U. S. NUCLEAR REGULATORY COMMISSION

REVIEW PLAN FOR HIGH-LEVEL WASTE REPOSITORY QUALITY ASSURANCE PROGRAM DESCRIPTIONS

DIVISION OF HIGH-LEVEL WASTE MANAGEMENT

DECEMBER 1988

INTRODUCTION

Under the Nuclear Waste Policy Act of 1982, as amended, the Department of Energy (DOE) is to characterize the Yucca Mountain site for a geologic repository to determine if it is suitable for safely isolating high-level nuclear waste. The Nuclear Regulatory Commission's (NRC) role as a regulatory agency during the site characterization phase is to review and comment on the DOE program in order to identify and help resolve potential licensing issues.

The NRC regulations in 10 CFR Part 60 Subpart G require the high-level waste repository program, including site characterization, to be performed under a quality assurance (QA) program which meets the nuclear power plant quality assurance requirements in 10 CFR Part 50 Appendix B, "as applicable." In June 1984 the NRC published the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories." This document provided the specific QA criteria which the NRC staff used to review the DOE QA program, i.e., it provided the staff's positions on the meaning of "as applicable" in the use of Appendix B in the repository program.

This revision to the NRC Review Plan endorses NQA-1, "QA Requirements for Nuclear Facilities, 1986," incorporates lessons learned from the Ford Study (NUREG-1055) such as the use of technical audits and readiness reviews; where necessary better accounts for differences between power reactor projects and the high-level nuclear waste repository program based on several years of use in reviewing the DOE program; and references the staff's Technical Positions which have been developed since the original Review Plan was issued.

This revised plan will be used by the staff to judge the acceptability of the QA program descriptions in the repository program, including site characterization. Additional revisions may be necessary from time to time based on experience in implementing the program.

CRITERIA FOR QA PROGRAM DESCRIPTION REVIEWS

Each section of this Standard Review Plan corresponds to each of the 18 criteria of Appendix B to 10 CFR 50 and provides acceptance criteria which are used by the NRC staff to evaluate QA program descriptions or plans. The structure of each section is organized in a way that elaborates on or identifies specific information needs for individual requirements as they appear within the 18 Appendix B criteria.

Criteria in this Review Plan represent solutions and approaches that are acceptable to the staff, but which may not be the only possible solutions and approaches. Various alternatives to the criteria in this Plan may be found acceptable provided these alternatives are documented and justified. A commitment to conform to the criteria in this Plan is considered to be a commitment to implement them unless exceptions or alternatives are specifically identified and found acceptable by the NRC staff.

1. The Organization elements responsible for the QA program are acceptable to the NRC staff if:

   1.1 The responsibility for the establishment and execution of the overall quality assurance program is retained and exercised by that organization or individual responsible for submitting the license application.

   1.2 The authority and duties of persons and organizations performing activities affecting important to safety or waste isolation functions* are clearly established and delineated in writing.

   1.3 The QA program assures that activities affecting safety functions include both the performing functions of attaining quality objectives and the quality assurance functions.

   1.4 The quality assurance functions are those of (a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety functions have been correctly performed.

   1.5 DOE and prime contractors describe major delegation of work involved in establishing and executing the QA program, or any part thereof to other organizations.

* Hereafter referred to as "safety functions."

1.6 DOE and prime contractors describe how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.

1.7 DOE and prime contractors evaluate the performance of work delegated to other organizations. This shall include audits of the prime contractors' QA programs and audits of subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.

1.8 Qualified individual(s) or organizational element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.

1.9 Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors to assure direction of the QA program.

1.10 Organization charts clearly identify all the "on-site" and "off-site" organizational elements which function under the cognizance of the QA program.

1.11 The QA organization is involved in portions of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.

1.12 DOE and its prime contractors describe the QA responsibilities of each of the organizational elements noted on the organization charts.

1.13 DOE and its prime contractors identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

b. Has effective communication channels with other senior management positions.

c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.

d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

1.15 Persons and organizations performing QA functions have sufficient authority and organizational freedom to:

a. Identify quality problems.

b. Initiate, recommend, or provide solutions through designated channels.

c. Verify implementation of solutions.

d. Assure that further processing, delivery, installation, or operation is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

1.16 Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

1.17 Policies regarding the implementation of the QA program are documented and made mandatory.

1.18 Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organizations(s) or from outside the responsible organizations(s).

2. Activities related to Quality Assurance Program are acceptable to the NRC staff if:

2.1 A quality assurance program is established and documented which complies with the QA controls of 10 CFR Part 60, Subpart G; with 10 CFR Part 50, Appendix B; and with this Review Plan.

2.2 The quality assurance program provides a commitment to comply with NQA-1 "QA Program Requirements for Nuclear Facilities, 1986" and the following position relative to the NQA-1 standard: Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," provides guidance on the qualifications of inspection and test personnel. The provisions of Appendix 2A-1 (or acceptable alternatives) should be met as part of Supplement 2S-1, "Supplementary Requirements for the Qualification of Inspection and Test Personnel."

2.3 The QA program is documented by written policies, procedures or instructions and carried out by qualified individual(s) in accordance with these program documents prior to initiation of activities.

2.4 Criteria are established and documented for determining and identifying structures, systems, components, software and activities which are to be controlled by the quality assurance program. Guidance for determining these items and activities is provided in NUREG-1318 "Technical Position on Items and Activities in the High Level Waste Geologic Repository Program Subject to Quality Assurance Requirements."

2.5 Activities affecting quality are to be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

2.6 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 and tests.

2.7 Provisions are established which demonstrate through a matrix system or other means that each requirement of Appendix B and the quality assurance program is properly documented and covered by implementing procedures and/or instructions.

2.8 A policy statement signed by a senior management official renders the implementation of the quality assurance program mandatory.

2.9 The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer codes for High-Level Waste Management."

NUREG/CR-4640 "Handbook of Software Quality Assurance Techniques Applicable to Nuclear Industry," may be used as a reference for developing software QA programs.

2.10 Provisions are established to assure that technical and quality assurance procedures required to implement the QA program are consistent with regulatory, licensing, and QA program requirements and are properly documented and controlled.

2.11 The QA organization or other designated organizations knowledgeable in QA controls reviews and documents concurrence with procedures pertaining to safety functions.

2.12 A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.

2.13 Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

2.16 Indoctrination, training, and qualification programs are established for personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained and that:

a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.

e. Qualified personnel are certified in accordance with applicable codes and standards.

2.15 Measures are provided describing the extent a readiness review program will be established and executed to complement the inspection program.

3. Activities related to Design Control are acceptable to the NRC staff if:

3.1 The definitions of design, design information, and design activities used in the design control program are as defined provided in this section. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes design inputs and outputs at each stage of design development (i.e. from conceptual design to final design). Design information and design activities refer to data collection and analyses activities and computer codes that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analyses. Data analyses includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954.

3.2 The design control program includes design and design activities as described in 3.1. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents.

3.3 Measures are established to assure that those applicable regulatory requirements, design bases and design features developed through the site characterization phase activities for those structures, systems, components, and software to which this appendix applies are correctly translated into specifications, drawings, plans, procedures, and instructions.

3.4 Design control measures are established and applied to the design of engineered items important to safety or waste isolation; the description of the geologic setting and plans for data collection and analysis activities that will generate information pertinent to the repository design and that will be relied on in licensing; and computer codes. These design control measures apply to the design inputs, outputs and implementation of the Site Characterization Plan into scientific investigation plans and study plans.

3.5 Design control measures are established and applied to conceptual designs, or parts thereof, which may at a later time become part of the final design.

3.6 The plans for data collection and analysis activities assure that the appropriate information for input to the description of the geologic setting and engineered design is provided.

3.7 Organizational responsibilities are described for preparing, reviewing, approving, verifying and validating design and design information documents.

3.8 Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

3.9 Design interfaces and interface controls among organizations or groups involved in design development and other design activities such as the review, approval, release, distribution and revisions of documents involving design interface are described and procedurally controlled.

3.10 Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA and/or technical organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements and that the appropriate quality standards are specified and included in design documents.

3.11 Procedural controls provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculation methods, or by the performance of a suitable testing program.

3.12 Procedures are established to assure the verification of plans for data collection and analyses is completed prior to performing the data collection and analysis activities, respectively.

3.13 Procedures are established to assure documentation of a design or technical review identifies, as a minimum, the reviewers, the area or features reviewed, the comments of the reviewers, and the resolution of the comments.

3.14 Design verification procedures assure the following:

a. criteria for determining the method of verification are established;

b. the persons performing verification and validation are qualified and not directly responsible for the design;

c. the verification and validation are completed prior to release for procurement, manufacturing, construction, or use;

d. the responsibilities of the persons performing the verification or validation are defined;

e. the areas and features to be verified are specified; and

f. the extent of documentation is defined.

3.15 Procedures are established and described for verification of designs and design activities. Individuals verifying designs should be qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification, provided:

a. The supervisor is the only technically qualified individual.

b. The need is individually documented and approved in advance with concurrence of the quality assurance manager.

3.16 Where a test program is used to verify the adequacy of a specific engineering design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions.

3.17 A peer review which complies with NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" is conducted for design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed.

3.18 Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system is in place at the earliest practicable time. These changes are analyzed to assure that change is required. Associated changes to procedures and training should be are considered, and changes should be communicated to all affected groups or individuals.

3.19 Procedures are established to assure that verified computer codes are certified for use and that their use is specified.

3.20 Procedures are established describing methods of reviewing and qualifying data which was gathered without adequate quality program controls. For guidance refer to NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories."

3.21 The design inputs are 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.

4. Activities related to Procurement Document Control are acceptable to the NRC staff if:

4.1 Procedures are established to assure that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and that procurement documents have been prepared, reviewed, and approved to confirm that these requirements have been correctly carried out.

4.2 Procurement documents specify that contractors, subcontractors and consultants are to provide an acceptable quality assurance program commensurate with the scope, complexity and safety of the activity.

4.3 Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

5. Activities related to Instructions, Procedures, and Drawings are acceptable to the NRC staff if:

5.1 Activities affecting quality are prescribed by documented instructions, procedures, or drawings and accomplished in accordance with these instructions, procedures, or drawings.

5.2 Organizational responsibilities are described for assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents.

5.3 Procedures are established to assure that instructions, procedures, and drawings include or reference quantitative or qualitative acceptance criteria for determining that quality-related activities have been satisfactorily accomplished.

5.4 Provisions are described for controlling changes to field and laboratory procedures associated with exploratory investigations within the site characterization program to assure that such changes are subsequently documented and verified in a timely manner by authorized personnel.

6. Activities related to Document Control are acceptable to the NRC staff if:

6.1 The scope of the document control program is described, and the types of controlled documents are identified (e.g., instructions, procedures, drawings, as-builts, design and technical supporting documents, QA documents, and nonconformance and corrective action reports including changes thereto).

6.2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure that the technical and quality requirements are correctly included prior to release through reviews by qualified authorized personnel who did not provide input to the document.

6.3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.

6.4 Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designated another responsible organization.

6.5 Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.

6.6 A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.

6.7 When documents which require verification are released prior to verification, they are so identified, controlled and authorized for release through signature approval with the described bases for release.

7. Activities related to Control of Purchased Materials, Equipment, Items and Services and Software are acceptable to the NRC staff if:

7.1 Measures are established and described to assure purchased items and services including software, whether purchased directly or through contractors and subcontractors, conform to procurement documents.

7.2 Organizational responsibilities are described for the control of purchased items, services and software.

7.3 Procedures governing procurement of items or services, provide for: (a) evaluation and selection of suppliers; (b) objective evidence of quality furnished by suppliers, (c) inspections and audits of supplier's activities, items, services and software; and (d) receiving inspections.

7.4 The organization providing items, materials, equipment, or services or software furnishes the following records to the purchaser:

a. Documentation that identifies the procurement and the specific procurement requirements (e.g., codes, standards, and specifications) met.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair".

A procedure which assures the review and acceptance of these documents prior to installation or use of the procured item should be described in the purchaser's QA program.

7.5 Documents attesting to the acceptability of procured items shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased item and retained in the records storage facilities for retrievability as necessary.

7.6 Provisions are established by the DOE or designee to assess and ensure the control of quality by contractors and subcontractors. These assessments are performed at intervals consistent with the importance, complexity, and quantity of the product or services.

7.7 Suppliers' certificates of conformance for items, services and software are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

8. Activities related to Identification and Control of Items (including samples), Services and Software are acceptable to the NRC staff if:

8.1 Controls are established and described to identify and control samples items (including samples) and consumables, services and software to assure the identity is maintained and traceable to technical and quality related documents.

8.2 Procedures are established which assure that identification is maintained either on the item, software and samples or on records and containers traceable thereto.

8.3 Identification can be traced to the appropriate documentation such as drawings, specifications, purchase orders, technical reports, drilling locations and logs, (including well bore and depth), test records, installation and use records, inspection documents, and nonconformance reports.

8.4 Correct identification of samples is verified and documented prior to release for use or analysis.

8.5 Controls are established to preclude the inadvertent use of incorrect or defective items, software and samples.

9. Activities related to Control of Special Processes are acceptable to the NRC staff if:

9.1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, is provided which are generally those processes where direct inspection is impossible or disadvantageous, such as heat treatment, welding, nondestructive testing, data collection and other site characterization activities.

9.2 Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

9.3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. Acceptable methods for qualifying those special processes associated with scientific investigations are:

(1) the conduct of a prototype test, if possible, that demonstrates the process maintains quality or produces a quality product; or

(2) a technical review; or

(3) a peer review.

9.4 Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9.5 Qualifications, records of procedures, equipment, and personnel associated with special processes are established and maintained.

10. Activities related to Inspection are acceptable to the NRC staff if:

10.1 The scope of the inspection program is described that indicates an effective program has been established to verify that items and services conform to documented instructions, procedures, drawings and specifications. Program procedures provide criteria for determining when inspections of each work operation are to be performed.

10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization or are qualified individuals independent of the organizational unit responsible for the activity being inspected.

10.3 A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.

10.4 Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

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

d. Acceptance and rejection criteria.

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

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

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

10.5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

10.6 Provisions are established to assure that when inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel is provided.

10.7 Provisions are established to assure that both inspection and process monitoring is provided when control is inadequate without both.

10.8 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.

11. Activities related to Test Control are acceptable to the NRC staff if:

11.1 A test program is established to assure that all testing associated with items, software, scientific investigations, acquiring data from samples is identified and performed in accordance with written test procedures incorporating, as appropriate the requirements and acceptance limits contained in applicable design documents.

11.2 Procedural controls are established to assure the test program includes, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during site characterization, construction and operation of the high level waste storage facilities.

11.3 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide for: (a) determining when a test is required and how testing activities are performed; and (b) assurance that the test program is conducted by trained and appropriately qualified personnel.

11.4 Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.15 and 3.17.

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

11.6 Test procedures or instructions provide for the following:

a. The requirements and acceptance limits, as appropriate, contained in applicable documents, including precision and accuracy.

b. Instructions for performing the test.

c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.

d. Mandatory inspection hold points (as required).

e. Acceptance and rejection criteria, including required levels of precision and accuracy.

f. Methods of documenting or recording test data and results.

g. Provisions for assuring test prerequisites have been met.

11.7 Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.

11.8 Items tested should be identified, controlled, and ultimately dispositioned or archived.

12. Activities related to Control of Measuring and Test Equipment are acceptable to the NRC staff if:

12.1 The scope of the program is described for assuring that tools, gauges, instruments and other measuring and testing devices are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.

12.4 Measuring and test equipment is labeled, tagged or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.

12.5 Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability, characteristics, and other conditions which could affect measurement.

12.6 Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.

12.7 When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.

12.8 Calibration standards should have greater accuracy than equipment or standards being calibrated. Calibration standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function should be identified.

13. Activities related to Handling, Storage, and Shipping are acceptable to the NRC staff if:

13.1 Handling, preservation, storage, packaging, shipping, cleaning and preservation requirements and procedures are established to prevent damage or deterioration of items and samples and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control cleaning, handling, storage, packaging, and shipping of items and samples in accordance with design and procurement requirements and manufacturer's recommendations to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

13.3 The methods of handling, storage and packaging of items and samples take into consideration controls as appropriate for limited life expectancy, and special cleanliness.

14. Activities related to Inspection, Test and Operating Status are acceptable to the NRC staff if:

14.1 Procedures are established to indicate by the use of markings the status of inspections, and tests, and operating status of on individual items and software.

14.2 Procedures are established for the identification of items which have passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests.

14.3 Measures are established for indicating the test and/or operating status of items such as by tagging to prevent inadvertent operation or use.

14.4 Procedures are established and described to control the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps.

14.5 Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval.

14.6 The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.

15. Activities related to Nonconformances are acceptable to the NRC staff if:

15.1 Measures are established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.

15.2 Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming or defective items, software, procedures, records, and activities. The procedures identify individuals authorized to dispose of and close out nonconformances.

15.3 QA responsibilities related to nonconformance control are described.

15.4 Documentation identifies and describes the dispositions, nonconformances, and includes authorized signature approval of the disposition.

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

16. Activities related to Corrective Action are acceptable to the NRC staff if:

16.1 Procedures are established indicating an effective corrective action program has been established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, nonconforming and defective items, samples, procedures, records are promptly identified and corrected. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.

16.3 Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

16.4 The cause of significant conditions adverse to quality is determined and the corrective action is taken to preclude repetition. These actions are documented and reported to immediate management and upper levels of management for review and assessment.

17. Activities related to Quality Assurance Records are acceptable to the NRC staff if:

17.1 The scope of the records program is described which assures that sufficient records affecting quality are identifiable, retrievable, and maintained. QA records include scientific, engineering, and operational data and logs; geotechnical data; results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, and corrective action reports.

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of record activities, particularly in the retention, duration and safe storage of records.

17.3 Inspection and test records contain the following where applicable:

a. Identification of procedure and item inspected or tested.

b. A description of the type of observation.

c. The date and results of the inspection or test.

d. Information related to conditions adverse to quality.

e. Inspector or data recorder identification.

f. Evidence as to the acceptability of the results with signature and organization.

g. Action taken to resolve any discrepancies noted.

17.4 Criteria are established and described in procedures for determining when a document becomes a quality assurance record subject to the controls of this section and the retention periods for such records.

17.5 Controls are established and described for controlling, protecting and maintaining those records prior to their being entered and stored in the quality record control storage area.

17.6 Procedures are established describing methods of documenting/recording, reviewing, and confirming accuracy of records which include laboratory and field notebooks and log books, data sheets, data reduction documents and software.

17.7 Suitable facilities for the storage and security of records are described and utilized to preclude deterioration, damage, loss and misuse of records.

18. Activities related to Audits are acceptable to the NRC staff if:

18.1 Internal and external audits are carried out by DOE and its contractors to verify that procedures and activities comply with all aspects of the the overall QA program and to determine the effectiveness of the program. DOE and its contractors should perform audits of the prime contractor and subcontractors, consultants, vendors, and laboratories.

18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules taking into consideration the complexity, safety, importance and degree of previous audits, inspections and surveillance. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA during design, procurement, site characterization, manufacturing, construction, installation, inspection and testing.

18.3 Audits include technical evaluations of the procedures, instructions, activities, and items. They should include the review of documents and records including software and test data from samples to ensure they are acceptable.

18.4 Audit results are documented and analyzed by the QA and technical staff organization and the results are reported to responsible management for review, assessment, and appropriate action.

18.5 Audits are performed in accordance with pre-established written approved procedures or checklists and conducted by trained, qualified, competent QA and technical personnel having expertise which encompasses the area being audited and having no direct responsibilities in the areas being audited.

18.6 A tracking system for audit findings is established to help assure that all findings are appropriately addressed, prioritized and trended.

18.7 The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.

18.8 Provisions are established and described to assure the cause of each finding is also identified, the corrective action for it described and follow up action is accomplished to assure proper close out of deficiencies.

REFERENCES

1. ANSI/ASME, NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," 1986.

2. U. S. Nuclear Regulatory Commission, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirments," NUREG-1318, 1988.

3. U. S. Nuclear Regulatory Commission, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," NUREG-0856, 1983.

4. U. S. Nuclear Regulatory Commission, "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry," NUREG/CR-4640, 1987.

5. U. S. Nuclear Regulatory Commission, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, 1987.

6. U. S. Nuclear Regulatory Commission, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298, 1987.