HOLMES & NARVER, INC. ENERGY SUPPORT DIVISION	NNWSI QUALITY ASSURANCE PROGRAM PLAN			
	EFFECTIVE DATE DECEMBER 1, 1988		SECTION N/A	
SUBJECT: NNWSI QAPP APPROVAL	REVISION NO. 2	SUPERSEDES 1	PAGE 1	OF 1

Manager, Nevada Operations — Date 8/26/88

Technical Project Officer — Date 8/26/88

Chief, Quality Assurance — Date 8/26/88

Received w/Ltr Dated 11/15/88

It is the policy of Holmes & Narver, Inc., (H&N), Energy Support Division, that the achievement of quality is essential to success. H&N is dedicated to provide high quality services to the Department of Energy (DOE).

In order to assist DOE to meet future licensing requirements of the Nuclear Regulatory Commission for a repository site, a Quality Assurance Program Plan (QAPP) has been established in accordance with NNWSI/88-9 Revision 1 for all Nevada Nuclear Waste Storage Investigations Project (NNWSI) activities performed by H&N. To meet responsibilities for achieving and ensuring quality, H&N has assigned a Technical Project Officer (TPO) for the management and direction of the NNWSI Project. The TPO has direct primary responsibility and accountability for the execution and implementation of the NNWSI Project activities.

This QAPP has the full endorsement and support of management. To be effective, this plan must be understood, accepted, and fully implemented by each H&N employee holding responsibility for NNWSI activities.

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

T. A. Wanniski
Manager, Nevada Operations

SECTION		REVISION	EFFECTIVE DATE
16	Corrective Action	1	12/01/88
17	Quality Assurance Records	1	12/01/88
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Appendices:			
A	Requirements for Qualification and Certification of Inspection and Test Personnel	2	12/01/88
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I. PURPOSE

This section describes the basic organizational structure, functional responsibilities, levels of authority, and lines of communication for administering and implementing the Holmes & Narver, Inc., Energy Support Division (H&N/ESD), Nevada Nuclear Waste Storage Investigation (NNWSI) Quality Assurance Program Plan (QAPP). The responsibility for establishing and executing the Quality Assurance (QA) Program shall be with H&N.

II. SCOPE

A. The internal organizational structure of H&N/ESD and the external interface organizations are covered in this section. Attachments A and B detail the interface.

B. H&N/ESD is responsible to DOE/Waste Management Project Office (WMPO) for providing architectural and engineering service to support the Exploratory Shaft Facility (ESF) as assigned to them by the NNWSI Project Work Breakdown Structure (WBS) Dictionary.

III. REQUIREMENTS

A. The Manager, Nevada Operations (MNO), administers and enforces the H&N/ESD QA policy, and ensures that appropriate quality requirements are included in projects assigned to the Nevada Operations. The MNO determines and establishes organizational structures.

B. The NNWSI Technical Project Officer (TPO), who reports to the Manager Technical Services, is responsible for directing the activities performed in support of the Project and ensuring that these activities are performed in accordance with this QAPP. The TPO is the prime interface with the WMPO, participating organizations, and supporting contractors. The Technical Project Office consists of Project Engineering, Design, Administration and Budgets and Field Engineering.

1. Project engineering provides qualified engineers to manage the criteria flow, set and monitor schedules, and to check and approve drawing specifications to criteria established by WMPO. Project Engineering is responsible for coordinating the internal and external interfaces to ensure the technical requirements and schedules are achieved.

2. Design provides qualified personnel to accomplish the design through all its phases. The group will be under the direction of the Design Section Chief. Design will produce drawings and specifications that are are timely and accurate, meet the criteria, and are appropriate to the project in form, constructibility, and cost.

3. Administration and Budgets is responsible for budgetary control and office administration including record processing.

4. Field Engineering is responsible for supporting the construction effort with inspection and engineering activities in the field.

C. Quality Assurance

1. The Chief, Quality Assurance (CQA), having the appropriate management and QA knowledge and expertise, is responsible to ensure that an appropriate QA program is established and executed effectively. The CQA's organization will verify by checking, auditing, surveilling and inspecting, that activities affecting quality have been performed correctly. The QA organization has sufficient authority, access to work area and organizational and freedom to identify quality problems; to initiate, recommend, or provide solutions through designated channels; to verify implementation of the solutions; and to ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. This includes the ability to stop unsatisfactory work. The CQA has direct access to responsible management including, if necessary, the WMPO Project Quality Manager, to resolve to quality problems. The CQA reports to a level of management at which this required authority and organizational freedom is provided, including sufficient independence from cost and schedule.

2. Full-time, dedicated, experienced QA personnel will be assigned by the CQA to the Project with additional qualified QA personnel made available to the project as necessary. The CQA shall have responsibility for approval of the QAPP, changes thereto, and interpretations thereof; and implementation procedures and all changes thereto. The assigned personnel shall have the responsibility and authority to verify the adequacy and effectiveness of the QA plans, requirements, and QA program implementation.

3. The external interfaces with WMPO, the participating organizations, And the Nevada Test Site (NTS) Support Contractors, are as shown on Attachment A. Specific interface requirements will be identified as appropriate in the other sections of the QAPP. Direction is received from and responses are given directly to DOE/WMPO.

4. Management, above and outside the QA organization, shall regularly receive information as to the scope, status, adequacy, compliance, etc., of the QA Program.

IV. SUPPORT ACTIVITIES

H&N/ESD also supports the ESF effort from other H&N/ESD organizations as required. The support activities will be controlled by the Technical Project Office. Project Engineering will authorize the work via an NNWSI Work Initiation issued directly to the manager/supervisor of the appropriate support organization.

A. The Engineering Records Library provides for the microfilming and storage of records for the entire NNWSI Project.

B. The Materials Testing Laboratory (MTL), a fully equipped testing laboratory, provides metal, concrete, rock, and soil testing by qualified personnel in support of the Project.

C. The Nondestructive Testing Section (NDT) provides the NDT expertise in support of the Project.

D. Field Survey provides survey control and information, both above and below ground, in support of the Project.

E. Communications Electronics provides consulting on the design of the life support systems and other electronic systems and hardware for the Project.

F. Communications Systems provides the expertise required to validate and control computer programs, and assists in the procurement of computer systems and hardware support for the Project.

G. Communications cable provides consulting on the design, procurement, and inspection of the cable for the Project.

V. ATTACHMENTS

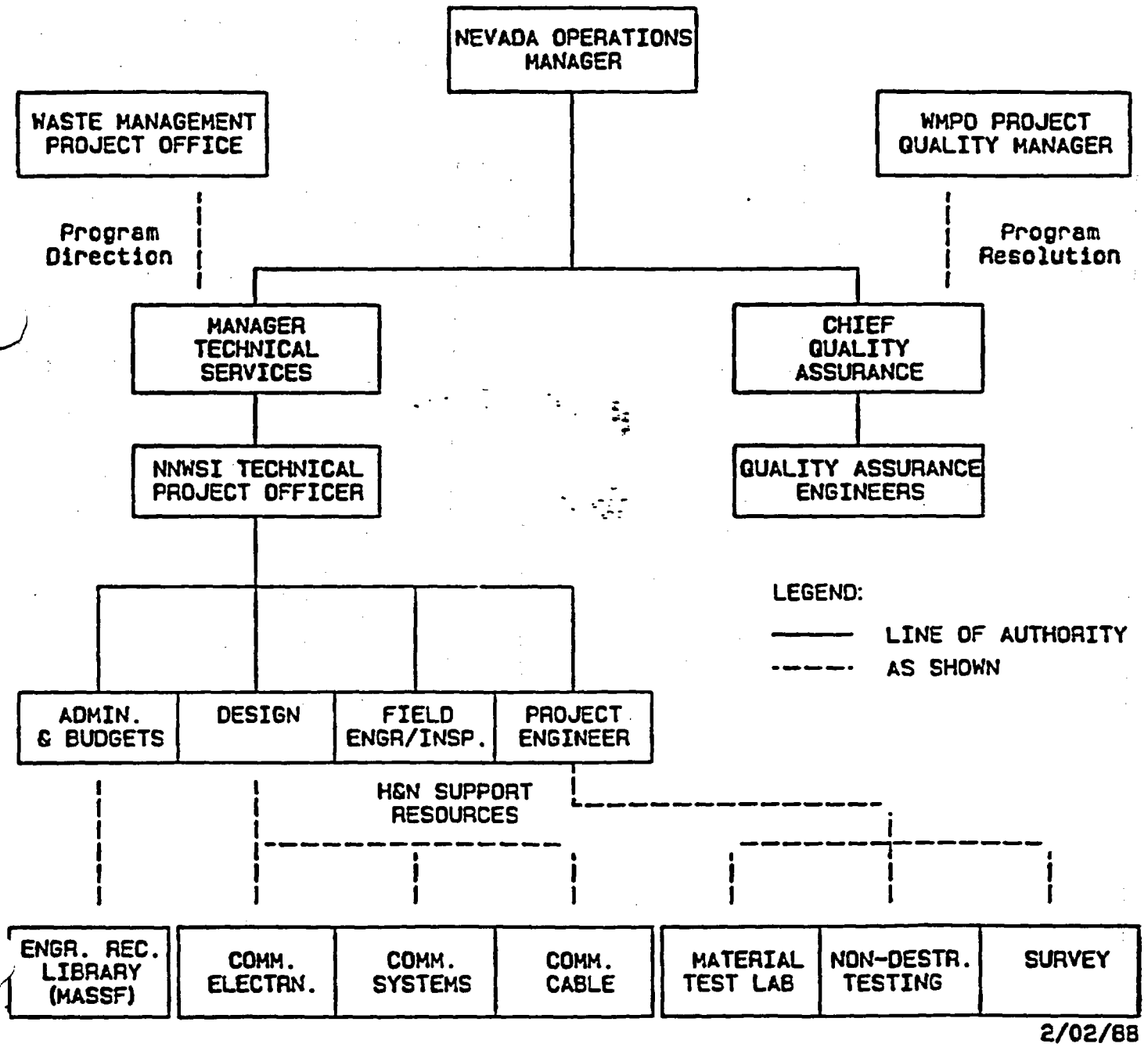
A. NNWSI Project Organization Chart

B. H&N NNWSI Project Organization Chart

ATTACHMENT B

HOLMES & NARVER, INC.

NNWSI PROJECT ORGANIZATION



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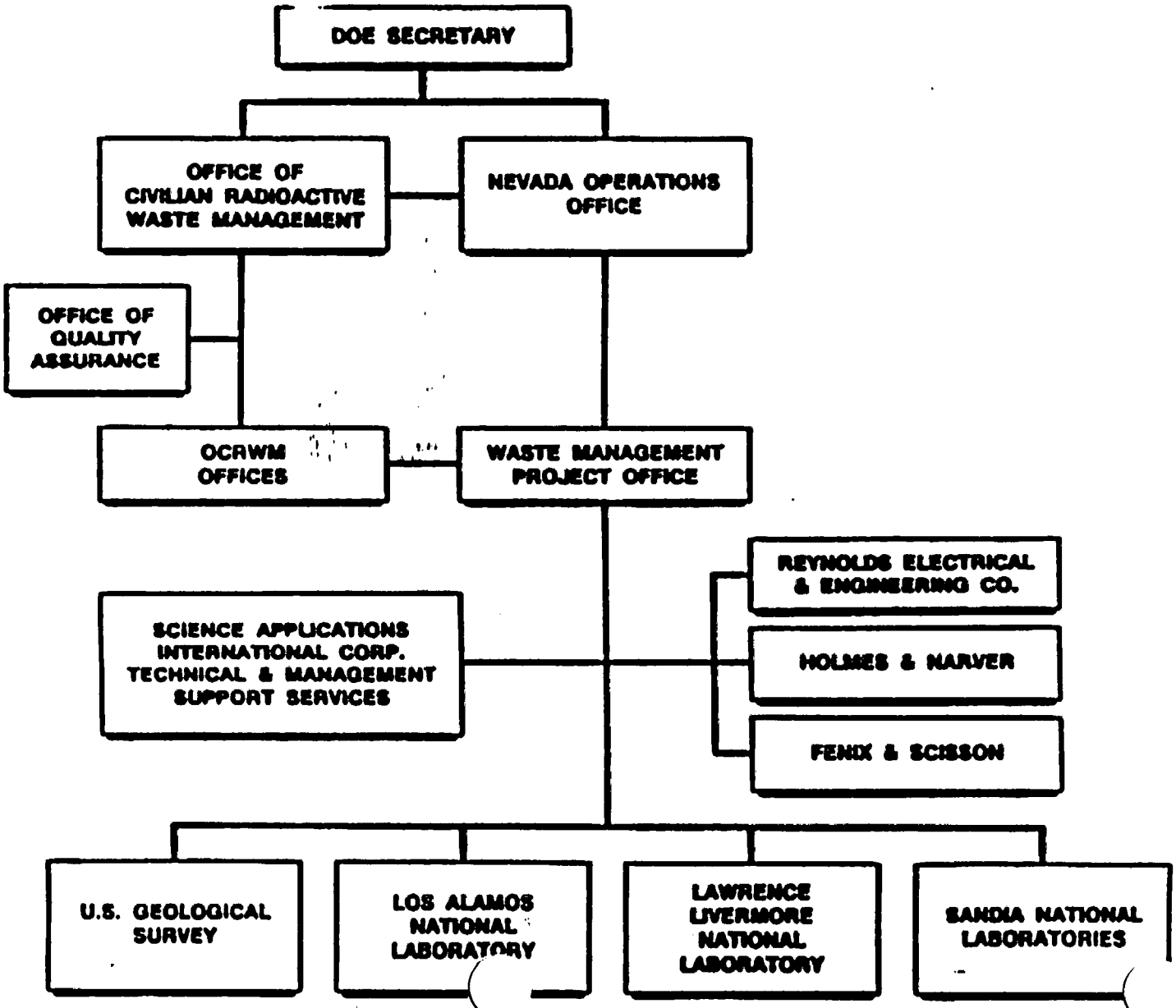
ATTACHMENT A

NNWSI PROJECT ORGANIZATION



I. PURPOSE

This section describes the basic Quality Assurance (QA) Program administered and implemented by Holmes & Narver, Inc., Energy Support Division (H&N/ESD) to provide appropriate controls of activities affecting quality.

II. SCOPE

A. Holmes and Narver, Inc. is the ESF A-E responsible for the design of the underground support systems and the above-ground facilities. Additional responsibilities include field engineering and inspection of facilities, Material Test Laboratory support, nondestructive examination services, field surveying services, and microfilming and storage of records for the NNWSI Project.

B. This Quality Assurance Program Plan (QAPP), which complies with NNWSI/88-9, is based on applying a graded QA system consistent with the activities importance to safety, waste isolation, and Department of Energy (DOE) mission objectives. These grades or levels have been established and defined as QA Levels I, II, and III.

C. This QAPP applies to QA Level I and II activities.

D. H&N/ESD QA Manual (HN-10471-1115) applies to QA Level III activities.

III. REQUIREMENTS

A. The Chief, Quality Assurance (CQA), shall be responsible for issuing and controlling the QAPP. The QAPP and revisions will be reviewed and approved by the CQA, TPO, and the Manager, Nevada Operations. The QAPP and subsequent revisions must be approved by the Waste Management Project Office (WMPO) prior to implementation. The submittal of the QAPP to WMPO for approval shall be supported by a checklist, based on NNWSI/88-9 which identifies where each requirement of NNWSI/88-9 is addressed.

B. The QA Program consists of this QAPP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. The activities that affect quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. The program takes into account the need for special controls, processes, test equipment, tools and skills

to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination thereof. The program provides for indoctrination and, as necessary, training of personnel performing activities that affect quality to ensure that suitable proficiency is achieved and maintained.

C. Implementing procedures, developed by qualified personnel, are reviewed and approved by the TPO and CQA, to ensure they meet the requirements of the QAPP, prior to their implementation. In addition all implementing procedures, with the exception of those procedures that implement technical activities only, shall be submitted to WMPO for review and approval. Pending receipt of WMPO approval, procedures may be issued for interim use. When procedures are issued for interim use, the transmittal record, should be appropriately marked. Upon final approval, procedure holders will be notified.

D. Personnel Selection, Indoctrination, and Training Procedures

1. Procedures shall be developed which establish the requirements for selection, indoctrination, and training of personnel performing or verifying activities that affect quality. Position descriptions shall establish minimum personnel qualifications, including education and experience. Procedures shall provide for appropriate indoctrination, training, or both, prior to initiation of activities that affect quality. In addition to the following requirements for idoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) shall be certified in accordance with the detailed requirements specified elsewhere in this QAPP.

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

3. Prior to performing activities affecting quality, personnel shall be indoctrinated as a minimum to the purpose, scope, methods of implementation, and applicability to the following documents, (including changes thereto), as they relate to the work to be accomplished. Indoctrination may be accomplished by the use of a mandatory reading list, group classroom presentation, or other approved instruction methods.

a. QAPP

b. Implementing procedures (applicable to the individual's responsibilities.)

c. Regulations

d. Project level documents

4. Prior to performing quality affecting activities that are complex in nature (i.e., assignments where it is deemed necessary to develop and demonstrate initial proficiency), personnel training shall be conducted to gain the required proficiency. The in-depth instruction shall include the principles, techniques, and requirements of the activity. Such in-depth instruction may be internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other approved instructional methods, or or combinations thereof.

5. The proficiency of personnel who perform activities affecting quality shall be evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with periodic or day-today employee performance evaluations. Proficiency evaluations shall be performed by managers or supervisors who have responsibility for the activities being performed or verified.

6. Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations shall be retained as lifetime QA records. These records shall include, as a minimum, the following:

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

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

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

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

E. The Technical Project Office (TPO) shall be responsible to annually conduct a management assessment for determining the effectiveness of the system and management controls established to achieve and assure quality; the adequacy of resources and personnel provided to the QA program; and to verify that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program. Procedures shall be developed for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are to be provided to the WMPO Project Manager and Project Quality Manager.

F. Readiness reviews of major scheduled/planned activities shall be performed by management as deemed appropriate. The readiness reviews shall be used in verifying that specific prerequisites, and programmatic requirements have been identified prior to starting major activities.

IV. DOCUMENTATION

All records required for implementing this section shall be collected, stored, and maintained in accordance with written procedures which conform to Section 17 of the QAPP.

V. REFERENCE

A. H&N/ESD Quality Assurance Manual (HN-10471-1115)

B. NNWSI/88-9 NNWSI Quality Assurance Plan

I. PURPOSE

This section establishes the requirements for the control of design activities.

II. SCOPE

A. This section applies to all design activities performed in support of the project. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system.

B. Scientific investigations will not be performed by Holmes & Narver, Inc., Energy Support Division (H&N/ESD).

III. REQUIREMENTS

A. General

1. All design phases must be assigned a Quality Assurance (QA) Level by a Participating Organization and be approved by the Waste Management Project Office (WMPO) prior to commencing of design activities.

2. Personnel performing or verifying design activities shall be indoctrinated, trained, and qualified as prescribed by Section 2 of the Quality Assurance Program Plan (QAPP).

3. All design activities shall be performed in accordance with instructions, procedures, or drawings developed in accordance with Section 5 of the QAPP.

B. Design Inputs

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

2. Changes to approved design input, including the reason for the changes, shall be identified, documented, approved, and/or accepted and controlled in the same manner as the original document.

3. A partial list of design inputs is provided for consideration in the Attachment.

C. Design Analysis

1. Design analyses shall be planned, controlled, and documented in sufficient detail as to purpose, method, assumptions, design input references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component) originator, reviewer, and date.

2. Documentation of design analysis shall include the following:

   a. A definition of the objective of the analysis.

   b. A definition of design input and their sources.

   c. A listing of applicable references.

   d. Results of literature searches or other background data.

   e. Identification of assumptions and indication of those which require verification as the design proceeds.

   f. 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.

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

D. Design Verification

1. Design control measures shall be applied in a timely manner to verify the adequacy of design. The responsible design organization shall identify and document the verification method used, the results of the verification, and the verifier.

2. Verification of the adequacy of design shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities. In those cases, where this timing cannot be met, the portion or portions of

design which have not been verified shall be identified and controlled. In all cases, the verification shall be completed prior to relying on the component, system, or structure to perform its function.

3. The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this section, the verification process need not be duplicated for identical designs. Standardized or previously proven designs shall meet pertinent design inputs and be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

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

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

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

      (1) Were the design inputs correctly selected?

      (2) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverification when the detailed design activities are completed?

      (3) Was an appropriate design method used?

      (4) Were the design inputs correctly incorporated into the design?

      (5) Is the design output reasonable compared to design inputs?

      (6) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

      (7) Are computer programs used for analysis identified and verified in accordance with the methods specified in the NNWSI Project Administrative Procedures Manual?

b. Alternate calculations are a form of analysis which may be used to determine the adequacy of the original analyses. The use of alternate calculations shall include a review of the appropriateness of assumptions, inputs, computer programs, or other calculation methods used.

c. Qualification tests that involve actual physical testing of systems, structures, or components may be used to verify the adequacy of design. Where design adequacy is to be verified qualification tests, the tests shall be identified. 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. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item 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 work shall be subject to error analysis where applicable, prior to use in the final design work.

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

6. Design verification shall be performed by any competent, certified individual or individuals, or certified group or groups other than those who performed the original design. The verification may be performed by the originator's supervisor provided that:

   a. The supervisor is the only individual in the organization competent to perform verification.

   b. The supervisor did not establish the design input used, specify a singular design approach, or rule out certain design considerations.

   c. The rationale for satisfying the two requirements above is documented and approved by management superior to the supervisor. The QA manager shall also concur with this rationale.

E. Design Change Control

1. Changes to approved designs, including field changes, shall be justified and subjected to design control measures commensurate with those applied to the original design.

2. Errors and deficiencies in approved design and design information documents shall be documented, and action taken to ensure that all errors and deficiencies are corrected. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be revieved and modified as necessary.

F. Design Interface Control

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

2. Design information transmitted across interfaces shall be documented and controlled. The transmittal shall identify the status of the information or document provided and, where necessary, identify incomplete items which require further evaluation, review and approval.

G. Design Output Documents, such as drawings and specifications, shall:

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

2. Identify assemblies or components or both that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3. Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. As a minimum, the review and approval cycle shall include the participation of technical and QA elements of both the responsible design organization and the WMPO. 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.

H. Computer Software

1. Computer software shall be controlled at a level commensurate with the complexity of the software and it's intended application.

2. When commercial software is utilized, it is recognized that source code is generally not available and controls are limited to unique version identification and user related manuals. All available documentation shall be obtained from the software supplier and controlled.

3. Computer software development (In House Software) shall be controlled in accordance with Appendix C to this QAPP.

4. Computer software shall be controlled in accordance with written procedures.

   a. The computer software control procedures shall be reviewed and approved by the next higher program organizational level.

   b. The computer software control procedures shall:

      1. Provide criteria for application requirements based on the complexity and importance of the software.

         NOTE: NNWSI PROJECT ADMINISTRATIVE PROCEDURE, AP 5.5Q PROVIDES CRITERIA FOR DETERMINING THE APPLICABILITY OF REQUIREMENTS AND MANAGING INTERFACE, DOCUMENTATION, CONFIGURATION MANAGEMENT, CHANGE, QUALIFICATION, VERIFICATION AND VALIDATION.

      2. Indicate methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.

      3. Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.

      4. Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.

      5. Specify the process to be used for verification and/or validation of the software.

      6. Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

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

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

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

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

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

10. 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. Software that has not been developed in accordance with this QA Plan may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.

11. Documentation of computer software shall include, as a minimum, the following:

    a. Software requirements specification

    b. Software design and change documentation

    c. Description of mathematical models and numerical methods

    d. Software verification and validation documentation

    e. User documentation

    f. Code assessment and support

g. Continuing documentation and code listings

h. Software summary

12. Software configuration management shall include, as a minimum, the following:

a. The inclusion of a unique software identification, including software version numbers where feasible, in the output.

b. Listings of the software.

c. A brief chronology of the software versions, including descriptions of the changes made between versions.

I. Peer Reviews

1. Peer reviews shall be conducted in accordance with a peer review process and plan, when applicable, to provide adequate confidence in the work being reviewed. Peer reviews shall be conducted in accordance with the requirements presented in Appendix D to this QAPP.

2. A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds it's 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.

J. Technical Reviews

1. Technical reviews shall be conducted in accordance with procedures that contain specific criteria for the performance of the technical review.

IV. DESIGN DOCUMENTATION

Design documentation, including design inputs, analyses, computer software, drawings, specifications, approved changes thereto, evidence of design verification, peer reviews, and records confirming interface control shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section 17 of this QAPP.

V. ATTACHMENTS

Design inputs (2 pages).

VI. REFERENCES

NNWSI-AP5.5Q, Software Quality Assurance

NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management"

NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories" (February 1988)

ATTACHMENT

DESIGN INPUTS

GENERAL

Design inputs include many characteristics and functions of an item or system. These Inputs vary depending on the application; however, the following inputs are a partial list that should be considered, depending on specific items or systems under

1. Basic functions of each structure, system, and component.
2. Performance requirements such as capacity rating and system output.
3. Codes, standards, and regulatory requirements including the application issue and/or agenda.
4. Design conditions such as pressure, temperature, fluid chemistry, and voltage.
5. Loads such as seismic, wind, thermal, and dynamic.
6. Environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure.
7. Interface requirements including definition of the functional and physical interface involving structures, systems, and components.
8. Material requirements including compatibility, electrical insulation, proper protective coating, and corrosion resistance.
9. Mechanical requirements such as vibration, stress, shock, and reaction forces.
10. Structural requirements covering items such as equipment foundations and pipe supports.
11. Hydraulic requirements such as pump net positive suction heads, allowable pressure drops, and allowable fluid velocities.
12. Chemistry requirements such as provisions for sampling and limitations on water chemistry.
13. Electrical requirements such as source of power, voltage, raceway requirements electrical insulation, and motor requirements.
14. Layout and arrangement requirements.
15. Operational requirements under various conditions such as site startup, normal site operation, site emergency operation, special or infrequent operation, system abnormal or emergency operation, site decontamination, decommissioning, and dismantling.

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

17. Access and administrative control requirements for site security.

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

19. Failure effects requirements of structures, systems, and components including a definition of those events and accidents which they must be designed to with- stand.

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

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

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

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

24. Fire protection or resistance requirements.

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

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

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

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

29. Quality control and QA requirements.

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

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

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

I. PURPOSE

This section establishes the requirements to ensure that the necessary requirements to assure adequate quality are suitably specified in procurement documents.

II. SCOPE

This section applies to the procurement of items and service for the project, including the support provided under NTS-SOP-5101, Major Equipment and Supply Acquisition (MESA), and the Major Acquisition Sequence for Subcontract (MASS) procedures for which Reynolds Electrical & Engineering Co., Inc., has primary procurement responsibility.

III. REQUIREMENTS

A. Procurement shall be controlled through the use of the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR).

B. A statement of the scope of the work to be performed by the supplier shall be in the procurement documents.

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

D. Quality Assurance Requirements

1. Procurement documents shall require that suppliers and subtier contractors have a documented QA program that is commensurate with and implements the pertinent provisions of this Quality Assurance Program Plan (QAPP) as required for the specific QA Level specified. The extent of the program required shall depend upon the type and use of the item or service being processed.

2. When developing requirements for tests and other equipment consideration should be given to whether proper performance of that equipment can be determined during or after its use.

3. An overview of suppliers QA activities shall be accomplished. The overview is to include the following as appropriate:

   a. Review and approval of QAPPs.

   b. Surveillance of activities effecting quality.

   c. Audits of the QA Program.

E. The procurement documents shall provide for access to the suppliers facilities and records by the purchaser, WMPO, or their authorized representative. For QA Level I procurements this requirement also applies to the suppliers subcontracts.

F. The procurement documents at all tiers shall identify the documentation required to be submitted to the purchaser. The time of submittal shall also be established. If the purchaser requires the supplier to maintain specific QA records, then the retention times and disposition requirements shall be specified in accordance with Section 17 of this QAPP.

G. The procurement documents shall prescribe the purchaser's requirements for reporting and approving disposition of nonconformances.

H. The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineatior of the technical and quality related data that are required for ordering these parts or assemblies. The technical and quality requirements shall be equal to or better than the original. If QA or technical requirements of the original item cannot be determined, then an engineering evaluation shall be conducted by qualified individuals to establish the requirements. The evaluation shall consider the interchangeability, function and safety of the item. The evaluation shall be documented.

I. Procurement Document Review

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

   a. QA requirements are correctly stated, inspectable, and controllable.

   b. There are adequate acceptance and rejection criteria.

   c. Procurement documents have been prepared, reviewed, and approved in accordance with this section.

2. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. Changes that are made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents prior to contract award.

J. Quality Level I purchase documents and changes thereto which identify the vendor, describe the scope of work, and detail when work is to start, shall be provided to the SAIC/T&MSS Project QA Department, QA Verification Division Manager.

IV. Procurement documents generated as a result of this section shall be processed in accordance with Section 17 of this QAPP.

V. REFERENCES

A. Federal Acquisition Regulation (FAR)

B. Department of Energy Acquisition Regulations (DEAR)

C. NTS-SOP-5101, Major Equipment and Supply Acquisition Procedure (MESA)

D. Major Acquisition Sequence for Subcontract Procedure (MASS)

I. PURPOSE

This section establishes the requirements for preparing instructions, procedures, and drawings.

II. SCOPE

This section applies to all activities affecting quality.

III. REQUIREMENTS

A. Activities affecting quality shall be prescribed by and performed in accordance with written instructions, procedures, plans, or drawings, as appropriate to the activity.

B. Instructions, plans, procedures, etc., shall:

1. Include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

2. Identify the Quality Assurance (QA) records that must be generated.

C. An independent review of all instructions, procedures, plans, and drawings shall be made to assure technical adequacy and inclusion of appropriate quality requirements.

D. Instructions, plans, procedures, and drawings shall be controlled in accordance with Section 6 of the Quality Assurance Program Plan. Controlled distribution of all implementing procedures, plans, and instructions for Level I and II activities shall be made to the Waste Management Project Office Project Quality Manager and the SAIC/T&MSS Project Quality Assurance Department Manager.

V. DOCUMENTATION

All records required for implementing this section shall be collected, stored, and maintained in accordance with written procedures or instructions which conform toSection 17 of the QA Program Plan.

I. PURPOSE

This section establishes the requirements to ensure that only correct documents are used.

II. SCOPE

This section applies to the preparation, review, approval, and issuance of instructions, procedures, plans, and drawings, including changes there to, that contain or specify quality requirements, or prescribe activities affecting quality.

III. REQUIREMENTS

A. The document control system shall be prescribed by written procedures appropriately reviewed and concurred with by Quality Assurance. The procedure shall provide for implementation of the following:

1. Identification of documents to be controlled.

2. Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.

3. Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements prior to approval and issuance.

4. A method for the removal or marking of obsolete or superseded documents to prevent inadvertent use.

5. A method for ensuring that the correct and applicable documents are available at the location where they are to be used.

6. A master list or equivalent to identify the correct and updated revisions of documents.

7. Coordination of interface documents.

B. Document Changes

1. Changes to documents, other than minor, shall be reviewed and approved by the same organization that performed the original review and approval, unless otherwise specified by appropriate levels of management. The reviewing organization shall have access to pertinent data information upon which to base their approval.

2. Minor changes, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original document. Procedures shall delineate the type of changes that do not require such review and approval, and the individuals who can authorize such a decision.

C. Distribution

1. The document control system shall ensure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified and controlled.

2. The master list or equivalent used to identify the correct and updated revision of documents shall be distributed to all individuals who received controlled distribution of the documents. Copies shall be provided to Waste Management Project Office (WMPO) Project Quality Manager (PQM), and the SAIC/T&MSS Project Quality Assurance Department Manager.

IV. DOCUMENTATION

Records generated in support of this section shall be processed in accordance with Section 17 of this QAPP.

I. PURPOSE

This section established the requirements for controlling purchased material, equipment, and services to ensure conformance to the procurement documents.

II. SCOPE

A. This section applies to all procurement activities provided in support of this project.

B. Direct service contracts let by H&N/ESD for this project shall be in accordance with this section.

C. Procurement of equipment and subcontracts is the responsibility of Reynolds Electrical & Engineering Co., Inc. (REECo). H&N/ESD supports REECo in equipment and subcontract procurement activities as prescribed by the DOE/NV approved "Major Equipment and Supply Acquisition (MESA)" and "Major Acquisition Reference for Subcontracts (MASS)" procedures. These support activities shall be in accordance with this section.

III. REQUIREMENTS

A. Procurement Planning

1. Procurement activities shall be planned and documented to ensure a systematic approach to the procurement process. Planning shall be accomplished as early as practicable and no later than at the start of those activities which are to be controlled. Procurement methods and organizational responsibilities shall be defined in procedures. Planning shall determine what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished. Appropriate QA participation shall be provided for evaluation and selection of suppliers, verification of suppliers activities, and receiving inspection.

2. Procedures shall provide for the integration of the following:

a. Procurement document preparation, reviev, and change control

b. Selection of procurement sources including organizational responsibilities for determining supplier capability

c. Verification activities by purchaser, including notification of hold and witness points

d. Control of nonconformances

e. Corrective action

f. Acceptance of items or services

g. QA records

B. Supplier Selection

1. Supplier selection evaluation is based on the capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.

2. Measures for evaluation and selection of procurement sources and the results thereof shall be documented and shall include one or more of the following:

a. Evaluation of the supplier history of providing an identical or similar product which performs satisfactorily in actual use.

b. Supplier's current capability and quality records supported by documented qualitative and quantitative information which can be objectively evaluated.

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

C. Bid Evaluation

1. Bids shall be evaluated to determine conformance to the procurement documents. This evaluation shall be performed by designated individuals or organizations for the following subjects, as applicable to the type of procurement:

a. Technical Considerations

b. QA Requirements

c. Supplier Personnel

d. Supplier Production Capabilities

e. Supplier Past Performance

f. Alternates

g. Exceptions

2. Prior to the award of the contract, unacceptable quality or technical condition resulting from the bid evaluation shall be resolved.

D. Supplier Performance Evaluation

1. The purchaser shall establish measures to interface with the supplier and to verify supplier performance. The measures shall include:

   a. Documentation of the understanding between the supplier and purchase of the provisions and specifications of the procurement documents.

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

   c. Reviewing supplier documents and establishing an exchange of information on documentation which are generated or processed during activities fulfilling procurement document requirements.

   d. Identifying and processing necessary change information.

   e. Establishing the extent of source surveillance and inspection.

2. The extent of verification activities, including planning, shall be a function of the relative importance, complexity and quantity of the item or services procured, and the supplier quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier activities as early as practicable.

3. Activities that verify conformance of procurement documents such as source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented and considered QA records, and controlled in accordance with Section 17 of this QAPP.

4. This documentation shall be evaluated to determine the supplier QA program effectiveness.

5. When a participating organization or another NTS support contractor is utilized to provide activities for which H&N/ESD is responsible, WMPO shall be requested to conduct a surveillance of that organization to determine that the item or activity is being produced or performed in accordance with our requirements.

E. Control of Changes in Items or Services: Measures to control changes in procurement documents shall be established, implemented, and documented, as prescribed by section 4 of this QAPP.

F. Control of Supplier-Generated Documents: Supplier generated documents shall be controlled and approved in accordance with documented procedures. Submittal of these documents shall be in accordance with the procurement document. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

G. Acceptance of Item or Service

1. Methods shall be established for accepting an item or service being furnished by the supplier. Prior to offering the item or service for acceptance, the supplier shall verify that the item or service complies with the procurement requirements. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the site prior to installation or use. This documentary evidence shall be sufficient to identify the specific requirements, such as codes, standards, or specifications that are to be met by the purchased material and equipment.

2. Methods used to accept an item or related service from a supplier shall be a supplier certificate of conformance, source verification, receiving inspection, or post-installation test at the facility site, or a combination thereof.

   a. Certificate of Conformance: When a certificate of conformance is used, the following minimum criteria shall be met:

      (1) The certificate shall identify the purchased material or equipment such as by the purchaser order number.

      (2) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, suc' as codes, standards, or other specifications. The procurement requirement shall include approved changes, waivers, and deviations.

      (3) The certificate shall include unresolved procurement requirements, and an explanation and means for resolving the nonconformance.

      (4) The certificate shall be attested to by a person who is responsible for this QA function and whose function and position are described in the supplier's QA program.

      (5) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates shall be described in the supplier's QA Program.

      (6) Independent inspection or testing of the item shall be made to verify the validity of the certificate by scheduled inspections or audits at intervals commensurate with past quality performance.

   b. Source Verification: When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service. It shall be implemented to monitor, witness, or observe activities. Source verification shall be implemented in accordance with plans to perform inspection, examinations, or tests at predetermined points

identified to the supplier. Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

c. Receiving Inspection: When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit documentation and the demonstrated quality of the supplier. Inspection records shall identify objective evidence used for acceptance, such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; cleanliness; and documentation reviews. Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

d. Post-installation Testing: When post-installation testing is used, post-installation test requirements and acceptance documentation shall be established mutually by both the purchaser and supplier.

3. Acceptance of Services Only: In certain cases involving procurement of services only, such as engineering and consulting, acceptance can be by any or all of the following methods:

a. Technical verification of data produced.

b. Surveillance and/or auditing of the activity.

c. Review of objective evidence for conformance to the procurement document requirements.

H. Control of Supplier Nonconformances: Purchaser and supplier shall establish and document methods for disposition of items and services that do not meet procurement document requirements and corrective action. These methods shall provide for the following:

1. Submittal of nonconformance notice to the purchaser as directed by the purchase order. These submittals shall include supplier recommended disposition (e.g., use as-is or repair) and technical justification.

2. Notices of nonconformances which consist of one or more of the following shall be submitted to the purchaser for approval of recommended disposition:

a. Technical or material requirements violated.

b. Violation of requirement in suppliers documents which have been approved by the purchaser.

c. Nonconformances which cannot be corrected by continuation of the original requirement even though the item can be restored so that the item function is unimpaired.

3. Purchaser disposition of supplier recommendation shall be in accordance with documented procedures.

4. Verification of the disposition action.

5. Maintenance of records of supplier nonconformances.

I. Commercial-Grade Items

1. Where commercial-grade items are used as an integral part of the design facility, they shall be identified in an approved design or design output document.

2. When the design specifies commercial-grade items, the following requirements are an acceptable alternative to this section's other requirements, except as noted:

a. Alternate commercial-grade item may be applied if the appropriate organization provides verification that the item will perform the intended function and will meet the design requirements applicable to both the replaced item and its application.

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

3. Upon receipt of a commercial-grade item, the Purchaser, shall determine that:

a. Damage was not sustained during shipment.

b. The item received was the item ordered.

c. Inspection and/or testing is accomplished in accordance with written procedure to ensure conformance with the manufacturer's published requirements. Acceptance of M&TE may be accomplished via the calibration program in accordance with the requirements of Section 12 of this QAPP.

d. Documentation for the item was received and is acceptable.

IV. DOCUMENTATION

A. All records required for implementation of this section shall be collected, stored, and maintained in accordance with written procedures or guidelines which conform to the H&N QA Program, Section 17 of this QAPP.

B. Records, as a minimum, shall be maintained for all source and bid evaluations, source and receipt inspections, nonconformance reports, and any supplier certificates.

I. PURPOSE

This section establishes requirements for the identification and control of samples and data to ensure that only the correct and acceptable samples and data are utilized.

II. SCOPE

A. This section applies to activities that process samples or produce data to be utilized by others.

B. Identification and control of items is not applicable.

III. REQUIREMENTS

A. Control and Identification of Samples

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

2. Identification

a. Identification shall be maintained from receipt to installation. The identification shall be verified prior to installation or 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 describe and used. All identification methods shall provide methods whereby identification of samples can be traced to the appropriate documentation such as dravings, specifications, drilling logs, test records, inspection documents, and nonconformance reports.

b. Samples shall be identified by placing the identification directly on the sample, on their container, or on records traceable thereto. If it is impractical to place the identification on the sample, methods shall be described and implemented to ensure that samples are mixed with like samples and that the correct identification of samples is verified and documented prior to release for use.

3. Procedures shall ensure that sample collection methods, techniques, and related equipment produce the intended sample.

4. Storage and handling methodology shall be developed and implemented to ensure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long term storage, as defined by the responsible organization depending on sensitivity of the sample to storage conditions, shall receive appropriate treatment to ensure that they do not degrade during storage. Measures shall be taken to maintain sample identification while in storage. These measures shall be consistent with the planned duration and conditions of storage and shall describe actions to be taken where samples may have a maximum life expectancy while in storage. Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.

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

6. Where samples are controlled by more than one organization, the organizational responsibilities shall be developed and implemented including assurance that sample identification is verified and maintained when handled, transported, or transferred from one organization's responsibility to another.

B. Identification and Control of Data.

1. Procedures shall be developed and implemented to describe organizational responsibilities and to ensure that data is appropriately identified prior to issue.

   a. The data shall include reference to origin (task, test, experiment, report, publication, etc.) and indication of quality level assigned to the activity that produced the data.

   b. Where data are the results of the efforts of more than one organization, the data shall be annotated to show what organization produced what portion of the data.

IV. DOCUMENTATION

Records generated shall be processed in accordance with Section 17 of the QAPP.

I. PURPOSE

This section establishes the requirements to ensure that processes that affect quality of items or services are controlled.

II. SCOPE

This section applies to all processes that affect quality.

III. REQUIREMENTS

A. All processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means which shall ensure that process parameters, including acceptance criteria, are identified and controlled, and that special environmental conditions are maintained.

B. Personnel implementing these processes shall be appropriately indoctrinted and trained as required by Section 2 of this Quality Assurance Program Plan (QAPP).

C. Special process procedures and personnel shall be qualified and/or certified in accordance with applicable codes, standards, and specifications, such as SNT-TC-1A and AWS D.1.1, as appropriate. The qualification process shall utilize the actual working procedure where possible.

D. All process procedures, instructions, etc., shall be prepared in accordance with Section 5 of this QAPP.

E. Special process equipment shall be checked out, qualified, and certified in accordance with specified requirements. These requirements shall implement the requirements of applicable codes, standards, and specifications.

F. Nondestructive examination personnel shall be qualified and certified in accordance with SNT-TC-1A, dated June 1980, as supplemented below:

1. Special physical characteristics needed in the performance of each activity, including the need for initital and subsequent physical examinations, shall be identified.

2. The certificate of qualification shall include the following:

a. Employer's name

b. Identification of person being certified

c. Activities certified to perform

d. Basis used for certification that includes such factors as:

1) Education, experience, and training (when necessary)
2) Test results (where applicable)
3) Results of capability demonstration

e. Results of periodic evaluation

f. Results of physical examinations (when required)

g. Signature of designated representative who is responsible for such certification

h. Dates of certification and certification expiration

IV. DOCUMENTATION

Records for the currently qualified personnel, procedures, and equipment of each special process shall be maintained and processed in accordance with Section 17 of this QAPP.

I. PURPOSE

This section establishes the requirements for the control of inspection activities.

II. SCOPE

This section applies to inspection activities which verify conformance and/or acceptance of an item or activity to specified requirements.

III. REQUIREMENTS

A. Inspection activities for the purpose of acceptance shall be planned and documented, and performed in accordance with inspection procedures, instructions, or checklists which shall provide for the following:

1. Identification of characteristics and activities to be inspected.

2. A description of the method of inspection.

3. Identification of the individuals or groups responsible for performing the inspection operation

4. Acceptance and rejection criteria.

5. Identification of required procedures, drawings, and specifications and revisions.

6. Recording inspector or data recorder and the results of the inspection operation.

7. Specifying necessary measuring and test equipment including accuracy requirements.

B. Inspection personnel shall:

1. Be qualified and certified in accordance with Appendix A.

2. Be independent from the supervision responsible for the activity inspected.

3. Have sufficient authority, access to work area, and organizational freedom to identify problems; initiate, recommend or provide solutions to quality problems through designated channels; verify implementation of solutions; and to ensure that further processing delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency or unsatisfactory condition has occurred.

C. Mandatory inspection and/or witness hold points, and criteria for determing how inspections are to be performed, shall be established and identified in appropriate documents that control the activity. Work shall not proceed beyond the hold points without written consent from the organization established the hold points.

D. In-process type inspections or monitoring, including indirect control by monitoring of process methods, equipment, and personnel shall be performed for work activities, where and when necessary, to ensure features or processes that cannot be verified during final inspection. Where a combination of inspection and process monitoring is used, it shall be performed in a systematic manner to ensure that specified requirements for control of the process and quality of the item are being achieved through the duration of the process.

E. Where sampling techniques are utilized to verify acceptability, the sampling shall be based on recognized sampling plans.

F. Modifications, repairs, or replacements of items performed subsequent to final inspection requires reinspection or retest, as appropriate, for acceptability.

G. Final inspection shall include a review of records, for accuracy and completeness, including the results and resolution of nonconformances, modifications, repairs, and replacements identified by previous inspections, to verify the acceptability of the item for conformance to specified requirements. Item acceptance shall be documented and approved by authorized personnel.

IV. DOCUMENTATION

A. Records of inspections shall include the following:

1. Item or activity
2. Date of the inspection
3. Name of the individual performing the inspection
4. Names of personnel contacted during inspection
5. Description of the type of observation (method of inspection).
6. Inspection criteria including identification of drawing, specification, and applicable revision.
7. Equipment used during the inspection
8. Evidence as to the acceptability of the results
9. Acceptance statement
10. References to information on action taken in connection with conditions adverse to quality, nonconformances, and/or actions taken to resolve any discrepancies

B. Inspection records and qualification records including actual examination and results, and certification, shall be processed in accordance with Section 17 of this QAPP.

I. PURPOSE

This section establishes the requirements for the control of tests required to verify conformance of items or systems to specified requirements and to demonstrate that items will perform satisfactorily in service.

II. SCOPE

This section applies to prototype, qualification, production, proof, construction, preoperational, and operational tests performed in support of the project.

III. REQUIREMENTS

A. Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be based upon the requirements specified in the applicable design or pertinent technical documents provided or approved by the organization responsible for the design, unless otherwise designated.

B. Test Procedures

1. Tests shall be conducted in accordance with written procedures, instructions, or drawings which identify the characteristics to be tested and test methods. Standard test methods such as those prescribed by the American Society for Testing and Materials (ASTM) and the American Petroleum Institute (API), are acceptable alternates. These documents shall include adequate instructions to ensure the required quality of work.

2. Test procedures or instructions shall include or reference the following, as appropriate:

a) Test objectives and provisions for ensuring prerequisites are met.

b) Criteria for determining when and how the test is to be performed.

c) Completeness of item to be tested.

d) Condition of test equipment and item to be tested.

e) Environmental requirements.

f) Special equipment and instrumentation required.

g) Personnel requirements.

h) Potential source of uncertainty or error that must be monitored and controlled.

i) Mandatory hold points.

j) Provisions for data acquisition and storage.

3. Test procedures or plans shall be reviewed in accordance with the design verification requirements specified in Section 3 of this Quality Assurance Program Plan (QAPP).

C. Testing personnel shall be appropriately trained, qualified, and certified prescribed by Appendix A.

D. Test Results

1. Test results shall be documented and the results evaluated by a responsible authority to ensure that the test requirements have been satisfied.

2. Test records shall identify the following:

a) Item tested

b) Test procedure used

c) Date of test

d) Tester and/or data recorder

e) Observations

f) Test results and the acceptability or unacceptability of the test results

g) Person evaluating test results

h) Action taken with deviations noted

IV. DOCUMENTATION

Records shall be processed in accordance with Section 17 of this QAPP.

I. PURPOSE

This section establishes the requirements for the control and use of measuring and test equipment (M&TE).

II. SCOPE

A. This section applies to all M&TE used to either control or acquire data to verify conformance to specified requirements, or to establish characteristics or values not previously known.

B. Calibration and control measures specified herein are not required for rulers, tapes, levels, and other such devices, if the normal commercial devices provide adequate accuracy.

III. REQUIREMENTS

A. Selection of M&TE shall be controlled to ensure that the equipment is of proper type, range, and accuracy necessary to perform its function of determining conformance to specified requirements. The type, range, and accuracy requirements for the measuring device shall be specified in test and inspection procedures.

B. Identification

1. M&TE shall be uniquely identified. This identification shall be recorded on test reports, travelers, logs, etc., to provide traceability to the device used to take the measurement along with the measurement taken.

2. Each piece of M&TE requiring calibration shall be identified with the due date of the next calibration and provide traceability to calibration data.

3. M&TE not in calibration shall be appropriately tagged and/or segregated to prevent inadvertent use.

C. Calibration

1. M&TE 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 documented. Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function shall be identified.

2. The method and frequency of calibration shall be defined, based upon the type of equipment, stability, characteristics, required accuracy, precision, intended use, degree of usage, recommendations of the manufacturer, and other conditions that affect measurement control.

3. Equipment found to be continually out of calibration shall be repaired or replaced.

4. Equipment shall be calibrated whenever its accuracy is suspect.

5. When M&TE is found to be out of calibration; an evaluation shall be made and documented of the validity of previous results obtained and the acceptability of the items previously inspected, tested or data gathered since the last calibration.

D. M&TE shall be handled and stored in a manner which will maintain equipment accuracy.

E. Calibration records shall identify the calibration procedure and revision utilized to perform the calibration.

IV. Documentation

Records generated in support of the section shall be collected, stored, and processed in accordance with Section 17 of this QAPP.

I. PURPOSE

This section establishes the requirements to control the packaging, handling, storing, shipping, and cleaning of material and equipment to prevent damage, loss, or deterioration.

II. SCOPE

This section applies to the design of, the handling, storage or shipping of materials or equipment that require special provisions to prevent damage, loss or deterioration.

III. REQUIREMENTS

A. Handling, storage, and shipping of items shall be conducted in accordance with established instructions, drawings, specifications, or other pertinent documents or procedures, specified for use in conducting the activity.

B. Equipment or items that are critical, sensitive, perishable or exceptionally expensive, may require special environmental protection, protective devices, tools, and procedures for their handling, storage, shipping, preservation, and packaging. When required, these special conditions shall be specified, provided, and their existence verified. Special handling tools and equipment shall be inspected and tested in accordance with procedures, at specified times, to verify that the tools and equipment are being properly maintained.

C. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

D. Marking and labeling for packaging, shipment, handling and storage shall be established and maintained as necessary, to adequately identify, maintain, and preserve the integrity of the item, including indication of special environments or controls.

IV. DOCUMENTATION

Records generated shall be controlled in accordance with Section 17 of this QAPP.

I. PURPOSE

This section establishes the status requirements for inspections and test activities, and for indicating the status of systems and components to ensure that only items, components, and systems that have been satisfactorily inspected and/or tested are installed and used.

II. SCOPE

A. This section applies to all inspection and test activities of engineered items and systems related to the project.

B. Holmes & Narver, Inc. is not responsible for operational testing.

III. REQUIREMENTS

A. The system of inspection and testing of engineered items shall be maintained through indicators such as physical location and tags, markings, travelers, stamps, inspection and test records, or other suitable means.

B. Procedures governing inspection and test shall describe the status indicators and their use. The procedure shall contain current actual samples of each type of indicator and the authority for their applications and removal.

I. PURPOSE

This section establishes the requirements for the control of nonconforming items to prevent their inadvertent installation or use.

II. SCOPE

A. This section applies to all personnel performing activities in support of the project.

B. This section also applies to the processing of Nonconformance Reports (NCR) initiated by other than Holmes & Narver, Inc. (H&N), for which H&N has been assigned disposition or disposition implementation responsibility.

III. REQUIREMENTS

A. The process of controlling nonconformances shall be prescribed by written procedures which shall cover the following:

1. Identification (adequately identify and describe the nonconformance)
2. NCR sequential numbering system
3. Documentation
4. Personnel responsibilities and authority
5. Segregation
6. Evaluation
7. Dispositioning of NCRs
8. Quality Assurance (QA) responsibilities
9. Interfaces (internal/external)
10. Distribution to affected organizations
11. Examination, verification, and close-out of corrective action
12. Trending

B. It is the responsibility of all personnel associated with the project to identify and report nonconforming items to the appropriate levels of management.

C. NCR Identification

1. Nonconforming items shall be identified by marking, tagging, or other suitable means that will not adversely affect its potential end use. The identification must be easily recognizable and reference the NCR number. If tags are used, they shall be securely attached to avoid loss during handling.

2. Nonconforming items shall be segregated and placed in a clearly identified and designated hold area until the NCR is dispositioned. When segregation is impractical because of physical conditions, other, precautions shall be employed to preclude their inadvertent use.

3. Identification of the package, container, or designated segregated storage area is acceptable if identification of each item is not practical.

D. The person or organization responsible for disposition of the NCR shall ensure:

1. The disposition is documented and in sufficient technical detail to permit implementation.

2. Appropriate justification is provided for "Use-as-is" or "Repair" disposition.

3. The disposition identifies documents that must be revised as a result of the "Use-as-is" or "Repair" disposition.

Note: Documents changed shall reference the NCR as the authority for the change.

4. The disposition identifies appropriate design documents, procedures, plans, work orders, etc., to be used for correcting the nonconforming condition, where appropriate.

5. The disposition complies with existing design documents, procedures, test plans, reports and regulatory requirements.

6. The disposition is classified as Repair, Rework, Use-as-is, or Reject/Scrap, as appropriate.

Note: Use-as-is and Repair-type disposition require WMPO approval prior to implementation of the disposition.

7. When recurring nonconforming conditions are identified, an evaluation shall be made to determine if further programmatic corrective action is warranted in accordance with Section 16 of this QAPP.

E. Work on nonconforming items shall be stopped and not reinitiated until the approved disposition to resolve the nonconformance is obtained.

1. If only a specific portion of an item is identified as nonconforming, work may proceed on all but the nonconforming portion.

2. A "Conditional Release" approved by the appropriate WMPO Branch Chief and WMPO PQM is required to continue work on any nonconforming item. The request for conditional release shall include the following:

   a. Justification for continuing work.

   b. Assurance that the continuing work will not prevent correcting the nonconformance without damage to the item or associated facility equipment, or structure at a later date.

   c. Assurance that the nonconforming item will be accessible for inspection.

   d. Limits for use of the nonconforming item is evaluated and identified.

   e. Traceability and identification of the nonconformance item is maintained.

F. Actions taken to correct nonconforming items shall be verified and documented. Repaired or reworked items shall be reexamined in accordance with the original acceptance criteria, unless the NCR disposition has established alternate acceptance criteria.

G. A tracking system or log shall be maintained that shall include the following:

   1. NCR number

   2. Brief description of the nonconformance

   3. Identification of the person or organization responsible for determing and carrying out the disposition

   4. Status of nonconformance (open/closed)

H. Nonconformances shall be evaluated by QA for adverse trends and to help identify root causes of nonconformances. Adverse trends shall be reported to appropriate levels of management for their evaluation and assessment.

IV. DOCUMENTATION

A. The NCR and supporting documentation shall be controlled in accordance with Section 17 of this QAPP.

B. Copies of the NCRs shall be distributed to WMPO PQM and the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) upon issuance and closure.

I. PURPOSE

This section establishes the system for identifying, reporting, and correcting conditions adverse or potentially adverse to quality.

II. SCOPE

A. This section is applicable to quality related activities performed in support of the project.

B. It is not the intent of this section to duplicate the requirements of Section 15, Nonconformance Control.

III. REQUIREMENTS

A. Significant conditions adverse to quality shall be identified and documened via Corrective Action Report (CAR), and reported to the appropriate levels of management for resolution.

Note: A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances.

B. Management upon notification of a significant condition adverse to quality or that an unusual occurrence exists shall ensure that:

1. Immediate action is taken to remedy the condition.

2. Determine corrective factors.

3. Controls have been reviewed, implemented, monitored, and revised as appropriate.

4. Notification provided to affected managers of conditions and of lessions learned to improve conditions or avoid simular occurrences.

C. The QA shall document concurrence of the adequacy of proposed corrective actions to ensure that QA requirements will be satisfied and, followup action taken to verify proper implementation of this corrective action and to close out the (CAR).

D. QA shall periodically evaluate CARs for adverse trends. Results shall be reported to appropriate levels of management for review and assessment.

IV. DOCUMENTATION

A. Corrective Action Reports and supporting documentation shall be controlled in accordance with Section 17 of this QAPP.

B. Copies of CARs shall be submitted to the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) upon issuance and closure.

I. PURPOSE

This section establishes the requirements for the control of Quality Assurance (QA) Records.

II. SCOPE

A. This section applies to the generation, validation, distribution, maintenance and storage, and retrievability of documents classified as QA Records.

B. Documents which furnish objective evidence of the quality of an item or activity are classified QA Records. The term records as used herein means QA Records.

C. Permanent storage of records is not the responsibility of Holmes & Narver, Inc.

III. REQUIREMENTS

A. A records management system shall be defined and implemented in accordance with written procedures. The record system shall include requirements for record transmittal, distribution, retention, maintenance, storage, disposition, retrievability, and for the prevention of delays between record completion and storage at the Project Record Center. QA records system shall comply with applicable Nevada Nuclear Waste Investigations (NNWSI) Administrative Procedures.

B. Data or data interpretations for use in licensing activities that were not generated under the controls of the NNWSI Project QA Plan (QAP) shall be "qualified" as prescribed in AP 5.9Q.

C. All NNWSI records, including superseded records, are classified as lifetime records and shall be retained for the life of the project.

D. Documents that are designated to be QA records shall be legible, identifiable, accurate, complete, reproducible, microfilmable, retrievable, and appropriate to the work accomplished. The record may be the original or a suitable reproduction. Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. A list of typical records is provided in the Attachment.

E. Generation of Records: The applicable specifications, procurement documents, implementing and operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for WMPO. Procurement type documents shall also invoke similar record management requirements as specified herein.

F. Validation of Records: Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. Authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is identified as a statement by the reporting individual or organization. Lists shall be maintained which contain the signature and initials of the personnel authorized to authenticate records.

G. Receipt of Records: Organizations responsible for the receipt of records shall designate a person responsible for receiving the records. The designee shall be responsible for organizing and implementing a documented system of receipt control of records for permanent and temporary storage in accordance with approved procedures.

1. The receipt control system shall include the following:

   a. A method for designating the required records.

   b. A method identifying the records received.

   c. Procedures for receipt and inspection of incoming records.

   d. A method for submittal of completed records to the storage facility without unnecessary delay.

2. The receipt control system shall be structured to permit a current and accurate assessment of the record's status.

3. The individuals responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.

H. Records Identification

1. Records, indexing systems, or both shall provide sufficient information to permit identification of the record to the item or activity to which it applies, location of the record within the system, and subsequent retrieval from the storage system. Records shall be identified with a unique identification number or other designation which shall not be duplicated. The record identification system shall be reviewed and approved by Waste Management Project Office (WMPO).

2. Final reports shall contain a listing that enables prompt retrieval of all documents used to compile or evaluate the report. This listing shall include, as a minimum, all referenced documents, peer review or

other review documents, computer codes, data sheets, procedures, and test plans. All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc., shall be retrievable from the Records Management System (RMS).

I. Records Corrections: Records may be corrected in accordance with written procedures which provide for appropriate review or approval of the originating organization. The correction shall not obliterate the original data, and shall identify the authorized individual making the correction and the date the correction was made.

J. Storage

1. Records shall be stored and maintained in a manner that minimizes the risk of theft and vandalism; damage, or destruction from winds, floods, fire; environmental conditions, such as temperature and humidity; infestation of insects, mold, rodents.

2. Records shall be filed in dual storage facilities or in Alternate Storage facilities such as a two-hour fire-rated vault or in two-hour rated Class B file containers which meet the requirements of the National Fire Protection Association (NFPA) 232.

3. Access to records storage areas shall preclude entry of unauthorized personnel and a list shall be maintained that designates those personnel who have access to the file.

4. Dual Facilities: If storage at dual facilities for each record is utilized, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

5. Provisions shall be made in the storage facilities for special processed records (e.g., radiographs, photographs, negatives, microfilm, magnetic material, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity and filing supplemental information.

6. Records shall be accessible to WMPO and/or their designee.

7. Records removed from storage shall be accounted for and controlled.

8. Replacement, restoration, or substitution of lost or damaged records shall be accomplished within 90 days following determination that a record is lost or damaged.

IV. ATTACHMENTS

List of typical QA records (7 pages).

ATTACHMENT

LIST OF TYPICAL QA RECORDS

I. GENERAL

The following is a list of typical QA records. The nomenclature of these may vary for each organization.

A. Site Characterization

1. Surveys of the underground facility excavations, shafts, and boreholes referenced to readily identifiable surface features
2. Description of the materials encountered
3. Geological maps and cross sections
4. Locations and amounts of seepage
5. Instrument locations, readings, analyses, and reports for in situ testing
6. Technical specifications
7. Sample extraction location maps
8. Site Characterization Report
9. Environmental Assessment
10. Peer review documentation
11. Test plans and procedures, and results thereof
12. Data reduction, evaluations, analyses, and reports for:
    a. Geomorphology
    b. Stratigraphy
    c. Tectonics
    d. Seismicity
    e. Geoengineering
    f. Hydrology
    g. Geochemistry
    h. Climatology and Meteorology

13. Environmental Impact Statement

14. Environmental Report

B. Design Records

1. Applicable codes and standards used in design

2. Design drawings

3. Design calculations and records of checks

4. Approved design change requests

5. Design deviations

6. Design reports

7. Design verification data

8. Design specifications and amendments

9. Safety analysis report

10. Stress reports for code items

11. Systems descriptions

12. Systems process and instrumentation diagrams

13. Technical analyses, evaluations, and reports

C. Procurement Records

1. Procurement specifications

2. Purchase order including amendments

D. Manufacturing Records

1. Applicable code data reports

2. 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).

3. Certificate of compliance

4. Eddy-current examination final results

5. Electrical control verification test results

6. Ferrite test results

7. Heat treatment records

8. Liquid penetrant examination final results
9. Location of weld filler material
10. Magnetic particle examination final results
11. Major defect repair records
12. Material properties records
13. Nonconformance reports
14. Performance test procedure and results records
15. Pipe and fitting location report
16. Pressure test results (hydrostatic or pneumatic)
17. Radiographs (for in-service inspection applications)
18. Radiograph review records
19. Ultrasonic examination final results
20. Welding procedures

E. Installation and Construction Records

1. Receiving and Storage: Nonconformance reports
2. Civil
   a. Concrete cylinder test reports and charts
   b. Concrete design mix reports
   c. Concrete placement records
   d. Inspection reports for channel pressure tests
   e. Material property reports on containment liner and accessories
   f. Material property reports on metal containment shell and accessories
   g. Material property reports on reinforcing steel
   h. Material property reports on reinforcing steel splice sleeve material
   i. Procedure for waste package vessel pressure-proof test and leak rate tests and results
   j. Reports of high-strength bolt torque testing
   k. Soil compaction test reports

l. Location and description of structural support systems

m. Details, methods of emplacement, and location of seals used

3. Welding

a. Ferrite test results

b. Heat treatment records

c. Liquid penetrant test final results

d. Material property records

e. Magnetic particle test final results

f. Major weld repair procedure and results

g. Radiographs (for in-service inspection application)

h. Radiograph review records

i. Ultrasonic test final results

j. Weld location diagrams

k. Weld procedures

4. Mechanical

a. Cleaning procedures and results

b. Code data reports

c. Installed lifting and handling equipment procedures, inspection, and test data

d. Lubrication procedures

e. Material properties records

f. Pipe and fitting location reports

g. Pipe hanger and restraint data

h. Pressure test results (hydrostatic or pneumatic)

i. Safety valve response test procedures

5. Electrical and Instrumentation and Control

a. Cable pulling tension data

b. Cable separation data

c. Cable splicing procedures

d. Cable terminating procedures

e. Certified cable test reports

f. Relay test procedures

g. Voltage breakdown test results on liquid insulation

6. General

a. As-built drawings and records

b. Final inspection reports and releases

c. Nonconformance reports

d. Specifications and drawings

e. Details of equipment, methods, progress, and sequence of work

f. Construction problems

g. Anomalous conditions encountered

F. Pre-Operational and Start-Up Test Records

1. Automatic emergency power source transfer procedures and results

2. Final system adjustment data

3. Pressure test results (hydrostatic or pneumatic)

4. Instrument AC systems and inverters test procedure and reports

5. Off-site power source energizing procedure and test reports

6. On-site emergency power source energizing procedure and test reports

7. Pre-operational test procedures and results

8. Repository protection system tests and results

G. Operation Records

1. Records and drawing changes that identify repository design modifications made to systems and equipment described in the Final Safety Analysis Report

2. Radioactive waste inventory, emplacement location, and transfer records

a. Off-site environmental monitoring survey records

b. Waste shipment records

c. Repository radiation and contamination survey results

d. Radiation exposure records for individuals entering radiation control areas

e. Records of gaseous and liquid radioactive material released to the environment

f. Records of transient or operational cycles for those repository components designed for a limited number of transients or cycles

g. Training and qualification records for members of the repository operating staff

h. In-service inspection records

i. Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments

j. Meeting minutes of the repository nuclear safety committee and licensee nuclear review board

k. Surveillance activities, inspections, and calibrations required by the technical specifications

l. Records of repository tests and experiments

m. Changes made to operating procedures

n. Sealed source leak-test results

o. Records of annual physical inventory of all sealed source material

p. Logs of repository operation

q. Records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components

r. Operational, shift supervisor, and control-room logs

s. Licensee event reports

t. Fire protection records

u. Nonconformance reports

v. Repository equipment operations instructions

w. Security plan and procedures

x. Emergency plan and procedures

y. Quality assurance and quality control manuals

z. Records of activities required by the security plan and procedures

aa. Applicable records noted in other sections of this attachment for any modifications or new construction applicable to structures, systems or components

bb. Evaluation of results of reportable safety concerns as required by regulations

cc. Annual environmental operating report

dd. Annual repository operating report

ee. Location and description of dewatering systems

I. PURPOSE

This section establishes requirements of the audit program and the qualifications of Quality Assurance (QA) audit personnel.

II. SCOPE

This section applies to the conduct of audits and surveillance to verify that procedures and activities comply to the overall Quality Assurance Program and to determine program effectiveness.

III. REQUIREMENTS

A. Scheduling

1. The Chief, Quality Assurance (CQA), is responsible for establishing the audit schedule which shall include dates of audit, the activity to be audited, and the requirements to which the activity are to be audited. The audit schedule and changes shall be distributed to the SAIC/T&MSS Project QA Department (QA Verification Division Manager).

2. Internal Audits: Elements of the H&N QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of the audit shall be established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA program.

3. External Audits: 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. If the activity or contract is less than four months in duration, audits need not be conducted unless considered necessary due to the complexity or importance of the activity performed. Justification for not performing the audit shall be documented and approved by the CQA. Evaluation of the supplier's QA program shall be documented and take into account the following, where applicable:

   a. Supplier's (furnished) documents and records such as certificates of conformance, nonconformance reports and corrective actions.

   b. Results of previous audits, source verifications and receiving inspection reports.

   c. Operating experience of identical or similar products furnished by the same supplier.

d. Results of audits from other sources, e.g., customer, ASME, or NRC audits.

4. Internal and external audits shall be scheduled in a manner to provide coverage of all applicable elements of this QAPP or the organization's QA Manual, as appropriate, commensurate with ongoing activities and early enough to assure effective QA Program implementation. The audit schedule shall be evaluated periodically and revised as necessary to ensure that coverage is adequate. The audit report should include an assessment of program effectiveness.

5. Surveillances and supplementary audits shall be conducted to supplement the audit program as deemed necessary based on relative impact or importance to the project.

B. Personnel Qualification

1. Personnel selected for auditing and surveillance assignments shall be qualified based on experience and training. Technical specialists may be used on audits for those activities for which they have specialized expertise. Personnel selected to perform an audit or surveillance shall be independent of any direct responsibility for the activity being audited or surveilled. Personnel who have direct responsibility for performing the activities to be audited or surveilled shall not be involved in the selection of the audit or surveillance personnel.

2. Auditors shall be adequately trained or oriented to perform their required duties competently. Their competence shall be developed, to the extent necessary, by one of the following methods:

a. Orientation that provides a working knowledge and understanding of: (1) 10CFR60; (2) the requirements of this QAPP; (3) implementing procedures, including those for conducting audits, reporting results, and closing audits; and (4) other directives, standards, guidelines, and regulations which are applicable to the project.

b. Participation in training programs that provide general and specialized training in audit performance. general training shall include auditing fundamentals, objectives, characteristics, organization, performance, and the results. specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods for closing out audit findings.

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

3. The orientation and training shall be accomplished prior to conducting an audit. Auditors who have not participated in an audit in the past two years shall be reoriented and retrained.

4. Qualification of Lead Auditors: The CQA shall be certified by the Manager, Nevada Operations. Subsequent certification of lead auditors will be performed by the CQA. Individuals considered for lead auditor certification shall meet the following requirements:

   a. Communication Skills: Prospective lead auditors shall have the capability to communicate effectively, both orally and in writing. These skills shall be attested to in writing on the Lead Auditor Qualification Form (attached) by the CQA.

   b. Training: Prospective lead auditors shall be trained to the extent necessary to ensure competence in auditing skills, general structure of Quality Assurance program and applications as defined in this QAPP, and audit planning in the functions related to quality for design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing statistics, nondestructive testing, maintenance, repair, and operation.

   c. Audit Participation: The prospective lead auditor shall have participated in a minimum of five audits within three years prior to the date of qualification. One of these shall have been a nuclear QA audit conducted within the year prior to qualification.

   d. Examination: Prospective lead auditors shall pass an examination which shall test their knowledge of audit activities, as per the above training requirements. The test may be oral, written, practical, or any combination of the three types, as determined by the CQA. If any portion of the examination is oral, written documentation of the oral examination question/content shall be maintained. Personnel previously certified in accordance with ANSI N45.2.23 or other applicable certification programs, as evaluated by the CQA, may be accepted as a lead auditor. External training courses with examinations that meet the requirements of this section can be accepted to meet certification requirements with the approval of the CQA. Integrity of the examination results and copies of the objective evidence regarding the type of tests and content of the examinations shall be maintained by CQA.

5. Maintenance of Lead Auditor Qualifications: Lead auditors shall maintain their proficiency through regular and active participation in audit process; review and study of codes, standards, procedures, instructions and other documents related to quality assurance program and program auditing; and participation in training programs. Based on annual assessment, the CQA may extend the qualification, require retraining or requalification.

6. Requalification: Lead auditors who fail to maintain their proficiency for a period of two years shall be required to requalify. Requalification shall be in accordance with the requirements of paragraph III B.4.

7. Certification of lead auditors shall be documented on attachment A.

C. Audit Preparation

1. An audit team shall be identified prior to the beginning of each audit. This team shall have one individual designated as lead auditor who shall organize and direct the audit, coordinate the performance and issuance of the audit report, and evaluate the responses. Auditors may be technical specialists, management representatives and/or auditors in training. Technical specialists assigned to an audit team shall be identified in the audit plan.

2. The lead auditor shall develop and document an audit plan which identifies the audit scope, the requirements, the activities to be audited, audit personnel, organizations to be notified, the applicable documents, the audit schedule, and written procedures or checklists.

3. The lead auditor shall ensure that the audit team is qualified and prepared prior to beginning the audit.

D. Audit Implementation

1. The audit shall be performed in accordance with written procedures using audit checklists, as early in the life of the activity as practical. Elements that have been selected for audit shall be evaluated against specified requirements including a review of corrective action taken on deficiencies in the areas being audited that were identified during previous audits. Objective evidence shall be examined to the extent necessary to ensure compliance with QA Program requirements and for determining the effectiveness of its implementation.

2. The audit team shall conduct a post-audit meeting with the management of the audited organization(s) to present the results of the audit.

3. The audit team shall immediately notify the affected management of conditions which warrant immediate corrective action.

E. Audit Report

Within 30 days of the post-audit meeting, the lead auditor shall prepare, sign, and issue an audit report which, as a minimum, shall contain the following:

1. Description of the audit scope.

2. Identification of the audit team.

3. Identification of the personnel contacted during the audit.
4. Summary of the audit results, including a statement of the effectiveness of the QA program elements audited.

5. Description of each reported finding in sufficient detail to enable corrective action to be taken by the audited organization.

F. Audit Response

1. The audited organization shall evaluate the audit report and findings (CAR) and provide a written response, to the CQA, with copies to their respective management, within 30 days, as prescribed by Section 16 of this QAPP.

2. The lead auditor shall evaluate and track the response, ensure that follow-up action, including verifications of corrective action has been performed and that any adverse trends are identified and reported to management for review, assessment and appropriate action.

G. Surveillances

Surveillances shall be performed in accordance with approved procedures, checklists, or surveillance plans whenever practical. The surveillance report shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of results and accuracy of any M&TE (when used) equipment necessary to perform the surveillance. The specification of acceptance criteria related to surveillance may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements." All deficiencies, nonconformances, and potential quality problems identified are to be documented and tracked until verification of effective corrective action is made.

IV. DOCUMENTATION

A. All records required for implementation of this section shall be collected, stored, and maintained in accordance with written procedures which conform to Section 17 of this QAPP.

B. Audit records shall be maintained and, as a minimum, shall include the following:

1. Identification of the organizations, activities, or items audited, and the individuals contacted.

2. Description of any deficiencies, nonconformances, or potential problems identified.

3. Audit plans, audit reports, written replies, records of completion of corrective action, and close-out of the audit.

4. Qualification of audit personnel.

C. Surveillance records shall identify the following:

1. Item or activity

2. Date of surveillance

3. Name of individual performing the surveillance

4. Identification of the organization(s) surveilled, including the name or names of personnel contacted

5. Description of any deficiencies, nonconformances, and potential Quality problems identified during the surveillance

6. Specification of recommended and/or approved corrective action resulting from the surveillance

7. Surveillance criteria

8. Equipment (including accuracy) used during the surveillance (if applicable)

9. Results

10. Acceptance statement

V. ATTACHMENTS

Lead Auditor Qualification Record (1 page)

VI. REFERENCES

A. ANSI N45.2.23, Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants

B. 10CFR 60, Code of Federal Regulation, Disposal of High Level Radioactive Waste in Geologic Repositories.

ATTACHMENT A

LEAD AUDITOR QUALIFICATION RECORD

HOLMES & NARVER, INC.

LEAD AUDITOR QUALIFICATION RECORD

Page ____ of ____

NAME	DATE

QUALIFICATION POINT REQUIREMENTS	CREDITS
EDUCATION — UNIVERSITY/DEGREE/DATE — 4 CREDITS MAXIMUM	
1. UNDERGRADUATE LEVEL	
2. GRADUATE LEVEL	
EXPERIENCE — COMPANY/DATES — 9 CREDITS MAXIMUM	
TECHNICAL (0-5 CREDITS) AND	
NUCLEAR INDUSTRY (0-1) CREDIT), OR	
QUALITY ASSURANCE (0-3 CREDITS), OR	
AUDITING (0-4 CREDITS)	
PROFESSIONAL ACCOMPLISHMENT — CERTIFICATE/DATE — 2 CREDITS MAXIMUM	
1. P.E.	
2. SOCIETY	
MANAGEMENT — JUSTIFICATION/EVALUATOR/DATE — 2 CREDITS MAXIMUM	
EXPLAIN:	
EVALUATED BY: ____ DATE	
TOTAL CREDITS	

SAMPLE

AUDIT COMMUNICATION SKILLS.
EVALUATED BY: ____ DATE

AUDIT TRAINING COURSES:

COURSE TITLE OR TOPIC	DATE
1.	
2.	
3.	

AUDIT PARTICIPATION.

	LOCATION	AUDIT SCOPE	DATE
1.			
2.			
3.			
4.			
5.			

EXAMINED BY: WRITTEN ☐ ORAL ☐ ON THE JOB ☐ OTHER ☐ PASSED DATE

CERTIFIED BY: (Supervisor) DATE CERTIFIED

ANNUAL EVALUATION (Signature/Title/Date)				

ESD-QA-18

I. PURPOSE

This attachment establishes the qualification and certification requirements. for test and inspection personnel.

II. SCOPE

A. This attachment applies to inspection and test personnel who verify conformance to specified requirements for the purpose of acceptance of items and systems for this project.

B. This attachment does not apply to nondestructive examination.

III. REQUIREMENTS

A. General Requirements

1. Qualification and certification of inspection and test personnel shall be prescribed by written procedures.

2. Personnel selected to perform inspections and tests shall have experience and/or training commensurate with the activity to be performed, and be indoctrinated to the technical objectives and requirements of the applicable codes, standards, and the Quality Assurance (QA) Programs Plan to be employed.

3. Personnel who do not meet the requirements of this appendix may assist an inspection or test team as data-recorders or equipment operators provided they are supervised by a qualified individual.

4. Training of inspection and test personnel shall be conducted and documented as required. Emphasis shall be placed on first-hand experience gained through actual performance (OJT) of inspections and tests.

5. Performance evaluations of inspection and test personnel shall be conducted at periodic intervals not to exceed three years.

   a. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability.

   b. If it is determined that the individual's capabilities are not satisfactory, the individual shall be prohibited from performing that activity until the individual is retrained and requalified.

   c. Individuals who have not performed inspection or testing in their qualified area(s) for a period of one year shall be reevaluated and a redetermination of their qualification made.

6. Special physical characteristics required for the performance of any inspection or test activity shall be identified, including frequency of examination.

B. Inspection and test personnel shall be qualified to one of the three functional qualification levels, depending upon the complexity of the functions involved. The requirements of each level are not limiting with regard to organizational position, professional status, but are limiting with regard to functional activities.

1. Level I: Level I personnel shall be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices.

2. Level II: Level II personnel shall have all of the capabilities of Level I personnel for the inspection, test category, or class in question. Additionally, Level II personnel shall have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in evaluating the validity and acceptability of inspection and test results.

3. Level III: Level III personnel shall have all of the capabilities of Level II personnel for the inspection, test category, or class in question. In addition, the individual shall also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this section.

C. Education and Experience Requirements

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

1. Level I:

a. Two years of related experience in equivalent inspection or testing activities; or

b. High school graduation and six months of related experience in equivalent inspection or testing activities; or

c. Completion of college-level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.

2. Level II:

   a. One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or

   b. High school graduation plus three years of related experience in equivalent inspection or testing activities; or

   c. Completion of college work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities; or

   d. Graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities. activities.

3. Level III:

   a. Six years satisfactory performance as a Level II in the corresponding inspection, test category, or class; or

   b. High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection of of testing activities with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with relevant QA aspects of a nuclear facility; or

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

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

D. Certification of Qualifiction

The qualification of inspection and test personnel shall be certified in writing. The certification shall include:

1. Employer's name.

2. Identification of person being certified.

3. Activities certified to perform.

4. Basis used for certification that includes such factors as:

   a. Education, experience, and training (when necessary).

   b. Test results (where applicable).

   c. Results of capability demonstration.

5. Results of periodic evaluation.

6. Results of physical examinations (when required).

7. Signature of individual responsible for such certification.

8. Dates of certification and certification expiration.

IV. DOCUMENTATION

Records of qualification, including actual examinations and results, and certification shall be processed in accordance with Section 17 of this QA Program Plan.

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

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

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The NNWSI 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) which influences or affects the achievement or verification of the objectives of the NNWSI Project as depicted in the WBS Dictionary.

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

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.

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

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

BASELINE: As used for computer software: (1) The stage of computer software at a completed and reviewed phase of the software 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:

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

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

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

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

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

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

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

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

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

CONTAINMENT, PERIOD OF: Know as the period during the first several hundred years following permanent closure of the geologic repository in which radiation and thermal levels are high and the uncertainties of 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 extend horizontally no more than 5 kilometers in any direction from the outer boundary of the underground facility and the underlying subsurface, which is an area that has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure. The controlled area is also known as the site.

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

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

CORROBORATIVE DATA: Information that may or may not have been acquired and controlled in a manner consistent with Quality Assurance Level I requirements and may be used to support or substantiate other existing data.

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

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

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

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

DEVIATION: A departure from specified requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NTS: Nevada Test Site.

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

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

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

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

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

PARTICIPATING ORGANIZATION: This term applies to the following: (1) the government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in NNWSI Project activities.

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

PEER REVIEW: A documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being performed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, their term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

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

PEER REVIEW REPORT: A documented in-depth report of the 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.

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

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

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

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

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

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

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

Q-LIST: A list of geologic repository engineered structures, systems, and components that have been determined to be important to safety, waste isolation, or both, and a list of activities that will provide site characterization data which will be used to assess the performance of natural barriers or activities whose undertaking could adversely affect the performance of the natural barriers. The items and activities on this list are subject to the highest quality assurance level (QA Level I) of the formal QA Plan.

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 quality assurance program or existing data qualified in accordance with Appendix G of this QA Plan.

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

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

QUALITY ASSURANCE RECORD: An individual document or other item that has been executed, completed, and approved and that furnished evidence of (1) the quality and completeness of data (including raw data), items, and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of Quality Assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents such as plans, correspondence, documentation 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 geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and

activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

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

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

QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document that describes the organization's Quality Assurance Program, the applicable QA requirements, and 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, to assure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of the project.

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

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

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

REPOSITORY: See Geologic Repository Operations Area.

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

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

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

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

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

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

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

SITE: Location of the controlled area.

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

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test or the product.

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

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

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

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

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

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

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

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

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

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

WAIVER: Documented authorization to depart from specified requirements.

WASTE MANAGEMENT PROJECT OFFICE (WMPO): The organization to which the U.S. Department of Energy, Nevada Operations Office (DOE/NV), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors associated with the NNWSI Project.

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

I. PURPOSE

A. This appendix provides criteria for the development, maintenance, and security of computer software. This appendix prescribes appropriate systematic practices that reduce the likelihood of defects entering executable code during development, ensure that the end product answers the requirements of its intended application, and reduce the likelihood that defects will be introduced into executable code during later maintenance and modification.

II. SCOPE

A. The requirements set forth in this appendix apply to computer software used to produce or manipulate data which is used directly in the design, analysis, performance assessment, and operation of repository structures, systems, and components. The extent to which these requirements apply is related to the nature, complexity, and importance of the software application.

III. REQUIREMENTS

A. The development and maintenance of computer software shall be prescribed by procedures that shall assure that the requirements specified herein are implemented in a consistent and systematic manner. The criteria for application of these requirements are prescribed per NNWSI administrative procedure, AP.5.5Q.

B. Software Life Cycle

1. Software development activities shall adhere to a software life cycle model that requires that software development proceed in a traceable, planned, and orderly manner. The relative emphasis placed on each phase of the software development cycle will depend on the nature and complexity of the software being developed.

2. Life cycle model shall include the following:

a. Requirements

b. Design

c. Implementation

d. Test

e. Installation and checkout

f. Operation and maintenance

3. Verification/validation shall be performed at each stage of the life cycle by the individual generating or modifying the software. It is not required to document all of these activities performed to satisfy the software developer. The results of this stage shall, however, form the input to a verification and/or validation plan that shall be documented, reviewed, and approved prior to independent tests. Each phase of the software development cycle shall provide specific attributes that shall be incorporated into verification and validation activities. The documentation for each phase of the software development cycle shall be reviewed and approved before succeeding phases can begin.

4. Verification/validation of the software shall be conducted, from the test plan created during the life cycl,e during installation and checkout by an independent individual or organization who did not work on the original software.

C. Software QA Plan

1. The application of the software life cycle to the development and/or use of the software shall be as described in the software QA plan. A software QA plan shall be prepared for each software development/ application effort at the start of the software life cycle. This plan may be prepared individually for each piece of software or may exist as a generic document to be applied to all software prepared within an organization. The software QA plan shall identify:

   a. The software products to which it applies,

   b. The organizations responsible for software quality and their tasks and responsibilities,

   c. Required documentation,

   d. Standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same,

   e. The required software reviews.

2. Regardless of the life cycle model used, the following requirements shall apply as interpreted and defined by the organizations software QA plan.

   a. Requirements 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 shall possess the following characteristics:

1. A format and language that is understood by the programming organization and the user,

2. Enough detail to allow for objective verification,

3. Adequate definition to provide for the response of the software to all realizable classes of input data,

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

b. Design Phase: Software design based on the requirements shall be specified, documented, and systematically reviewed. The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control, logic, and data structures). the design may necessitate the modification of the requirements documentation. Design phase verification and validation activities during this phase shall consist of:

1. The generation of design-based test cases,

2. The review and analysis of the software design,

3. The verification of the software design.

c. Implementation Phase: The design shall be translated into a programming language and the implemented software shall be debugged. Only minor, if any, design issues shall be resolved at this phase. Verification and validation activities during this phase shall consist of:

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

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

d. Testing Phase: The design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases may require the modification of the requirements, the design, the implementation, or the test plans and test cases. Verification and validation activities during this phase shall consist of:

1. The evaluation of the completed software to assure adherences to the requirements.

2. The preparation of a report on the results of software verification and validation.

e. Installation and Checkout Phase: The software becomes part of a system incorporating other software components, the hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included. Testing activities during this phase shall consist of the execution of test cases for installation and integration.. The cases from earlier phases shall be enhanced and used for installation testing.

f. Operations and Maintenance Phase: In this phase the software has already been approved for operational use. Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to responds to new or revised requirements (perfective maintenance), or to adapt the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested (including regression testing as appropriate), and controlled in accordance with the software verification and validation section.

D. Software Verification and Validation

1. Verification and validation plans shall employ methods such as inspection, analysis, demonstration, and test to assure that the software adequately and correctly performs all intended functions, an that the software does not perform any function that either by itself or in combination with other functions can degrade the entire system.

2. Verification and validation activities shall be planned and performed relative to specific hardware configurations. The amount of verification and validation activity shall be determined by the type and complexity of the software. The results of all verification and validation activities shall be documented in the Verification and Validation Report.

a. Verification activities shall be integrated into all phases of the software life cycle and shall be performed to an extent proportional to the critical importance of the software. Software verification shall be performed to assure that the software design is implemented in code. Appropriate methods such as inspection, analysis, test, or demonstration shall be applied to accomplish verification objectives.

b. Validation activities are performed at the end of the software development cycle to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. This is accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in site testing. Specific sets of data used in the validation process shall be identified and justification shall be made for their use. When data is not available from the

sources mentioned above, alternative approaches used shall be documented, including an evaluation of the degree of validity of the model. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. The results of the validation shall be reported in the Verification and Validation Report.

E. Software Configuration Management

1. A software configuration management system shall be established to assure positive identification of software and control of all software baseline changes.

   a. Configuration Identification: A configuration baseline shall be identified at the completion of each major phase of the software development cycle. Approved changes to a baseline shall be added periodically to the baseline as updates. A baseline plus updates shall specify the most recent software configuration. Updates shall be incorporated into subsequent baselines. Both baselines and updates shall be defined by their composition of software configuration items. A labeling system for configuration items shall be implemented that:

      1. Uniquely identifies each configuration item or version number.

      2. Identifies changes to configuration items by revision.

      3. Places the configuration item in a relationship with other configuration items.

      4. Provides the ability to reconstruct the configuration of the software from the requirements phase up to the present time.

   b. Configuration Change Control: A proposal for changes to baseline software shall be formally documented. This documentation shall contain a description of the proposed change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The proposal shall be formally evaluated by a qualified individual or organization with the ability to approve or disapproved the proposed change. Assurance shall be provided that only authorized changes are made to software baselines.

   c. Configuration Status Accounting: The information that is needed to manage configuration control of software shall be recorded and reported. This information shall include a listing of the approved configuration identification, the status of proposed changes to the configuration, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.

F. Reviews

1. Reviews of software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each phase of development prior to proceeding to the next development phase. The procedures used for reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review report.

2. The documentation for all reviews shall contain a record of review comments, a plan, and timetable for the resolution of the review comments, and the personnel responsible for this resolution.

3. After review comments are resolved, the approved documents shall be updated and placed under configuration management.

   a. Software Requirements Review: The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the requirements are complete, verifiable, consistent, and formatted to provide traceability of requirements throughout the development cycle. The review shall also assure that there is sufficient detail available to complete the software design.

   b. Software Design Review: The software design review will be held at the completion of the software design documentation. This review shall evaluate the technical adequacy of the design approach, and assure that the design answers all the requirements in the requirements documentation. The complexity of the software design may require the performance of two design reviews; one at the completion of the overall software architecture, and the second at the completion of the total design.

   c. Software Implementation Review: The software implementation review is an evaluation of the completed requirements, design and implementation process prior to independent verification and validation and concludes in review and approval of the verification and validation plan.

   d. Software Verification and Validation Review: The software verification and validation review is an evaluation of the adequacy of completed software verification and validation activities and concludes in review and approval of the Verification and Validation Report.

G. Discrepancy Reporting and Corrective Action

1. A formal procedure of software discrepancy reporting and corrective action shall be established. This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions. Software discrepancy reporting and corrective action shall assure that, as a minimum:

a. Defects are documented and corrected,

b. Defects are assessed for criticality and impact on previous applications,

c. Corrections are reviewed and approved before changes to the software configuration are made,

d. Preventive and corrective actions provide for appropriate notification of affected organizations.

H. Acquired Software

1. Requirements shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. Software transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this appendix and the needs of the organization's computer system. Those requirements not met by the software received shall be completed by the organization in the relative phase of the software life cycle that is incomplete or, if that is not possible, the reason shall be documented and maintained with the software and distributed to the users. The software shall be used only for those applications for which the documentation is complete.

2. 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 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 in the user's manual 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.

I. Computer Software Applications

1. Procedures shall be established for controlling the application of verified and/or validated computer software to technical calculations in support of design, analysis, performance assessment, and operation of repository structures, systems, and components.

2. Procedures shall be established for documenting and reviewing software application and analyses and assuring that all results are accurate and reproducible. Requirements shall be established for identifying or otherwise marking record copies of all analyses and supporting documentation. Supporting documentation includes computer output

(results), code input data including data bases and original source/references of and assumptions used to obtain such data, code design user's and/or operation manuals, verification/validation test results and/or hand calculations.

3. Technical calculations using software shall be performed with applicable computer codes and with software operating procedures defined sufficiently to allow independent repetition of the entire computation.

4. Controls shall be established for generating and documenting software used to perform technical calculations. All auxiliary software used shall be included in documentation of technical calculations performed and shall be included in independent review as part of the calculation.

5. All applications of computer software shall be independently reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

IV. DOCUMENTATION

The following is the minimum acceptable documentation of computer software developed or modified for use:

A. Software Requirements Specification

1. A specific capability of software can be called a requirement only if its achievement can be verified by a prescribed method. Software requirements documentation shall outline the requirements that the proposed software must fulfill. The requirements shall address the following:

a. Functionality - the functions the software are to perform,

b. Performance - The time-related issues of software operation such as speed, recovery time, response time, etc.,

c. Design constraints imposed on implementation - any elements that will restrict design options,

d. Attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc,

e. External Interfaces - interactions with other participants, hardware, and other software.

B. Software design documentation is a document or series of documents that shall contain:

1. A description of the major components of the software design as they relate to the requirements of the software requirements specification,

2. A technical description of the software with respect to control flow, data flow, control logic, and data structure,

3. A description of the allowable and tolerable ranges for inputs and outputs,

4. The design described in a manner that is easily traceable to the software requirements,

5. Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856,

6. Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

C. Any design changes made to the requirement and design phase documents shall be assessed as to the impact on the design. The revised requirement and design phase documents shall be revieved to the same level of reviev as the original documents. The results of this phase shall be the basis for the software Verification and Validation Plan.

D. Software verification and validation documentation shall include a plan that describes the tasks and criteria for accomplishing the verification of the software in each phase, and the validation of the software at the end of the development cycle. The documentation shall also specify the hardware and system software configuration pertinent to the software. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. This documentation will also include a report on the results of the execution of the software verification and validation activities. This report shall include the results of all reviews, audits, and tests, and a summary of the status of the software.

E. User documentation shall be prepared in accordance with NUREG-0856 and shall include a description of:

1. Program considerations, options, and initialization procedures,

2. Anticipated error situations and how the user can correct them,

3. Internal and external data files, their input sequence, structures, units, and ranges,

4. Input and output options, defaults, and formats,

5. System interface features and limitations,

6. Information for obtaining user and maintenance support,

7. Sample problems.

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

IV. REFERENCES

NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

I. PURPOSE

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.

II. SCOPE

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

III. REQUIREMENTS

A. General Requirements

1. The following conditions are indicative of situations in which a peer review shall be considered:

a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing,

b. Decisions or interpretations having significant impact on performance assessment conclusions will be made,

c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized,

d. Detailed technical criteria or standard industry procedures do not exist or are being developed,

e. Results of tests are not reproducible or repeatable,

f. Data or interpretations are ambiguous,

g. Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.

2. 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.

B. Structure of Peer Review

1. The number of peers and structure comprising a peer review group shall vary commersurate with the following:

   a. The complexity of the work to be reviewed,

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

   c. The number of technical disciplines involved,

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

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

2. 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.

C. Acceptability of Peers

1. 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. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.

2. 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 assure the work is impartially reviewed. In some cases (i.e. funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.

D. Peer Review Process

1. 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.

2. The peer review group shall evaluate the report on:

   a. Validity of assumptions,

   b. Alternate interpretations,

   c. Uncertainly of results and consequences if incorrect,

   d. Appropriateness and limitations of methodology and procedures,

   e. Adequacy of application,

   f. Accuracy of calculations,

   g. Adequacy of requirements and criteria,

   h. Validity of conclusions.

3. The chairperson of the peer group shall be responsible for having documentation prepared to indicate the results of meetings, deliberations, and activities of the peer review process.

E. Peer Review Report

1. A report documenting the results of the peer review shall be prepared and issued. The peer review report shall include the following:

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

   b. Conclusions reached by the peer review process,

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

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

IV. DOCUMENTATION

Records of peer review meetings and reports shall be processed in accordance with section 17 of this QA Program Plan.