procedures for software QA requirements (See Subsection 3.3, Appendix H of this QAPP, and NUREG-0856.)

3.1.6 The Use of Scientific Notebooks Versus the Use of Detailed Technical Procedures

There are two kinds of documentation that can be used for the QA documentation and control of scientific work: the scientific notebook and the detailed technical procedure (DP). Scientific notebooks generally are used by qualified individuals who are largely guided by professional judgment and who use trial and error methods in their work. A DP generally is used when a qualified individual performs repetitive work that is not guided by professional judgement and does not involve trial and error methods. DPs shall be required when deviation from a prescribed sequence of actions endangers the validity of the results. Bound notebooks, logbooks, or appropriate forms shall be used to document the performance of DPs and the control over all other aspects of the work. Documentation of scientific work, i.e., experiments and research, shall be performed to provide a written record of the experiment or research.

3.1.6.1 Detailed Technical Procedures

DPs, together with other supporting documents or notebooks, shall be used whenever the work is repetitive and is performed by individuals who may not be directly supervised by a PI. Modifications of the technical aspects of DPs shall be approved by an appropriately qualified reviewer. DPs shall be developed, reviewed, changed, or modified in accordance with the requirements given in Section 5 of this QAPP.

Acceptance or rejection criteria of the performance of a DP, including required levels of precision and accuracy, shall be provided by the organization responsible for the scientific investigation.

DPs used for scientific investigations shall provide for the following as appropriate:

- objectives, methods and/or characteristics to be tested or observed.
- 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 shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions shall be designed to ensure validity of data throughout the scientific investigation.

- mandatory verification points.
- acceptance and rejection limits and criteria, including required levels of precision and accuracy. (Note: "Accept/reject criteria" means those features or characteristics of a DP that make it possible to determine whether that the results were produced by work that was performed properly and according to the DP. 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 DP.)
- methods of documenting or recording data and results, including precision and accuracy.
- methods of data reduction.
- provision for ensuring that prerequisites have been met.
- special training or qualification requirements for personnel performing the scientific investigation.
- personnel responsibilities.

DPs shall be complete to the extent that another qualified individual may, at a later date, repeat the procedure and gather similar results.

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

For instrumentation and/or equipment used in data collection, consideration shall be 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 will include any special provisions for equipment and instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.

Changes to field and laboratory procedures associated with scientific investigations shall be controlled to ensure that such changes are subsequently documented and verified in a timely manner by authorized personnel. Any procedural deviation encountered during activities shall be documented, reported, and evaluated for significance.

3.1.6.2 Scientific Notebooks

Bound scientific notebooks may be used with other appropriate documents to record scientific investigations and experiments. A competent technical reviewer will sign the notebook. When using notebooks, documentation shall be sufficiently detailed so that another qualified scientist can trace the investigation and confirm the results or repeat the experiment and achieve similar results without recourse to the PI. Notebooks must be maintained as stipulated in LANL QPs.

When recording results of scientific investigations in notebooks, investigators shall include the acceptance/rejection criteria for the process of generating the data.

Initial Entries

Initial entries are considered to be the "general" procedure. Modifications to this "general" procedure shall be recorded in the notebook in process entries.

Where appropriate, before initiation of the experiment or research, the following entries shall be made or referenced, as applicable:

- the title of the experiment or research;
- the name of the qualified individual(s) performing the experiment or research;
- a description of the experiment's objective(s);
- equipment and materials to be used during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material;
- calibration requirements;
- the dated signature of the individual(s) making the initial entries;
- special training or personnel qualification requirements;
- documentation of suitable and controlled environmental conditions; and
- the potential sources of uncertainty and error in scientific investigations which must be controlled and measured to ensure that the investigations are well controlled.

In-Process Entries

In-process entries shall include or reference, as applicable:

- the date and name of the individual making the entry;
- provisions for ensuring that prerequisites have been met;
- a description of the experiment or research attempted, including the detailed step-by-step process followed (reference may be made to the use of a DP if one is used);
- a description of any conditions that 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;
- all data taken during the experiment and a brief description of the results, including notation of any unexpected results;
- any deviations from the planned experiment or research;
- any interim conclusions reached, as appropriate; and
- when final results have been reached, a summary of the outcome of the experiments or research, including a discussion of whether the experiment's objectives as outlined in the initial entries were achieved. The final results and summary shall be included in a report. Reference to the report shall be made in the notebook. The report shall become part of the QA records for the activity.

Final Entries

The final entries of experiments or research require, as a minimum, the signature of the investigator and a competent technical reviewer as described in the LANL implementing procedure.

3.1.6.3 Logbooks

A logbook is associated with a specific activity, an operating device, or sample location. Logbooks and entries thereto shall be controlled according to a LANL QP. Logbooks may also be used to note any pertinent data concerning their assignment, including such entries as data runs and results, calibration runs and results, downtimes, and sample withdrawals.

3.1.7 Interface Control

Internal and external scientific investigation interfaces and efforts shall be coordinated between LANL participants and other YMP participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within participating organizations for the review, approval, release, distribution, and revision of documents involved with scientific investigations and interfaces. Interfaces within LANL shall be coordinated according to LANL QPs. Interfaces between scientific investigations, or between a scientific investigation and any other YMP activities, shall be coordinated among YMP participants in accordance with LANL QPs. Interfaces between LANL and suppliers shall be controlled in accordance with QPs established in the procurement documents. The transmittal of information or items (including samples of natural or man-made materials) across interfaces shall be documented according to LANL policy.

Ongoing field or laboratory investigations, where several organizations may be involved, shall be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification shall be clearly evident on the location. Field surveys shall identify the location of the scientific investigation.

3.1.8 Verification of Scientific Investigation

3.1.8.1 Verification Planning

Planning and performance of verification activities shall be accomplished and documented using LANL QPs. Verification procedures shall 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 used);
- recording identification of the verifier and the results of the verification.

The LANL QA organization shall perform surveys (according to Section 18 of this QAPP) of all scientific investigations, as deemed appropriate for the purposes and the complexity of the work. The QA verification team for a scientific investigation shall consist of one or more technically qualified individuals who are familiar with the scientific investigation planning document and one or more QA personnel. This verification team shall determine the timing and number of surveys.

3.1.8.2 Verification Hold Points

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

3.1.8.3 Reporting Independence of Personnel

Verifications shall be performed by personnel who do not report directly to the immediate supervisor(s) who is (are) responsible for performing the activity being verified. If these personnel are not part of the formal QA organization, they shall 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) ensure that further processing, delivery, installation, or use is controlled until proper disposition has occurred. When the persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the QA organization shall overview and monitor the activity.

3.1.9 Reports, Conclusions, and Recommendations

Technical review of the results and documentation of scientific investigations shall be accomplished in accordance with LANL QPs that specify that all final reports shall be submitted to the Project Office for review and approval.

3.1.10 Close-Out Verification

Because a considerable period of time may pass before data from a completed scientific investigation are used in the licensing process, close-out verification shall be performed upon completion of any scientific investigation to ensure that the QA records for that investigation are adequate and complete. Close-out verifications shall be performed by a team consisting of technically qualified personnel as well as by QA personnel.

3.2 Design Control

LANL, at present, has direct responsibility for design control activities. This section is included for LANL design control activities and for pass-through to LANL subcontractors. (Currently this function is performed by EG&G for design of the integrated data system.)

3.2.1 General

The design shall be defined, controlled, and verified. The term "design" refers to specifications, drawings, design criteria, and performance requirements for the natural and engineered components of the repository system. Design control measures shall be applied to conceptual designs, or parts thereof, which may at a later time become part of the final design. Design information and design activities refer to the data collection and analyses used in supporting design development and verification. This includes general plans and technical procedures for data collection and analyses and related information such as test results and analyses. Plans for data collection and analyses shall be complete before performing the data collection and analysis activities. Data collection activities resulting from scientific investigations can produce design input. Data analysis includes the initial step of data reduction as well as broad systems analyses

(such as performance assessments), which integrate many other data and analyses of individual parameters.

It is the policy of the YMP that the 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. For organizations responsible for design, the number and length of design phases required to complete the design of any particular item or facility may vary according to the timeliness and availability of pertinent information and the complexity of the item or facility. However, producing a unified facility design depends on the coordinated interfaces among all YMP design organizations.

3.2.1.1 Quality Assurance Level Assignment

All design phases shall be assigned a QA level before execution in accordance with the methods specified in LANL QPs.

3.2.1.2 Qualification of Personnel

Personnel performing design work shall be oriented, trained, and qualified in accordance with the requirements of Subsection 2.4 of this document. Instructions, procedures, and drawings for design work shall comply with the requirements of Section 5 of this document.

3.2.1.3 Peer Review

A peer review is an acceptable method of design verification for design activities or design documents that are beyond the state-of-the-art. These design activities or design documents may involve or specify the use of untried testing and design analysis procedures and methods or detailed technical criteria and requirements that do not exist or are being developed. (See also Appendix J of this QAPP.)

The peer review shall meet the requirements of Subsection 3.5 of this QAPP.

3.2.2 Design 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) shall be identified and documented, and their selection shall be reviewed and approved by the responsible design organization and QA organization. The purpose of this QA review, at the input stage, is to ensure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements. Changes in approved design input, including the reason for the changes, shall be identified, documented, reviewed, approved, and controlled by the responsible design organization. Design input (see Appendix B) shall be specified and approved on a timely basis to the level of detail necessary to permit design activities 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.

3.2.3 Design Analysis

Design analysis shall be planned, controlled, and documented in sufficient detail, including purpose, method, assumptions, design input, references, and units, to enable a technically qualified person to review, understand, and verify the analysis without recourse to the originator. These documents shall be produced in a form suitable for reproduction, filing, and

retrieval. Calculations shall be identified by subject, including structure, system, or component; originator; reviewer; and date.

3.2.3.1 Documentation of Design Analysis

Documentation of design analysis shall include the following:

- a definition of the objective of the analysis;
- a definition of the design input and its sources;
- a listing of applicable references;
- results of literature searches and other background data;
- identification of assumptions and an indication of those that require verification as the design proceeds;
- identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem; and
- signatures and dates of review and approval by appropriate personnel, including QA personnel. The purpose of this QA review, at the analysis stage, is to ensure that the documents are prepared, reviewed and approved in accordance with documented procedures and QA requirements.

3.2.3.2 Use of Computer Programs

Computer programs used to support a license application shall be verified and controlled as specified in QPs for software QA requirements (see Subsection 3.3).

3.2.4 Design Verification

3.2.4.1 Identification and Documentation

The organization responsible for a design shall verify the adequacy of the design in a timely manner, according to the design control measures and shall identify and document the verification method used, the results of the verification, and the personnel involved.

3.2.4.2 Timing of Verification

Verification of the adequacy of the design shall be performed before its release for procurement, manufacture, construction, or release to another organization for use in other design activities. In cases where this timing cannot be met, the portions of the design that have not been verified shall be identified and controlled. In all cases, the verification shall be completed before the component, system, or structure is used.

3.2.4.3 Extent of Verification

The extent of the design verification necessary shall be a function of the importance to the safety of the item under consideration, the complexity of the design, the degree of standardization, and the similarity with previously proven designs. The verification process need not be duplicated for identical designs that have been verified in accordance with the requirements of this section. However, if new design inputs affect the application of standardized or previously proven designs, those designs shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effect on other features shall be considered. The original

design and associated verification measures shall be referenced in the files of subsequent applications of the design.

3.2.4.4 Changes in Verified Designs

Changes in previously verified designs shall require further verification steps, including the evaluations of the effects of those changes on the overall design.

3.2.4.5 Persons Performing Verification

Design verification shall be performed by any certified individual(s) or certified group(s) other than those who performed the original design. Those individuals qualified to verify designs include

- individuals or groups from the originator's organization,
- individuals or groups from other organizations contracted for this purpose, and
- 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 the design approach, or rule out certain design considerations; and
  - the rationale for satisfying the two requirements above shall be documented and approved by management superior to the supervisor (the QAPL must concur with the rationale).

3.2.4.6 Methods of Design Verification

Design verification shall be accomplished by design reviews, alternate calculations, qualification testing, and/or peer reviews. LANL QPs shall establish responsibilities, areas and features to be verified, pertinent considerations, and the extent of documentation needed.

Design Reviews

Design reviews shall be detailed critical reviews meant to ensure that the design is correct and satisfactory. At a minimum, the reviewers shall consider the items below and document the results of such deliberations.

- Have the design inputs been selected correctly?
- Have the assumptions used to perform the design activity been adequately described and are they reasonable?
- Upon completion, are the assumptions reverified when necessary?
- Has an appropriate design method been used?
- Have the design inputs been incorporated into the design correctly?
- Is the design output reasonable as compared with the design input?
- Have the design input and verification requirements needed by interfacing organizations been specified in the design documents or in supporting procedures or instructions?
- Have the computer programs used for analysis been identified and verified in accordance with the methods specified in LANL QPs and DPs?

Alternate Calculations

Alternate calculations may be used to determine the adequacy of the original analyses. The use of alternate calculations requires a technical review of the assumptions, inputs, and computer programs or other methods used in the calculation.

Qualification Tests

Qualification tests that involve physical testing of systems, structures, or components may be used to verify the adequacy of a design or a specific design feature. Where design adequacy is to be verified by qualification tests, the tests shall be identified in the design document. The following stipulations shall apply to the use of qualification tests.

- The test configuration shall be clearly defined and documented.
- Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.
- Other features of the design shall be verified by other means when the test is intended to verify only specific design features.
- Test results shall be documented and evaluated by the organization responsible for the design to ensure that test requirements have been met.
- If qualification testing indicates that modifications of the item are necessary to obtain adequate performance, the modification shall be documented and the item shall be modified and retested or otherwise verified to ensure satisfactory performance.
- When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test shall be subject to error analysis, where applicable, before its use in the final design work.

3.2.5 Design Change Control

Changes in approved designs, including field changes, shall be justified. They shall be subjected to the same control measures applied to the original design and shall be approved by the same organizations that reviewed and approved the original design document. In the case where the organization originally responsible for approving a particular design is no longer responsible, the Project Office will designate a new responsible organization that 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 designs and in design information documents shall be documented, and action shall be taken to correct them. Where a significant design change is necessary, the design process and verification procedure shall be reviewed and the procedure shall be modified as indicated. Additionally, training for needed changes shall be considered and the changes with the required training shall be communicated to all affected groups or individuals.

3.2.6 Design Interface Control

Design interfaces internal and external to LANL shall be identified and controlled, and the design efforts shall be coordinated. Interface controls include the documented assignment of responsibility and the establishment of procedures for the review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of design information or documents provided and, when

necessary, identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information informally, the design information shall be confirmed promptly by a controlled document.

3.2.7 Design Output Requirements

Completed designs shall be documented and shall relate to design input in sufficient detail to permit design verification. This documentation shall identify assemblies or components that are part of the designed item. When such an assembly or component part is a commercial-grade item and is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial-grade item, and the difference is defined and documented.

The design document shall show evidence that the required review and approval cycle has been achieved before its release for use in procurement or construction or release to another organization for use in other design activities. As a minimum, the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the Project Office. The purpose of the QA review is to ensure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements.

3.2.8 Design Documents as Quality Assurance Records

Design documentation, including design input, analyses, drawings, specifications and approved changes, evidence of design verification, and records confirming interface control, shall be collected, controlled, stored, and maintained as QA records in accordance with LANL records management procedures.

3.3 Software Quality Assurance Requirements

Appendix H of this QAPP describes the software requirements for the LANL YMP and shall be used in conjunction with the following sections.

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

Where commercial auxiliary software is used, all available documentation from the software supplier shall be 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 are contained in Appendix H.

3.3.1 Computer Software Documentation and Control

Appendix H to this QAPP provides detailed requirements on the content of software documentation used on the YMP. Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856. This requirement may be met in part by existing documentation, if properly referenced and related to NUREG-0856 requirements.

Software QA documentation is a QA record and shall be controlled as per Section 17 of this QAPP.

3.3.2 Software Description

LANL shall prepare a Software QA Plan (SQAP) as described in Appendix H to describe its software design, test, and configuration management system. The SQAP shall be submitted to the Project Office for review and approval.

3.3.2.1 Baseline Elements

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

3.3.2.2 Software Changes

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

3.3.2.3 Software Testing

Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, to 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 a high probability of detecting the errors in order to determine the conditions under which the software will not perform properly.

3.3.2.4 Qualification of Existing Software

Existing software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section and Appendix H.2. Software that has not been developed in accordance with this QAPP may be qualified for use, provided that the software is verified and validated, a software baseline is established, and applicable documentation is prepared to support the software.

3.3.2.5 Interface Management

Methods for determining the applicability of requirements and managing interfaces involving software, documentation, configuration management, change, qualification, verification, and validation will be described in the SQAP.

3.3.2.6 Software Configuration Management

The minimum requirements for a configuration management QP shall include a unique identification, including software version numbers, whenever feasible, in the output;

listings of the software; and a brief chronology of the software versions, including descriptions of the changes made between controlled versions of the software.

3.4 Technical Reviews

Technical reviews shall be performed in accordance with a QP that defines the following:

- the criteria for selection of the technical reviewers,
- the procedure for technical reviews, and
- the method of review documentation.

3.5 Peer Reviews

When applicable, LANL shall institute a peer review process to provide adequate confidence in the work being reviewed. A peer review QP shall meet the requirements of NUREG-1297 and Appendix J of this QAPP.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Procurement Document Requirements

Documents for procurement of material, equipment, and services used in LANL YMP activities shall include or reference applicable regulatory requirements, design or site investigation bases, and other requirements necessary to ensure quality.

Procurement documents shall contain the following information as appropriate:

- a scope of work description,
- the technical requirements for the work,
- QA Program requirements,
- a right-of-access provision,
- subcontracting requirements (including the subcontractor's pass-through of appropriate QA requirements),
- documentation requirements, and
- nonconformance provisions.

4.1.1 Scope of Work

The procurement documents shall clearly define the scope of the work to be performed by the supplier or subcontractor.

4.1.2 Technical Requirements

The procurement documents shall specify the technical requirements for the work. Where necessary, these requirements shall reference specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including any revisions thereto, that describe the items or services to be furnished. The procurement documents shall identify test, inspection, and acceptance requirements for monitoring and evaluating supplier or contractor performance.

4.1.3 Quality Assurance Program Requirements

For noncommercial-grade procurements, a LANL supplier or subcontractor shall be required to have a documented QA Program that implements all the applicable QA requirements of this document as selected by the requester. Subcontractors' QAPPs and related documents, including changes thereto, shall be reviewed and approved by the requester and QA representative. Upon review, if additional QA elements are required, they shall be specified and incorporated in the subcontractor's QA Program before the initiation of procured activities. The extent of the program required depends upon the type and use of the item or service being procured.

In the development of QA requirements for measuring and other equipment, consideration shall be 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).

4.1.4 Right of Access

QA Level I and II procurement documents shall provide for access to the suppliers' facilities or their subcontractors' facilities and to their records for inspection or audit by the purchaser and appropriate Project Office personnel. When audits of suppliers or their subcontractors are performed by LANL or other YMP personnel, the LANL procurement organization shall be notified and then coordinate with the requester to arrange access.

4.1.5 Documentation Requirements

Procurement documents shall identify the documentation (reports, manuals, certification, etc.) required from the supplier or their subcontractors and shall specify the time of submittal. QA Level I procurements from LANL in-house suppliers shall be considered internal supplies and are not documented as procurement but shall be appropriately qualified for its intended use. Measuring and test equipment are qualified for the Project through calibration.

4.1.6 Nonconformance

Procurement documents shall prescribe the requirements for reporting and approving the disposition of nonconformances as appropriate to the specific procurement. Section 15 contains more information on nonconformance.

4.2 Review of Procurement Documents

A review of the procurement requests and of changes in procurement specifications shall be made to ensure that documents transmitted to the prospective supplier or contractor include all appropriate provisions to require that items or services meet the specifications.

Before a contract is awarded, personnel who have access to pertinent information and an adequate understanding of the requirements and intent of the procurement documents shall perform and document the review. The review shall be performed by the requester and QA representative, as a minimum. The QA review shall ensure that

- the QA requirements are stated correctly and are inspectable and controllable;
- there are adequate acceptance and rejection criteria; and
- the procurement documents have been properly prepared, reviewed, and approved.

4.3 Procurement Document Changes

Changes in procurement documents shall be subject to the same degree of control used in the preparation of the original documents. Changes made as a result of the bid evaluation or precontract negotiations shall be incorporated in the procurement documents. Before a contract is awarded, a review and evaluation of such changes and their effects will be completed, documented, and approved by the requester.

The review of changes shall include

- that appropriate content is included within the procurement documents;
- that additional or modified design/site investigation criteria is determined, if applicable; and
- that supplier requested changes or exceptions are evaluated for impact on the intent of the original procurement document.

4.4 Distribution of Procurement Documents

Copies of QA Level I procurement documents and changes therein that state the vendor, the scope of work, and the date when work is to start shall be sent to the Project Office QA Department.

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1 General

Activities affecting quality shall be prescribed by, and performed in accordance with, documented instructions, procedures, plans, or drawings written according to QPs. LANL procedures consist of QPs and DPs prepared in accordance with this QAPP. These documents, including drawings, shall be developed by qualified personnel, controlled as required by Sections 6 and 17 of this document and distributed according to QPs. For the production of drawings, the initiating organization shall establish procedures, when directed, for the initiation, review, approval, issue, and change control.

5.2 Criteria

Instructions, procedures, and plans shall specify appropriate quantitative or qualitative criteria for determining satisfactory work performance and QA compliance and identify the QA records to be generated during implementation of the document. The documents shall specify the checkpoints in the work process at which compliance with the criteria shall be determined and verified. Criteria for approval or rejection shall be provided for all inspections of products and for construction and monitoring of methods, and equipment. Means for identifying approved or rejected products or services shall also be provided.

5.3 Reviews

Independent technical reviews of all instructions, procedures, plans, and drawings shall be performed by the originating organization in accordance with QPs before their implementation. The technical adequacy of procedures for conducting scientific investigations shall be reviewed and approved by qualified persons other than those who prepared the procedures. Before instructions, procedures, and plans are implemented at LANL, they shall be reviewed by the QA organization, in accordance with QPs, to ensure that they meet all requirements of this QAPP. Reviews of instructions, plans, procedures, and drawings should consider if the activities described therein (1) are repeatable, (2) will affect waste isolation capabilities, and/or (3) will interfere with other site characterization activities.

5.4 Distribution

The QAPP and all procedures, plans, instructions and drawings shall be maintained and provided to the PQM as part of the controlled distribution for all QA Level I and II activities documents.

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6.0 DOCUMENT CONTROL

6.1 Document Preparation, Review, Approval, and Issue

The preparation, review, approval, and issue of documents (such as instructions, administrative procedures, plans, and drawings, including changes therein) shall be controlled to ensure that correct documents are available for use at the proper location. Document control shall be implemented through procedures and shall be applied to documents that contain or specify quality requirements and documents that prescribe activities affecting quality.

The document control system shall be prescribed in a QP, and the QA organization shall provide review, resolution of comments, and approval of quality-related aspects of the documents.

6.2 Implementation of Document Control

Documents shall be controlled according to a QP that

- identifies documents to be controlled;
- assigns responsibility for preparing, reviewing, approving, and issuing documents;
- defines instructions for reviewing documents for adequacy, completeness, correctness, and inclusion of appropriate quality requirements before approval and issue;
- prescribes a method for removing or marking obsolete or superseded documents, in a timely manner, to prevent inadvertent use;
- prescribes a method for ensuring that the correct and applicable documents are available at the location where they are to be used;
- requires a master list or equivalent to identify the correct and updated revisions of documents; and
- delineates interface documents.

6.3 Changes in Documents

Changes in documents shall be reviewed and approved by the same organizations that originally reviewed and approved the document, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organizations shall have access to pertinent background data or information upon which to base their approval. Reviewers shall specifically consider whether changes to the process are not repeatable, have the potential to affect waste isolation capability of the site, or interfere with other site characterization activities.

Minor changes in documents limited to inconsequential editorial corrections do not require the same review and approval as the original documents. Editorial corrections will be verified that they do not substantially change the document before the documents are issued.

6.4 Distribution of Documents

The document control system shall ensure that documents requiring verification are not released before verification or, if they must be released before verification, that they are uniquely identified and controlled in accordance with Subsection 6.2 above. A master list or equivalent used to identify the correct, current, and updated versions of documents shall be submitted to the PQM by the Records Coordinator. LANL shall issue to the PQM controlled copies of all LANL implementing procedures, plans, instructions, and the QAPP used for QA Level I and II activities. In addition, procedures, plans, and instructions for QA Level I and II activities shall be accessible for review in the area where the activity is performed.

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7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 General Requirements

Procurement shall be conducted in accordance with LANL QPs. Purchased material, equipment, and services shall conform to the requirements of procurement documents. These methods include source evaluation and selection, the examination of objective evidence of quality, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery as specified in the procurement documents. Organizational responsibilities shall be stated in a QP. This documentary evidence shall be handled as specified in Section 17. Specific requirements for the purchase of items and services are listed below.

7.1.1 Procurement Planning

Procurement activities shall be planned and documented to ensure a systematic approach to procurement. The QA organization shall participate in the qualification of supplier, verification of supplier activities, and monitoring receipt inspection. Planning shall be accomplished as early as practicable and no later than the start of YMP procurement activities. Planning shall determine what is done, who does it, how it is done, and when it is to be accomplished.

Planning results in the documented identification of procurement methods, the sequence of actions and milestones that indicate the completion of these activities, and the preparation of applicable procedures before the initiation of each individual activity listed below. Planning considers the following:

- preparation, review, and change control of procurement documents;
- selection of procurement suppliers;
- control of supplier performance;
- verification through survey, inspection, or audit of activities, including specification of hold-and-witness points;
- control of nonconformances;
- execution of corrective action;
- acceptance of an item or service; and
- preparation of QA records.

7.1.2 Evaluation and Selection of Suppliers

Before a contract is awarded, suppliers shall be selected based on an evaluation of their ability to provide items or services in accordance with the requirements of the procurement documents.

Criteria for evaluation and selection of procurement sources, and the results thereof, shall be documented and shall include one or more of the following items:

- an evaluation of the suppliers' histories, including current capabilities, of providing identical or similar products that perform satisfactorily in actual use;
- an evaluation of the suppliers' current QA records supported by documented qualitative and quantitative information that can be objectively evaluated; and
- an evaluation of the suppliers' technical and quality capabilities as determined by a direct evaluation of their facilities and personnel and the implementation of their QA Program.

7.1.3 Bid Evaluation

Bid evaluation shall determine the extent of conformance to the procurement documents. The evaluation, by the designated organizations, shall consider the following, as applicable to the type of procurement:

- technical considerations,
- QA requirements,
- personnel,
- production capabilities,
- past performance,
- alternates, and
- exceptions.

Before the contract is awarded, the purchaser shall resolve unacceptable QA conditions identified during the bid evaluation.

7.1.4 Interface Measures

The interface between the supplier and the purchaser includes the following:

- review of supplier documents that are generated or processed during activities fulfilling procurement document requirements,
- supplier identification of planning techniques and processes, when applicable;
- methods of exchanging document information; and
- a method of identifying and processing necessary change information. (Measures to control changes in procurement documents shall be established, implemented, and documented in accordance with the requirements of Subsection 4.3 of this QAPP.)

7.1.5 Evaluation of Supplier Performance

7.1.5.1 Verification Measures

The purchaser of items and services shall establish measures to verify the supplier's performance and to establish the extent of source survey and inspection activities. The extent of verification activities, including planning, is a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier's activities (i.e., a preaward survey).

These verification activities shall be conducted as early as practicable. However, LANL's verification activities do not relieve the suppliers of their responsibilities for verification of quality achievement.

When using another participating organization, LANL will request the PQM to conduct a survey to determine that the item or activity is being produced or performed in accordance with LANL requirements.

7.1.5.2 Record of Evaluation and Verification

Activities shall be performed to verify conformance with requirements of procurement documents and their results shall be recorded. Source surveys and inspections, audits,

receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented. These completed documents shall be considered QA records and shall be controlled in accordance with Section 17 of this QAPP. This documentation is evaluated to determine the supplier's QA Program effectiveness.

7.1.6 Control of Documents Generated by Suppliers

Documents generated by suppliers shall be submitted in accordance with requirements of the procurement documents and shall be handled, approved, and controlled according to LANL QPs for document control. The documents shall be evaluated against the criteria for procurement acceptance.

7.1.7 Acceptance of Item or Service

Methods shall be established for the acceptance of items or services being furnished by the supplier. The supplier or contractor shall verify that an item or service complies with the procurement requirements before its submission for acceptance. Documentation of acceptance shall be considered a QA record and maintained in accordance with Section 17 of this QAPP.

Acceptance of services performed shall require documentation of surveys and audits, a technical review of data generated, or other objective evidence of satisfactory performance.

Methods of acceptance for items include

- a supplier certificate of conformance,
- a source verification,
- a receiving inspection,
- a postinstallation test at the facility site, or
- a combination of the above.

7.1.7.1 Certificate of Conformance

The following minimum criteria apply to a certificate of conformance.

- The certificate shall identify the purchased material or equipment.
- The certificate shall identify the specific procurement requirements met by the purchased material or equipment, including codes, standards, or other specifications. Identification shall be accomplished by including a list of the specific requirements or by providing, at the point of receipt, copies of the purchase order, the procurement specifications or drawings, and a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certificate shall identify any procurement requirements that have not been met, shall explain the nonconformance, and shall propose a means of resolution.
- The certificate shall be validated by a person responsible for this QA function described in the supplier's QA Program.
- The certificate system, including the procedures followed in completing a certificate and the administrative procedures for the review and approval of the certificates, shall be described in the supplier's QA Program.
- The validity of supplier certificates and the effectiveness of the certification system shall be verified during the performance of audits of the supplier, or independent inspection, or test of the items. Such verification shall be conducted at intervals commensurate with the supplier's past quality performance.

7.1.7.2 Source Verification

If source verification is performed, it shall be done at intervals that are consistent with the importance and complexity of the item or service. Source verification shall be implemented to monitor, witness, or observe activities. Verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Once the source verification is accepted, LANL (the receiving destination of the item) and the supplier shall be furnished with documented evidence of acceptance of the item.

7.1.7.3 Receiving Inspection

Purchased items shall be inspected as necessary to verify their conformance to specified requirements. Inspections shall take into account source verification, audit documentation, and the demonstrated quality performance of the supplier. Receiving inspection shall be performed in accordance with LANL QPs. Supplier documentation that material or equipment conform to procurement requirements will be available for review at receipt inspection and/or prior to installation or use. Receiving inspections shall be based on objective evidence criteria—such as physical, dimensional, damage—or other measurable characteristics. Technical personnel, who are familiar with the objectives of the research and have been indoctrinated to the applicable codes, standards, and QA requirements shall perform the receipt inspections. These technical personnel shall have the experience and training commensurate with the scope, complexity, or special nature of receipt inspection.

7.1.7.4 Postinstallation Testing

Postinstallation testing requirements and acceptance documentation shall be established between LANL and the supplier in the procurement document.

7.1.8 Procurement of Services

In cases involving procurement of services, including third-party inspections, engineering, analysis, consulting, installation, repair, overhaul, or maintenance work, acceptance shall be made according to the following methods:

- technical verification of data produced;
- a survey and/or audit of the activity; or
- a review of evidence, such as certifications and stress reports, for conformance to the requirements for procurement documents.

7.1.9 Control of Supplier-Issued Nonconformances

Requirements involving the control of supplier-issued nonconformances for the item or service being procured shall be stipulated in the purchasing document.

The nonconformance report (NCR) issued by the supplier shall contain the following minimal information:

- the technical or material requirement violated, with reference to the procurement document;
- a consideration of whether the nonconformance can be corrected by continuation of the original process or rework;

- an evaluation of nonconforming items;
- a submittal of a nonconformance notice to the requester;
- the process correction proposed, when applicable;
- the recommended disposition (i.e., use-as-is, repair, rework, or reject); and
- technical justification for the disposition.

The submittal of a nonconformance notice shall include a disposition recommendation (e.g., use-as-is or repair) and technical justification. Supplier dispositions are approved and implementation is verified by the requester in accordance with the LANL QP. Supplier nonconformance reports shall be processed and reviewed by the requestor according to a LANL QP and maintained as QA records.

Disposition of nonconformances by the requester includes

- an evaluation and approval of the supplier's corrective action (if applicable),
- maintenance of records of nonconformance, and
- verification of the corrective actions.

7.2 Commercial-Grade Items

If a design or scientific investigation requires commercial-grade items, then the following requirements and the requirements of Section 4 of this QAPP shall be used to accept the items.

7.2.1 Identification of Commercial-Grade Items

Where the commercial-grade item is to be used, it shall be properly identified in approved design or design activity documents and will meet applicable requirements. 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 will meet the requirements applicable to both the replaced item and its application.

7.2.2 Source Evaluation and Selection

Source evaluation and selection shall be in accordance with Subsection 7.1.2 when the requestor determines that such activity is necessary based on the complexity of the item and its importance to safety.

7.2.3 Purchase Order

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

7.2.4 Receipt of Commercial-Grade Items

Receipt of a commercial-grade item shall determine that

- damage was not sustained during shipment;
- the item received was the item ordered;
- the required receipt inspection or testing is accomplished in accordance with written procedures to ensure conformance with the manufacturer's published requirements, and, if applicable, acceptance of the item may be accomplished by way of a calibration program in accordance with Section 12 of this QAPP and the associated procedure; and
- documentation, as applicable to the item, has been received and accepted.

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8.0 IDENTIFICATION AND CONTROL OF SAMPLES AND DATA

8.1 Identification and Control of Samples

These requirements shall apply to samples used in or resulting from scientific investigations.

Samples shall be identified and controlled according to LANL DPs. Such procedures shall define the responsibilities (including interface between organizations) for the collection, identification, handling, storage, and transportation of samples and for the generation of records regarding such.

Samples shall be collected according to LANL DPs to ensure that collection methods produce the intended sample. Sample-handling methods shall be documented and shall be used to ensure that all samples meet the technical objectives dictated by the scientific investigation for which the samples are collected.

Transportation methods shall be described in, and effected by, LANL DPs prescribing appropriate containers, methods of handling, and any other environmental or safety considerations for the sample. Where multiple organizations are involved, appropriate procedures shall define responsibilities and documentation methods to be used.

Controls shall be implemented to ensure that sample identification is verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another for use or analysis.

Samples shall be identified by placing the identification directly on the sample, on its container, or on records traceable thereto. When it is impractical to place the identification on the samples, an alternative method shall be implemented to ensure that samples are not mixed with like samples and that the correct identification of samples is verified and documented before the samples are released for use.

Physical identification shall be used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods shall be used whereby identification of samples can be traced to the appropriate documentation, such as drawings, specifications, drilling logs, test records, inspection documents, and NCRs.

Samples shall be stored and maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long-term storage shall receive treatment to ensure that they do not degrade during storage. "Long term" is defined by the scientific investigation planning document for each sample collection case.

Measures shall be taken to maintain sample identification consistent with the planned duration and conditions of storage. Consideration shall be given to the maximum storage life expected of the sample. Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.

LANL procedures shall be based upon the YMP AP describing the ultimate storage of all types of samples, including liquids, gases, and solids. The procedures shall, as a minimum, address the transportation, handling, storage, and retrievability of samples and the generation and retention of records. All records generated as a result of the testing of the samples shall be handled in accordance with Section 17 of this document.

8.2 Identification and Control of Data

The requirements included here shall apply to data generated by a LANL YMP scientific investigation. Data generated by a scientific investigation shall be identified to assist in the determination of their correct use. Identification of such data shall be provided in all documents and information systems in which such data appear. The identification of data shall include a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the QA level assigned to the activity that produced the data.
Control measures shall be implemented to ensure that data are properly identified. These measures shall include verification of the identification of data before their release for use.

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

9.0 CONTROL OF PROCESSES

The requirements for process control shall apply to engineered items and scientific investigations; the requirements for special process control apply to engineered items only that are not a part of the LANL scope-of-work. All processes shall be controlled by instructions, procedures, plans, drawings, checklists, travelers, or other appropriate means to ensure that process parameters are controlled and that specific environmental conditions are maintained.

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10.0 INSPECTION

The requirements of this section of the Project Office QAP apply to engineered items and do not apply to scientific investigation activities.

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11.0 TESTING

LANL does not currently conduct any activities to which testing requirements apply.

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12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Scope of Control Program

Tools, gauges, instruments, fixtures, reference or transfer standards, nondestructive test equipment and other measuring and test equipment used in activities affecting quality shall be controlled. They shall be calibrated and adjusted at specified periods to maintain measurement accuracy within specified limits. The scope and methodology of the control program includes all equipment or systems used to calibrate, measure, gauge, 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. Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy. Procedures shall be established for calibration (technique and frequency), maintenance, and control of measuring and test equipment used for measurement, inspection, and monitoring. The review and documented concurrence of these functions shall be identified in the procedures.

12.2 Description of Responsibilities

All organizations using and calibrating measuring and test equipment shall establish and implement a calibration program through DPs. The QAPL shall be responsible for evaluating each program and for ensuring that it is effective and complies with the QP.

12.3 Program Requirements

Calibration programs shall include specifications for selection, calibration, capability, handling, and storage of measuring and test equipment.

12.3.1 Selection

Selection of measuring and test equipment shall be controlled to ensure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the intended function. The type, range, accuracy, and tolerance of a measuring device shall be specified in DPs, logbooks, instruction books, or other appropriate places. Each device shall have a unique identification number. This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability.

12.3.2 Calibration

Measuring and test equipment covered by these requirements shall be calibrated against certified equipment having known valid relationships to the National Bureau of Standards (NBS) or other nationally recognized standards and shall be calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration shall be specified and documented in a DP, QP, logbooks, or notebooks. Calibrating standards shall have equal or greater accuracy than that required of the equipment being calibrated. Calibrating standards with the same accuracy may be used, provided they can be shown to be adequate for the requirements and that the basis of acceptance is documented and approved by the PI.

12.3.3 Capability

The method and interval of calibration for each item shall be 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 shall be

labeled, tagged, or otherwise documented in a fashion that indicates the due date of the next calibration and that provides traceability to calibration data. If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented that includes the validity of previously obtained results and the acceptability of previous investigations or data-gathering activities of these items since the expiration of the last calibration. Devices that are out of calibration shall be tagged or segregated and shall not be used until they have been recalibrated. If any measuring and test equipment is found to be consistently out of calibration, then it shall be repaired or replaced. During the normal course of an investigation, calibration shall be performed whenever the accuracy of equipment is suspect.

12.3.4 Handling and Storage

Measuring and test equipment shall be handled and stored according to the manufacturer's recommendation or approved procedures to maintain accuracy.

12.4 Records

Records and documents related to calibration activities shall be maintained as specified in this section and the LANL QPs.

Equipment shall be marked to indicate calibration status. Calibration records shall identify the calibration procedure (including revision) used to perform the calibration.

13.0 HANDLING, SHIPPING, AND STORAGE

13.1 General

Work and inspection instructions, drawings, specifications, shipment instructions, or other procedures, shall be established as necessary to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Such instructions shall specify the following:

- special equipment and protective environments,
- specific procedures,
- inspection and testing of any special tools and equipment,
- training of special equipment operators, and
- marking and labeling.

13.2 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) shall be specified in the pertinent instructions provided by the responsible organization, and their existence shall be verified by the QA organization.

13.3 Specific Procedures

When required for critical, sensitive, perishable, or exceptionally expensive articles, DPs shall be written for handling, storage, packaging, shipping, and preservation. DPs shall be subject to LANL QAPL approval.

13.4 Inspection and Testing of Special Tools and Equipment

Any special-handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special-handling tools and equipment shall be inspected and tested in accordance with approved procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.

13.5 Training of Special Equipment Operators

Operators of lifting and special-handling equipment shall be experienced or shall be trained to use the equipment. Verification and documentation of this training shall be maintained as QA records in accordance with LANL QPs.

13.6 Marking and Labeling

Marking and labeling instructions for packaging, shipment, handling, and storage of items shall be specified in LANL DPs to adequately identify, maintain, and preserve the item. Marking requirements for special environments or special controls shall also be specified in LANL DPs.

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14.0 INSPECTION, TEST, AND OPERATING STATUS OF ENGINEERED ITEMS

The Project Office QAP requirements of inspection, test, and operating status apply to engineered items and do not apply to scientific investigations.

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15.0 CONTROL OF NONCONFORMANCES

15.1 General

Measures shall be established to control nonconforming items and activities and to prevent their inadvertent installation, use, or performance. These measures shall include the use of documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All LANL YMP personnel shall be responsible for reporting nonconformances in accordance with their approved procedures for nonconformance control. These procedures shall be consistent with the requirements discussed below.

15.2 Identification

Identification of nonconforming items shall be made by marking, tagging, or other methods that do not adversely affect the end use of the item. The identification shall be legible and easily recognizable and shall contain the NCR number. The method for tracking the NCR status and QA organizational responsibilities shall be clearly stated in a QP. Internal and external interfaces shall be clearly defined.

15.3 Nonconformance Control Log

Nonconformances shall be tracked in a nonconformance control log that contains the following information:

- the NCR number (a sequential number preceded by "LANL"),
- a brief description of the nonconforming condition,
- identification of the person or organization responsible for determining and carrying out the nonconformance disposition, and
- the status of each NCR (open or closed).

15.4 Segregation

When practical, nonconforming items shall be segregated by placing them in a clearly identified and designated holding area until their dispositions are accomplished. When segregation is impractical or impossible because of physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of nonconforming items. Tags shall be permitted if they are securely attached to the items, or the items shall be placed within a unique storage area if a place is so designated. Segregation is not applicable to nonconforming activities.

15.5 Disposition

Processing, delivery, installation, use, or performance of a nonconformance shall be controlled pending an evaluation and approved disposition by authorized personnel. Recommended dispositions of nonconforming items shall be proposed, reviewed, and approved in accordance with documented procedures. Nonconformance documentation shall be distributed to all affected organizations upon issue and closure.

15.5.1 Responsibility and Authority

The organization using or producing the nonconformance shall be responsible for its evaluation, disposition, and close-out. Those persons who are assigned signature approval of the disposition shall be identified in the QP. The QA responsibilities shall include approval of the disposition and verifying closeout of nonconformances.

15.5.2 Personnel

Persons selected to evaluate nonconformances to determine a disposition shall have demonstrated competence in the specific area under evaluation and an adequate understanding of the requirements and shall have access to pertinent background information.

15.5.3 Disposition of the NCR

Persons responsible for dispositioning the NCR shall ensure that the following requirements are met.

- Nonconformance documentation shall adequately identify and describe the nonconformance.
- Appropriate justification for the disposition shall be documented. In the case of use-as-is or repair dispositions of the item, technical justification shall be required. Such dispositions shall require the approval of the appropriate YMP Branch Chief and the PQM prior to implementation. The records of as-built items, if such records are required, shall reflect the accepted deviation.
- The NCR shall refer to any approved design documents, procedures, plans, work orders, etc., to be used for the correction of the nonconforming condition.
- The technical details for correction of the nonconforming condition shall be adequate for the recommended disposition.
- If continuance is requested, justification for the continuance will be documented and then approved by the TPO, QAPL, PQM, and YMP Branch Chief.
- The disposition shall comply with existing design documents, test plans or procedures, reports, and regulatory requirements.
- If a change is appropriate to reflect the as-built condition of an item, then the disposition shall address the action needed to change the existing design documents, test plans or procedures, reports, etc. Any documents changed shall have a cross reference on the NCR.
- The disposition shall identify and document the correction as repair, rework, use-as-is, or reject/scrap.
- The disposition shall identify the personnel responsible for implementing the disposition.
- The disposition shall describe the cause of the nonconforming condition.
- The disposition shall document action needed to preclude recurrence of the nonconforming condition.

15.5.4 Project Office Notification

Copies of NCRs shall be sent to the PQM upon issuance and closure.

15.5.5 Corrective Action

Action taken to correct the nonconformance shall be verified and documented. Repaired or reworked items shall be re-examined in accordance with applicable procedures and with the original acceptance criteria, unless the disposition has established alternate acceptance criteria.

15.6 Conditional Release

Work on a nonconformance shall be stopped until the NCR disposition is complete. If only a specific portion of an item or activity is in nonconformance, then that specific portion shall be identified and work may proceed on the remaining areas or subtasks. However, work on a nonconformance may

TPO, PQM, and YMP Branch Chief. Requests for conditional releases on nonconformance shall document that the following conditions are met:

- the nonconformance can be removed or corrected at a later date without damage to, or contamination of, the associated permanent facility equipment or structures;
- if the nonconformance is related to an item, the item shall remain accessible for inspection;
- the nonconformance shall have been evaluated and limitations for use of the equipment or system established; and
- traceability and identification of the nonconformance shall be maintained.

15.7 Nonconformances and Trending

The NCRs shall be periodically analyzed by the QA organization to establish quality trends and to help identify root causes of nonconformances. The results shall be reported to the TPO and QAPL for review and assessment. When repetitive or recurring nonconforming conditions are identified (as a trend), an evaluation shall be made as to whether further programmatic corrective action (Section 16) is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition of the existing NCRs and shall be processed in accordance with LANL corrective action procedures.

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16.0 CORRECTIVE ACTION

16.1 General

The corrective action system shall ensure that repetitive nonconformances and/or conditions adverse to quality, including supplier nonconforming activities and services, shall be identified promptly, documented on corrective action reports, and corrected as soon as practical.

16.2 Significant Adverse Conditions

For significant conditions adverse to quality, the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment. Assessment may result in a stop work order. A significant condition adverse to quality is one that, if not corrected, could have a serious effect on safety or operability. Significant conditions shall include, but shall not be limited to, breakdowns in the QA Program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality exists, LANL shall ensure that

- immediate action has been taken to remedy the specific condition(s);
- any root cause has been determined;
- controls are reviewed, implemented, monitored, and revised, if necessary; and
- affected managers at all levels are notified of the adverse condition(s) and of additional training, if necessary, to improve conditions or to avoid similar occurrences.

16.3 QA Follow-Up Action

The QA organization shall document concurrence with the adequacy of proposed corrective actions to ensure that QA requirements are met. Follow-up action shall be taken by the QA organization to verify proper implementation of the corrective action, to document its acceptance, and to close-out the action. The organization responsible for implementing the corrective action shall ensure that the corrective action is completed in a timely manner. Failure to properly complete corrective action steps in a timely manner may result in a stop work order.

16.4 Corrective Action Reports

The QA organization shall periodically analyze corrective action reports to establish quality trends. The results shall be reported to the TPO and QAPL for review and assessment. Copies of corrective action reports shall be sent to the PQM by the QAPL upon issue and closure.

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17.0 RECORDS

17.1 General

Records that furnish evidence of quality shall be specified, prepared, and maintained in accordance with QPs that meet the requirements of this section. Records management QPs shall be issued at the earliest practical time consistent with the schedule and work activities. The term "records" used in this section means QA records.

17.2 Management, Control, and Preservation of Records

QPs shall be consistent with the Project Office AP-1.7Q, YMP QA Records Management. Responsibilities and methods for record transmittal, distribution, retention, maintenance, retrievability, and status of QA records shall be specified in the QPs.

QPs shall define the implementation of the record system and shall identify measures for the prevention of delays between record completion and storage at the LANL Records Processing Center (RPC) and for the preservation and safekeeping of the records.

For purposes of record retention, all LANL YMP records, including superseded records, shall be classified as lifetime records and shall be retained for the life of the LANL YMP.

17.3 Minimum Records

Sufficient records shall be specified, prepared, and maintained to furnish evidence of the activities that affected quality. All operating logs and the results of reviews, receipt inspections, audits, monitoring of work performance, materials analysis, qualifications of personnel, and procedures shall be maintained as QA records. Final reports shall contain a listing, by unique number, that enables prompt retrieval of all documents used to compile or evaluate the reports. This listing shall include all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and plans. All documents referenced by final reports, except references readily available to the public, shall be retrievable from the LANL RPC. A list of typical QA records is contained in Appendix E.

17.4 Generation of Records

A document is not considered to be a QA record until it satisfies the definition of a QA record (Appendix A). Records to be generated, supplied, or maintained by or for LANL shall be specified in design documents, procurement documents, implementing procedures, or other documents. Records shall be legible, identifiable, accurate, complete, reproducible on microfilm and other media, and appropriate to the work accomplished. A completed record is defined as a record that will either receive no more entries or whose revision would normally consist of the reissue of the record and that is signed and dated by the originator and, as applicable, by personnel authorized to approve the record. Records shall be completed in accordance with LANL QPs and DPs.

17.5 Validation and Authentication of Records

Records shall be considered valid only if stamped, initialed or signed, and dated by authorized persons or otherwise authenticated in accordance with QPs. Validated records may be originals or reproduced copies.

Record authentication may be a statement by the responsible individual or organization. Handwritten signatures are not required if the record is clearly identified as a statement by the reporting individual

or organization. LANL shall maintain a list that contains the signature and initials of the persons authorized to authenticate records.

17.6 Receipt of Records

Each LANL organization that is responsible for the receipt of records shall designate a person to be responsible for receiving the records. The designee shall be responsible for organizing and implementing a system for receipt control of records for dual storage. The receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process. The receipt control system shall include the following:

- a method for designating the required records,
- a method for identifying the records received,
- a method for acknowledging receipt, and
- procedures for receipt and inspection of incoming records.

LANL organizations responsible for receiving records shall provide protection from damage, deterioration, or loss during the time that the records are in their possession. Each LANL group shall process its records and transfer them to the LANL RPC for further processing and transfer to the Project Office without unnecessary delays.

17.7 Records Identification

The YMP-approved indexing system shall identify the connection between the record and the item or activity to which it applies. Records shall be identified by a unique number or other designation that is directly traceable to controlling program information (e.g., project, contract number, task number, preparing organization, author, date, title, and subject). This identification number or other designation shall not be repeated anywhere in the YMP. The indexing system shall include the location of the record within the records system.

17.8 Storage of Records

Records shall be controlled from the time they are completed until the time they are stored in a permanent storage facility. Temporary storage, preservation, safekeeping, and retrievability of completed records shall be done in accordance with a QP describing the permanent storage of records. The QP shall include 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,
- the rules governing access to and control of the files including retrieval times,
- the method for maintaining control of and accountability for records removed from the storage facility, and
- a method for filing supplemental information.

17.8.1 Responsibilities

The RPC shall be responsible for ensuring that the requirements of QPs for the storage of records are met.

17.8.2 Storage Facilities

Methods for the permanent and temporary storage of records and documents shall be stated in QPs. Records and documents shall be stored in dual 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; infestation of insects or rodents; or mold. The dual facilities shall be predetermined locations sufficiently remote from each other to reduce the chance of simultaneous exposure to a hazard.

17.8.3 Preservation

Records shall be stored in a manner approved by the QAPL. Deterioration of the records shall be precluded by the following.

- Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.
- Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or shall be placed in containers and stored on shelves.
- Special-processed records (radiographs, photographs, negatives, microfilm, magnetic material, etc.) shall be protected from damage caused by excessive light, stacking, electromagnetic fields, temperatures, and humidity.

17.8.4 Safekeeping

The QP shall include safekeeping measures to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.

17.8.5 Replacement, Restoration, or Substitution

Lost or damaged records shall be replaced, restored, or substituted within ninety days of the discovery of the loss or the determination that the damaged record is incomplete or illegible.

17.9 Corrected Information in Records

Records shall be corrected in accordance with LANL QPs that stipulate appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction and shall not obliterate the corrected data.

17.10 Access to QA Records

A list shall be maintained that designates those personnel who have access to the QA record files. Records maintained by LANL at LANL or at any other location (on an interim or other basis) shall be accessible to the Project Office or its designated alternate.

17.11 Transfer of QA Records

The RPC shall review each group's records turnover and shall acknowledge receipt of, inventory, and transfer the records to the Project Office.

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18.0 AUDITS

18.1 General Requirements

All LANL YMP activities are subject to scheduled and planned internal and external audits to ensure that procedures and activities comply with the overall QA Program and to determine the program's effectiveness. The audits shall be performed using check lists in accordance with QPs. Qualified personnel who do not have direct responsibility for performing the activities being audited shall conduct the audits. Audit results, including deficiencies, nonconformances, and potential quality problems, shall be documented and monitored, reviewed by the QAPL, reported to the TPO, and monitored until verification of effective corrective action is made. On the form supplied by the audit organization, the audited organization shall describe the corrective action to be taken to address findings and shall submit the completed form to the QAPL and the audited organization's own management. The audit organization shall track audit findings to ensure that all findings are properly closed and to identify quality trends.

Audits shall be performed by the QA support (QAS) and shall include follow-up action, verification of corrective action, or reaudit of specific areas.

18.2 Audits

LANL shall conduct internal and external audits of activities under its direct control and shall not conduct audits of other participating organizations. These audits shall be scheduled, planned, conducted, and reported as described below and in accordance with QPs.

18.2.1 Scheduling

Internal and external QA audits shall be scheduled annually (date, activity, and requirements) to provide complete coverage of QA Program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity and initiated early enough in the activity to ensure effective QA. The audit schedule shall be prepared annually and evaluated periodically and revised as necessary to ensure that coverage is maintained current. Revisions of the audit schedule shall be documented. LANL shall perform or arrange for annual evaluations of suppliers. This evaluation shall be documented and shall take into account, where applicable, (1) review of suppliers' 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, American Society of Mechanical Engineers, or NRC audits. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. The audit schedule, including dates and any revisions thereof, shall be sent to the PQM. The audit schedule shall identify the date of the audit, the activities to be audited, and the requirements to which the activities will be audited.

18.2.2 Internal Audits

All applicable elements of LANL's internal QA Program shall be audited at least annually or 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 the QA Program.

18.2.3 External Audits

Applicable elements of an external organization's QA Program shall be audited at least annually or once during the life of the activity, whichever is the shorter period. Exception: If the activity is less than four months in duration, an audit is not required unless it is necessary because of 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 shall be documented, approved by the QAPL, and sent to the PQM.

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 shall satisfy the needs of all of the purchasers, and the audit report shall be 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.

18.2.4 Audit Plan

An audit plan shall be developed and documented for each audit. This plan identifies the audit scope, audit requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and checklists.

18.2.5 Audit Personnel

Auditors shall be independent of any direct responsibility for the performance of the activities that they are to audit. If the audit is internal, the personnel who have direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team. Auditors shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA auditors.

An audit team shall be identified before the beginning of each audit. This team shall contain one or more auditors, one of whom is qualified as a lead auditor, to organize and direct the audit, to coordinate the preparation and issue of the audit report, and to evaluate the responses. The audit team leader identifies technical specialists (if they are necessary) and includes their names in the audit plan. The technical specialists shall have appropriate technical expertise or experience in the work being audited and shall be independent from the work performed. Multidisciplinary teams shall be used when more than a single technical area is to be audited. The audit team leader shall ensure that the audit team is prepared before the audit begins.

18.2.6 Performance

Audits shall be performed using checklists as early in the life of the activity as practicable and shall be continued at intervals consistent with the schedule for accomplishing the activity. The elements selected for an audit shall be evaluated against specified requirements, including a review of any corrective actions taken on deficiencies identified during previous audits in the area being audited. Objective evidence shall be evaluated to determine whether the selected elements are effective and are being implemented properly. The audit results shall be documented by auditors and shall be reviewed by the management responsible for the area audited. Conditions that require prompt corrective action shall be reported

immediately to the management of the audited organization. Audit findings shall be reviewed with the audited organizations at the closing meeting.

18.2.7 Reporting

The audit report shall be signed by the audit team leader and shall be issued to the audited organization within thirty calendar days of the audit in accordance with LANL QPs. The audit report shall include the following information, as appropriate:

- a description of the audit scope;
- identification of the auditors;
- identification of persons contacted during audit activities;
- a summary of audit results, including an evaluation of the effectiveness of the QA Program elements that were audited; and
- a description of each adverse audit finding in sufficient detail to enable the audited organization to take corrective action.

18.2.8 Response

Line management of the audited organization or activity shall investigate any audit finding, shall determine any root cause, shall schedule corrective action that include measures to prevent recurrence, and shall notify the QAS in writing of action taken or planned within thirty calendar days of receipt of the audit report. The adequacy of audit responses shall be evaluated by the QAS.

18.2.9 Follow-Up Action

Follow-up action, including reaudits of specific areas, shall be taken to determine whether corrective action has been accomplished as scheduled and shall be verified by the auditing organization. Audit results shall be analyzed by QAS to identify quality trends. The results of the analysis shall be reported to responsible management for review, assessment, and appropriate action.

18.2.10 Records

Audit records shall include

- identification of the organizations, activities, or items audited and the individuals contacted during the audit;
- a description of any deficiencies, nonconformances, or potential quality problems; and
- audit plans, audit reports, written replies, and the record of completed corrective actions and close-out of the audit.

Qualification records for auditors and lead auditors shall be established and maintained. Records for all auditors shall be updated annually.

18.3 Surveys

The audit program shall be supplemented by survey activities. The purpose of a survey shall be to monitor or observe items or activities to verify conformance to specified requirements. These surveys may be conducted by the QAS and/or a QAL on a scheduled and/or random basis.

Surveys shall be conducted in accordance with QPs. Surveys shall be scheduled and conducted based on the activity's relative effect on or importance to the YMP. All deficiencies, nonconformances, and potential quality problems identified during surveys shall be documented and monitored to ensure and verify that effective corrective action is made.

18.3.1 Planning

Surveys shall be performed according to written checklists or plans whenever practical. The planning documentation shall identify characteristics; define methods and acceptance criteria; and provide for the recording of objective evidence of results and the accuracy of the equipment necessary to perform the survey. Acceptance criteria related to surveillances may be as simple as to verify proper implementation of procedures or to verify conformance to requirements.

18.3.2 Reporting Independence

Survey personnel shall not report directly to the immediate supervisors who are responsible for the work being surveyed.

18.3.3 Records

Survey reports shall include the following:

- the identification of the organizations, activities, or items surveyed, including the names of persons contacted;
- the date of the survey;
- the name of the individual performing the survey;
- the survey criteria;
- any equipment used during the survey;
- a description of any deficiencies, nonconformances, and potential quality problems identified during the survey (nonconformances shall be handled per QAPP Section 15 or 16, as applicable);
- the survey results; and
- an acceptance statement related to the effectiveness of the QA Program as surveyed.

APPENDIX A

TERMS AND DEFINITIONS

ACCEPTANCE CRITERIA: Specified limits that are defined in codes, standards, or other requirements documents and placed on the 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 area.

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The Project Office QA Program 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 QA Program 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 shall be 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) that influences or affects the achievement or verification of the objectives of the YMP as depicted in the WBS.

AP (YMP ADMINISTRATIVE PROCEDURE): An implementing procedure that identifies the interface control methods that govern Project-wide systems and are implemented by all Project participants. APs that implement QA requirements are identified with a "Q" suffix (i.e., AP-1.1Q).

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) issuance of a document that is clearly identified as a statement by the reporting individual or organization. A document cannot become a 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 a 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 life cycle; (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:

- The item is not subject to design or specification requirements that are unique to mined geologic disposal systems.
- 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).
- The item is used in applications other than mined geologic disposal systems.

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 with a hand calculation, to an analytical solution or approximation, or to a verified code designed to perform the same type of analysis (e.g., benchmarking).

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

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) and usually accomplished by comparing code results with physical data or with 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.

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 that, if not corrected, could have a serious effect on safety or operability.

CONFIGURATION MANAGEMENT: As used for computer software: (1) a system for the 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: 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 ensuring 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 extends horizontally no more than five 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 that needs to be considered in the design of a geologic repository.

DESIGN: The act of developing designs for construction or of analyzing the performance of 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 requirements upon which the detailed final design is based.

DESIGN OUTPUT: Documents, such as drawings and specifications, 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.

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

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 QA record until it satisfies the definition of QA 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 do not include information that is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws.)

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 Office of Geologic Repositories Program or other Federal regulatory documents.

GEOLOGIC REPOSITORY: A system that is either intended to 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: 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 for 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 10 CFR 60, Subpart E.)

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

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

INSPECTOR: A person who performs inspection activities to verify whether or not 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: QA records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All YMP QA records are classified lifetime records.

LOGBOOK: A document that may be used to provide a written record of repetitive activities performed in accordance with technical procedures. Examples include calibration, data runs, and inventory of controlled materials.

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 YMP. Hardware and geologic specimens include, but are not limited to, test apparatus or equipment, special nuclear material, cores, geologic samples, and water and gas samples.

MEASURING AND TEST EQUIPMENT: Devices or systems used to calibrate, measure, gauge, 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.

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.

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

NONMECHANISTIC FAILURES: Postulated failures that are not based on previously observed models or mechanisms but that are assumed to provide conservatism in safety assessments.

NUMERICAL METHOD: A procedure for solving a problem primarily by a sequence of arithmetic operations.

NUMERICAL MODEL: A representation of a process or system using numerical methods.

NEVADA TEST SITE SUPPORT CONTRACTOR: Organizations that are directly under contract to DOE/NV for activities at the Nevada Test Site 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 the emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes the sealing of shafts.

OVERVIEW: An analysis and assessment by management of the scope, status, adequacy, and effectiveness of the quality achievement and assurance activities for the YMP. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveys, 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 YMP 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 those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgement to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art. 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 adequacy 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 or 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 proceedings 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.

PERFORMANCE CONFIRMATION: The program of tests, experiments, and analyses that will 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.

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

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable QA Level I requirements and that is necessary for the resolution of the NRC performance objectives of 10 CFR 60 in accordance with the YMP Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with Project Office AP-5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the YMP QA Program."

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 depending upon the YMP participant.

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

PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means for acquiring 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, 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 10 CFR 60, Subpart G, QA 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 characterization, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

QUALITY ASSURANCE (QA): 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 RECORD: An individual document or other item that has been executed, completed, and approved and that furnishes evidence of the (1) quality and completeness of data (including raw data), items, and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of 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 that must meet the criteria that address postclosure 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 10 CFR 60 and 40 CFR 191.

QUALITY ASSURANCE LEVEL II: Those activities and items related to the systems, structures, and components that require a level of QA 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 YMP 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 QA Program and the applicable QA requirements and that defines how compliance with the QA criteria will be accomplished.

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 and to ensure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of a 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, survey, or QA 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 that are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation, and 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, undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the procedures under 10 CFR 60. Site characterization includes borings, surface excavations, excavation of 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.

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.

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process, 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/NV, to a participating organization, or to a Nevada Test Site support contractor for YMP activities.

SURVEY: 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 YMP participant's organization who has been assigned overall responsibility for the organization's scope or work as detailed in the WBS.

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 track 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.

TRAVELER: A document that accompanies and tracks the progress of an item, sample, or activity.

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

UNRESTRICTED AREA: Any area to which access 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 items, processes, services, or documents conform to specified requirements.

WAIVER: Documented authorization to depart from specified requirements.

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE: The organization to which the DOE/NV has assigned the responsibility of administering and coordinating the activities of various participating organizations and Nevada Test Site support contractors associated with the YMP.

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT PARTICIPANTS: An all-inclusive term used to describe (generically) the various organizations involved in the YMP. This term includes the Project Office, participating organizations, and Nevada Test Site support contractors. These contractors are required to have a Project Office-approved QAPP for the conduct of their activities.

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT PERSONNEL: All DOE participating organizations and Nevada Test Site support contractor personnel involved in YMP activities.

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic QA requirements that are applicable to the YMP.

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT WORK BREAKDOWN STRUCTURE (WBS) DICTIONARY: A controlled document that establishes a product-oriented framework for organizing and defining work to be accomplished.

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

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APPENDIX B

B.0 DESIGN INPUTS

B.1 Introduction

Design inputs include many characteristics and functions of an item or system. For a more detailed discussion on design control activities, see QAPP Section 3.

B.2 Applicable Design Inputs

Applicable design inputs are identified and documented, and their selection is reviewed and approved by the responsible design and QA organizations. The purpose of the QA review is to ensure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements. Changes in approved design inputs, including the reason for the changes, are identified, documented, approved, and controlled by the responsible design organization. Although these inputs vary depending on the application, LANL or its subcontractor will consider the following list of inputs as they apply to specific items or systems of the repository:

- basic functions of each structure, system, and component;
- performance requirements such as capacity rating and system output;
- codes, standards, and regulatory requirements, including the applicable issue, agenda, or both;
- design conditions such as pressure, temperature, fluid chemistry, and voltage;
- loads such as seismic, wind, thermal, and dynamic;
- environmental conditions anticipated during storage, construction, and operation, including pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure;
- interface requirements, including definition of the functional and physical interfaces involving structures, systems, and components;
- material requirements, including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance;
- mechanical requirements such as vibration, stress, shock, and reaction forces;
- structural requirements covering such items as equipment foundations and pipe supports;
- hydraulic requirements such as pump net positive suction heads, allowable pressure drops, and allowable fluid velocities;
- chemistry requirements, including provisions for sampling and limitations on water chemistry;
- electrical requirements such as source of power, voltage, raceway requirements, electrical insulation, and motor requirements;
- layout and arrangement requirements;
- operational requirements under various conditions, including repository start-up, normal repository operation, repository emergency operation, special or infrequent operation, system abnormal or emergency operation, and repository decontamination, decommissioning, and dismantling;
- 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);

- access and administrative control requirements for repository security;
- redundancy, diversity, and separation requirements of structures, systems, and components;
- requirements for failure effects of structures, systems, and components, including a definition of those events and accidents that these structures, systems, and components must be designed to withstand;
- test requirements, including preoperational and subsequent periodic in-service tests and the conditions under which these tests will be performed;
- accessibility, maintenance, repair, and in-service inspection requirements for the repository, including the conditions under which these inspections will be performed;
- 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;
- transportability requirements, including size and shipping weight, limitation, and Interstate Commerce Commission regulations;
- fire protection or resistance requirements;
- handling, storage, cleaning, and shipping requirements;
- other requirements to prevent undue risk to the health and safety of the public;
- materials, processes, parts, and equipment suitable for application;
- safety requirements for preventing injury to personnel, including radiation safety to restrict the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems;
- quality control and QA requirements;
- reliability requirements of structures, systems, and components, including their interactions, which may impair functions that are important to safety;
- interface requirements between repository equipment and operation and maintenance personnel; and
- requirements for criticality control and accountability of nuclear materials.

APPENDIX C

C.0 REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL

LANL does not currently conduct any YMP activities to which these requirements apply.

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APPENDIX D

D.0 REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

LANL does not currently conduct any YMP activities to which these requirements apply.

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APPENDIX E

E.0 LIST OF TYPICAL QUALITY ASSURANCE RECORDS

The following is a list of typical LANL YMP QA records. The YMP retention period for these records is defined as lifetime. QA records shall be specified, prepared, and maintained in accordance with QAPP Section 17 and the LANL QPs. In addition, the control of QA records shall comply with the applicable requirements of Project Office AP-1.7Q, "Yucca Mountain Project QA Records Management."

E.1 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.
- Data reduction, evaluations, analyses, and reports for
  - — Geomorphology.
  - — Stratigraphy.
  - — Tectonics.
  - — Seismicity.
  - — Geoengineering.
  - — Hydrology.
  - — Geochemistry.
  - — Climatology and Meteorology.
- Environmental Impact Statement.
- Environmental Report.

E.2 Design Records

- Applicable codes and standards used in design.
- Design drawings.
- Design calculations and records of checks.
- Approved design change requests.
- Design deviations.
- Design reports.
- Design verification data.
- Design specifications and amendments.
- Safety analysis report.
- Stress reports for code items.
- Systems descriptions.
- Systems process and instrumentation diagrams.
- Technical analysis, evaluations, and reports.

E.3 Procurement Records

- Procurement specifications.
- Purchase order including amendments.

E.4 Manufacturing Records for Procured Equipment

- Applicable code data reports.
- 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.)
- Certificate of compliance.

E.5 Installation and Construction Records

E.5.1 Receiving and Storage - Nonconformance Reports

E.5.2 General

- Scientific investigation planning documents.
- QA level assignment documents.
- Review and approval documents including comments and resolution.
- Data interpretation and analysis documents.
- Software configuration management, including software QA requirements in accordance with Section 3.3 of this QAPP.
- Scientific notebooks and logbooks.
- Detailed technical procedures.
- Audit and survey documentation.
- Verification documentation.
- Recommendations.
- Close-out verification.
- Personnel qualification documents.
- Peer reviews.
- Design analysis.
- Design change control.
- Anomalous conditions encountered.
- Nonconformance reports.
- Corrective action reports.
- Audit reports.
- Trending reports.

APPENDIX F
F.0 REQUIREMENTS FOR THE QUALIFICATIONS OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

F.1 Introduction

All LANL YMP activities are subject to scheduled and planned internal and external audits to ensure that procedures and activities comply with the overall QA Program and to determine the program's effectiveness. This appendix provides requirements for the qualification of lead auditors. A lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions. This appendix also provides amplified requirements for the qualifications of individuals, hereinafter referred to as auditors, who participate in an audit, including technical specialists, management representatives, and auditors-in-training.

F.1.1 Qualification of Auditors

LANL and its subcontractors will establish the qualifications for audit personnel and the requirements for the use of technical specialists to accomplish the auditing of QA Programs. Personnel selected for QA auditing assignments will have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors will either have or will be given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions will be developed by one or more of the methods listed below.

F.1.1.1 Orientation

Orientation will provide a working knowledge and understanding of this document and procedures used by LANL and its subcontractors for implementing audits and reporting results.

F.1.1.2 Training Programs

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

F.1.1.3 On-the-Job Training

On-the-job training, guidance, and counseling will be under the direct supervision of the lead auditor. Such training will include planning, performing, reporting, and follow-up action involved in conducting audits.

F.1.2 Qualification of Lead Auditors

An individual will meet the requirements listed below before being designated a lead auditor.

F.1.2.1 Communication Skills

The prospective lead auditor will have the capability to communicate effectively, both orally and in writing. These skills will be attested to in writing by LANL.

F.1.2.2 Training

Prospective lead auditors will have training to the extent necessary to ensure their competence in auditing skills. Training will be given in the following areas based upon management evaluation of the particular needs of each prospective lead auditor:

- knowledge and understanding of this document, 10 CFR 60, and other nuclear- and/or DOE-related codes, standards, regulations, and regulatory guides, as applicable to the YMP;
- general structure of QA 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 procedures for 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, including applicable elements of the audit program.

F.1.2.3 Audit Participation

The prospective lead auditor will have participated in a minimum of five QA audits within a period of time not to exceed three years before the qualification date. One of the audits will be a nuclear facility QA audit that will be made within the year before qualification.

F.1.2.4 Examination

The prospective lead auditor shall pass an examination that shall evaluate his comprehension of, and ability to apply, the body of knowledge identified in Paragraph F.1.2.2 of this appendix. 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 shall be maintained. The development and administration of the examination shall be in accordance with Section F.3 of this appendix.

F.2 Maintenance of Qualification

F.2.1 Maintenance of Proficiency

Lead auditors will 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 a QA Program and program auditing; and participation in training programs. Based on an annual assessment, LANL may extend the qualifications, require retraining, or require requalification. These evaluations will be documented.

F.2.2 Requalification

Lead auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification will include retraining in accordance with the requirements of Subsection F.1.2.2 of this appendix, re-examination in accordance with Subsection F.3.2 of this appendix, and participation as an auditor in at least one nuclear facility QA audit.

F.3 Administration

F.3.1 Organizational Responsibility

Training of auditors will be LANL's responsibility. LANL or its subcontractors will select and assign personnel who are independent of any direct responsibility for the performance of the activities that they will audit. The lead auditor will, before commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

F.3.2 Qualification Examination

The development and administration of the examination for a lead auditor required by Subsection F.1.2.4 of this appendix is LANL's responsibility. LANL may delegate this activity to an independent certifying agency but will retain responsibility for the examination and its administration for conformance to this document. The integrity of the examination will be maintained by LANL or by a certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. LANL will retain copies of the objective evidence regarding the type or types and content of the examination or examinations.

F.4 Certification of Qualification

Each lead auditor will be certified by LANL as being qualified to lead audits. As a minimum, this certification will document the following:

- the employer's name;
- the lead auditor's name;
- the date of certification or recertification;
- the basis of qualification (i.e., education, experience, communication skills, training, and examination); and
- the signature of LANL's designated representative who is responsible for such certification.

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APPENDIX G

G.0 REQUIREMENTS FOR QUALIFICATION OF EXISTING DATA NOT GENERATED UNDER A QUALITY ASSURANCE PROGRAM MEETING THE REQUIREMENTS OF 10 CFR 60, SUBPART G

G.1 General

This appendix provides the requirements for the qualification for 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 10 CFR 60, Subpart G.

G. 2 Methods for Qualification of Existing Data

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

- The execution of the peer review process in accordance with the requirements of Appendix J of this QAPP.
- The use of corroborating data that are defined as existing data used to support or substantiate other existing data. Inferences drawn to corroborate the existing data shall be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it developed and the number of independent data sets. The amount of corroborating data needed shall be dealt with on a case-by-case basis in the documented reviews for qualifications.
- The use of confirmatory testing, which is defined as testing conducted under a 10 CFR 60, Subpart G, QA Program that investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing database. 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 that generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but that still investigates the same parameter of interest. The amount of confirmatory testing required shall be dealt with on a case-by-case basis in the documented reviews for qualification.
- Demonstrating that the existing data were collected under a QA Program equivalent to a 10 CFR 60, Subpart G, QA Program.

G.3 Selection and Documentation of Qualification Methodology

When the methods indicated in the last three bullets of Section G.2 are utilized to qualify existing data, a technical review shall be conducted to support the quality of the data. Additional confidence/credibility can be achieved when a combination of methods is used.

Documentation of the decision process shall provide 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 shall be commensurate with the intended use of the data. Attributes which shall be considered in the qualification process are

- Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G, program.
- The technical adequacy of equipment and procedures used to collect and analyze the data.
- The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).

- The environmental conditions under which the data were obtained, if germane to the quality of data.
- The quality and reliability of the measurement control program under which the data were generated.
- The extent to which conditions under which the data were generated may partially meet Subpart G.
- Prior uses of the data and associated verification processes.
- Prior peer or other professional reviews of the data and their results.
- Extent and reliability of the documentation associated with the data.
- Extent and quality of corroborating data or confirmatory testing results.
- The degree to which independent audits of the process that generated the data were conducted.
- The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.
- 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).

APPENDIX H

H.0 REQUIREMENTS FOR COMPUTER SOFTWARE

H.1 Objectives and Scope

The purpose of this appendix is to describe the requirements for the development, management, control, and documentation of the software used to support the LANL YMP. The software requirements of this appendix are intended to ensure software quality and to provide the NRC with part of the basis on which it will evaluate the soundness of the software used.

This appendix supplements and shall be used in conjunction with Section 3.3 of the QAPP. Appendix A contains the definitions for the terms used in this appendix.

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. LANL shall prepare QPs that ensure the requirements of this appendix are implemented in a consistent and systematic manner. The extent to which these requirements apply is related to the nature, complexity, and importance of the software applications and are defined in LANL's Software QA Plan (SQAP).

H.2 Verification and Validation

Verification and validation methodologies will be described in the SQAP. QPs will be used to implement the chosen methodology. Verification and validation of software shall be performed before 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 that have not been verified or validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed before relying on the software to support the license application.

H.2.1 Software Verification

Verification plans shall use methods such as analyses, demonstrations, and test runs to ensure that the software adequately and correctly performs all intended functions and to provide confidence that it does not perform any function that, either by itself or in combination with other functions, could degrade the entire system.

Verification activities shall be performed according to QPs and relative to specific hardware configurations prior to the use of the software in support of the license application. The amount of verification activity shall be determined by the type and complexity of the software. The results of verification shall be documented according to the QP.

H.2.2 Model Validation

Model validation activities shall be performed according to QPs and will demonstrate that the models embodied in computer software are adequate representations of the process or system for which they are intended. Validation shall be accomplished by comparing software results with verified and traceable data obtained from laboratory experiments, field experiments or observations, or *in situ* testing. Specific sets of data used in the validation process shall be identified, and justification for their use shall be documented. When data are not available

from the sources mentioned above, alternative approaches may be used and shall be documented. Alternative approaches may include peer review and comparisons with the results of similar analyses performed with verified software. The results of model validation, including an evaluation of the degree of validity of the model, shall be documented in accordance with the QP.

Model validation shall be accomplished prior to the use of the software-generated data in final reports used for licensing. Data generated prior to model validation may be used in reports with the designation that the data was generated using models that have not been validated.

H.3 Software Configuration Management

A software configuration management system shall be described in the SQAP with implementation direction contained in QPs to ensure positive identification of software and control of all software baseline changes and provide appropriate documentation to the YMP local records center.

H.3.1 Configuration Identification

Software configuration baseline items shall be identified at the appropriate phase of each code's software life cycle. Approved changes in a baseline shall be added to the baseline as updates. A baseline and its updates shall specify the most recent software configuration. A labeling system for configuration items shall be implemented that

- uniquely identifies each software configuration item or version identifier,
- identifies changes in software configuration items by revision identifiers, and
- facilitates placement of the software configuration item in a relationship with other configuration items.

H.3.2 Configuration Change Control

Changes in software configuration items shall be formally controlled and documented. This documentation shall contain a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The change will be formally evaluated by a qualified individual or organization with the ability to approve or disapprove the proposed change. Assurance shall be provided that only authorized changes are made in software baselines and software configuration items.

H.3.3 Configuration Status Accounting

The information needed to manage software configuration items shall be recorded and reported. This information shall include the approved configuration identification, the status of formal proposals for changes in software configuration items, the implementation status of approved changes, and all information to support the functions of configuration identification and configuration control.

H.4 Discrepancy Reporting and Corrective Action

QPs shall be prepared to describe the software discrepancy and corrective action reporting system. This discrepancy reporting system shall be integrated with the configuration management system to ensure formal processing of discrepancy resolutions.

Software discrepancy procedures shall ensure 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 in software configuration items are entered in baselines, and
- preventive and corrective actions provide for appropriate notification of organizations to which controlled copies have been distributed.

H.5 Media Control and Security

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

H.6 Software Acquisition, Procurement, and Transfer

Procedures shall be 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 LANL groups shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QAPP. Requirements not satisfied at the time the software is received shall be completed by the organization in the appropriate phase of the applicable software life cycle. For those requirements that are not satisfied, the reasons shall be documented and distributed to the users.

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

Configuration management change controls shall be established for documenting the conversion of software to be used on a computer system, and/or peripheral hardware, other than that for which it was designed. Conversion includes all modifications and tests made to input/output or the source code or additional software written to run the original software on the new system. Software conversion shall be documented and maintained for the specific version of the software and the computer system on which it is installed. Software conversion changes shall be evaluated and activities performed in accordance with the appropriate configuration management system elements.

H.7 Software Quality Assurance Plan

A LANL SQAP shall be prepared that describes the software design, test and configuration management system for software used to support the design of a geologic repository. This description shall provide criteria for the application of Appendix H requirements, based on the complexity and importance of the software used; indicate the methods used to develop computer program requirements and translate those requirements into a detailed design and executable code; describe the documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use; state the methodology for establishing a software baseline and change control system, which includes change control tracking throughout the life of the software; describe the process used for verification and validation of the software developed; and identify procedures used for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determination of the appropriate corrective actions.

The LANL SQAP shall identify the

- organizational responsibilities for the management, application, control, and acquisition of software, and the interfacing of these activities;
- software products to which the SQAP applies;
- software development life cycle model used, including documentation.
- minimum required documentation;
- software configuration management system used;
- verification and validation methodologies; and
- software review procedures and the attendant documentation.

H.8 Software Life Cycle

Each LANL group shall use the life cycle controls below.

LANL shall adhere to a software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner. The relative emphasis placed on the phases of the software life cycle will depend on the nature, complexity, importance, and intended application of the software.

Documentation is required as defined in this portion of the appendix and described in the SQAP. All software documentation is considered to be a QA record.

Documentation produced during software development, acquisition, implementation, testing, and use shall receive the appropriate reviews as described in the SQAP.

Reviews of software life cycle activities shall be performed, as applicable, for each life cycle phase completed. The QPs used for reviews shall identify the reviewers and their responsibilities.

The documentation for all reviews shall contain a record of review comments and the personnel responsible for comment resolution. After review comments have been resolved, the approved documents shall be updated and placed under configuration management.

The following are the life cycle elements that shall apply, as appropriate for the software, as defined, interpreted, and described in the LANL SQAP.

H.8.1 Life Cycle Requirements Phase

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

- format and language that is understood by the programming organization and the user,
- enough detail to allow for objective verification,
- adequate definition to provide for the response of the software to the identified input data, and
- the information necessary to design the software without prescribing the software design itself.

Software requirements documentation shall outline the requirements that the software must fulfill. A specific capability of software should be referred to as a requirement only if its

achievement can be verified by a prescribed method. The requirements shall address the following, as applicable to the software application:

- functionality—the functions the software is to perform;
- performance—the time-related issues of software operation such as speed, recovery time, and response time;
- design constraints imposed on implementation—any elements that will restrict design options;
- attributes—non-time-related issues of software operation such as portability, correctness, security, and maintainability; and
- external interfaces—interactions with other participants, hardware, and other software.

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

H.8.2 Life Cycle Design Phase

During the design phase, a software design based on the requirements shall be specified, documented, and systematically reviewed. The design specifies the overall structure (control and data flow) and the reduction of the overall structure to 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, and
- the verification of the software design.

Software design documentation shall address the following, as applicable to the software application:

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

The software design review shall be held at the completion of the software design documentation. This review includes an evaluation of the technical adequacy of the design approach and ensures that the design satisfies all the requirements in the requirements documentation. Depending on the complexity of the software design, the design may require multiple design reviews.

H.8.3 Life Cycle Coding Phase

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

Verification activities during this phase shall consist of

- the possible modification of test cases necessitated by design changes made during coding and
- the examination of source code listings to ensure adherence to coding standards and conventions.

Software coding documentation shall address the following, as applicable:

- source code listings,
- revised requirements documents, and
- revised design documents.

Any design changes made in the requirements and design-phase documents shall be assessed to determine the impact on the design. The revised requirements and design-phase documents shall be reviewed at the same review level as that performed for the original documents.

The software coding phase review is an evaluation to determine that the requirements and design specifications are implemented in the completed code. The review is conducted prior to verification and validation.

H.8.4 Life Cycle Testing Phase

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

- execution of the test cases and evaluation of the results,
- evaluation of the completed software to ensure adherence to the requirements, and
- preparation of a report describing the results of software verification.

Life cycle testing activities shall be 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 have been met in the software design, test documentation shall provide 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. The report includes the results of all previous reviews, audits, and tests, and a summary of the status of the software.

Model validation will be conducted in accordance with Section H.2.2 of this appendix. Because model validation is dependent on application, model validation may not be completed at this stage.

The software testing review is an evaluation of the adequacy of completed software life cycle verification activities and model validation plans. The review results in an approval of verification and validation documentation.

H.8.5 Life Cycle Installation and Checkout Phase

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

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

H.8.6 Life Cycle Application and Maintenance Phase

During the application and maintenance phase, the software is approved for operational use. Further activities may consist of maintenance of the software to identify and 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 shall be approved, documented, tested, and controlled in accordance with software configuration management requirements. User notification of changes and corrections is a vital aspect of the maintenance phase.

LANL shall establish procedures for controlling the application of software that performs technical calculations in support of site characterization and performance assessment analyses and for the design, analysis, and operation of repository structures, systems, and components. These software applications shall be reviewed and approved to ensure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

LANL shall include in QPs, methods for documenting software applications that perform technical calculations to ensure that these applications and the results of these applications may be independently reproduced.

Procedures shall be 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 shall include the computer code, the input data, the assumptions or approximations used to develop the input data, and appropriate user documentation for performing the application or analysis.

H.9 Mandatory Documentation

The following documentation is mandatory as applicable to the particular software and is maintained as a QA record (reference Section 3.3.1 of the QAPP):

- software summary form,
- software requirements,
- software design and change,
- software verification and validation,
- continuing documentation and code listings,
- mathematic and numerical models,
- user's manual,
- code assessment and support, and
- configuration management support.

Mandatory documents shall be reviewed in accordance with LANL review procedures. These documents shall comply will the documentation requirements of NUREG-0856.

APPENDIX I

I.0 REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS AND ACTIVITIES TO BE INCLUDED ON THE Q-LIST

I.1 Introduction

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 shall be listed on a Q-List.

The Project Office will prepare the appropriate AP or APs for determining the items and activities to be placed on the Q-List. This procedure will describe the Probabilistic Risk Assessment (PRA) techniques and performance allocation methods used for identifying Q-listed items and activities.

I.2 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 60. These requirements describe the performance objectives and other technical criteria to ensure 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 QA Plan specify the QA Program for those items and related activities important to safety and/or waste isolation to ensure that their characterization, design, construction, and operation comply with the requirements of 10 CFR 60.

I.2.1 Criteria for the Q-List and Quality Activities List

The QA Level I requirements of this QAPP apply to items and activities important to safety and/or waste isolation. As derived from 10 CFR 60 (60.152), this QA Program is based on the eighteen criteria of 10 CFR 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.

I.2.2 Criteria for Non-Q-List Items

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR 60 requirements, such as those associated with meeting the design criteria in 10 CFR 131 (a) for protection of worker health safety. While these items are not subject to the QA Level I requirements of this QAPP, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318 (April 1988), paragraph 5.1(b).

I.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 related to "important to safety" and/or "waste isolation" in the licensing process shall be technically and procedurally defensible. "Existing data" shall be 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 10 CFR 60, Subpart G, QA Program. Supporting documentation on these materials (e.g., the technical specifications and QA records) shall be reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they shall be "qualified" for use to ensure they will perform their intended function.

I.3 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 shall be 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/quality control and design requirements, that they should perform their designated function.

PRA shall be 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 high-level waste program is consistent with the approach prescribed by the Environmental Protection Agency standard (40 CFR 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 shall be used. Conservative assumptions shall include nonmechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, nonmechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

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

PRAs shall utilize the following techniques:

- System modeling to depict the combination of safety function and system successes or failures that constitute accident scenarios. Two modeling techniques that 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 shall be compiled to ensure that the event trees properly depict all important sequences.

- The 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 shall be examined to determine how failures of components within that system could cause the failure of the entire system.

- If failure of a mitigating system should contribute to an offsite dose, individual components within the mitigating system shall be 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.

- Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides that 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 high-level waste facility. The energy, magnitude, and timing of radiological releases resulting from various accidents shall be considered in this analysis.

- 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 preclosure accidents can be found in NUREG-1318 (April 1988), paragraph 5.2(a).

I.3.1 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 shall not comprise or prevent the associated safety function from being performed. For the HLW repository, 10 CFR 60 [60.131(b) (5) (ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the Q-List.

I.3.2 Use of Previously Established Guidelines and Standards

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs that may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities that 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 shall be considered, to the extent practicable, to eliminate the need to develop new approaches.

I.3.3 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 shall be conducted at that time to identify Q-List items.

I.4 Identification of Items and Activities Important to Waste Isolation

The term "important to waste isolation" refers to engineered and 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

- groundwater 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 Environmental Protection Agency standard in 40 CFR 191).

The items and activities important to waste isolation shall 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 affect postclosure 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 1,000-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 shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR 60. The initial allocations 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 shall be 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 assessments or will be duplicated later in accordance with QA Level I requirements of this QAPP and, therefore, would not have to be performed in accordance with QA Level I requirements at this time. For example, 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).

APPENDIX J

J.0 REQUIREMENTS FOR PEER REVIEW

J.1 Introduction

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.

J.2 Applicability of Peer Review

A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions) 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.

In general, the following conditions are indicative of situations in which a peer review shall be considered.

- Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- Novel or untried testing, plan, procedure, and/or analyses are, or will be, utilized.
- Detailed technical criteria or standard industry procedures do not exist or are being developed.
- Results of tests are not reproducible or repeatable.
- Data or interpretations are ambiguous.
- Data adequacy is questionable—such as, data may not have been collected in conformance with an established QA program.

A peer review shall be 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.

J.3 Structure of Peer Review Group

The number of peers composing a peer review group shall vary, commensurate with the following:

- the complexity of the work to be reviewed,
- its importance to establishing that safety or waste isolation performance goals are met,
- the number of technical disciplines involved,
- the degree to which uncertainties in the data or technical approach exist, and
- the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

The collective technical expertise and qualifications of peer review group members shall span 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 shall be minimized by selecting peers to provide a balanced peer review group. Technical areas more central to the work to be reviewed shall receive proportionally more representation in the peer review group.

J.4 Acceptability of Peers

The technical qualification of the peer reviewers in their review areas shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection process. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.

Members of the peer review group shall be 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 ensure 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 shall be included in the peer review report.

J.5 Peer Review Process

Since the peer review process may vary from case to case, a peer review plan shall be prepared prior to initiating a peer review. The peer review plan shall describe 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.

The peer review group shall evaluate and report on

- validity of assumptions,
- alternate interpretations,
- uncertainty of results and consequences if incorrect,
- appropriateness and limitations of methodology and procedures,
- adequacy of application,
- accuracy of calculations,
- adequacy of requirements and criteria, and
- validity of conclusions.

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

J.6 Peer Review Report

A report documenting the results of the peer review shall be prepared and issued under the direction of the peer review group chairperson. The report shall be signed by each peer review group member. The peer review report shall include the following:

- a clear description of the work or issue that was peer reviewed;
- conclusions reached by the peer review process;

- individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate; and
- 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 this subject can be found in NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories" (February 1988).

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APPENDIX K

K.0 FORMAT AND CONTENT REQUIREMENTS FOR SITE CHARACTERIZATION PLAN STUDY PLANS

K.1 Purpose and Objectives of Studies

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used.
- Provide the rationale and justification for the information to be obtained by the study. The study plan 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 Site Characterization Plan); (2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); and (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.

K.2 Rationale for Selected Study

- 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
- 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 that evaluate alternatives considered.
- Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include
  - potential impacts on the site from testing;
  - whether the study needs to simulate repository conditions;
  - required accuracy and precision of parameters to be measured with test instrumentation;
  - limits of analytical methods that will use the information from the tests;
  - capability of analytical methods to support the study;
  - time required versus time available to complete the study;
  - 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;
  - interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and
  - interrelationships involving significant interference among tests and exploratory shaft facility design and construction, as appropriate (refer to Section 8.4 of the Site Characterization Plan or its references for specific Exploratory Shaft Facility design information).

K.3 Description of Tests and Analyses

- Because studies comprise tests and analyses, provide the following for each type of test:
  - 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, Exploratory Shaft Facility elements, repository layout, stratigraphic units, depth, and test location).

- Summarize the test methods. Reference any standard procedures (e.g., ASTM or API) 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 QA level and provide a rationale for any tests that are not judged to be QA Level I. Reference the applicable specific QA requirements that will be applied to the test.
- Specify the tolerance, accuracy, and precision required in the test, where appropriate.
- Indicate the range of expected results of the test and the basis for those expected results.
- List the equipment required for the test and describe briefly any such equipment that is special.
- Describe techniques to be used for data reduction and analysis of the results.
- 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.
- Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests.
- Show the relationship of the test to the set performance goals and confidence levels.

- For each type of analysis, do the following:
  - 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.
  - Describe the methods of analysis including any analytical expressions and numerical models that will be employed.
  - 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 QA level 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.
  - Identify the data input requirements of the analysis.
  - Describe the expected output and accuracy of the analysis.
  - 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.

K.4 Application of Results

- Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies).
- For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the Site Characterization Plan) that will use the information produced from the studies described above, and refer to any use of the results for model validation.
- 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 engineered barriers, and shaft and borehole seals).
- For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

K.5 Schedule and Milestones

- 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.
- 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.
- 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 Site Characterization Plan.

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