DRAFT NRC REVIEW PLAN

QUALITY ASSURANCE PROGRAMS

FOR HIGH LEVEL WASTE REPOSITORY

SITE INVESTIGATIONS

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1.0 INTRODUCTION

1.1 BACKGROUND

DOE and its contractors are currently involved in performing laboratory and field investigations (site characterization activities) involving various technical disciplines such as geology, hydrology, seismology, geophysics, geochemistry, and rock mechanics - all of which are generally considered part of geotechnical studies and/or investigations. Data being gathered and analyzed under these activities will be used by DOE to support a license application to NRC for the construction and operation of geological repositories to be used for permanent disposal of high-level nuclear wastes. NRC concerns regarding public health and safety have been established in the regulatory requirements (10 CFR 60) for nuclear waste repositories. As part of the regulatory requirements, a quality assurance (QA) program must be implemented by DOE for site characterization activities. Therefore, an NRC review plan is necessary to establish the acceptance criteria used in reviewing the DOE QA program.

1.2 REGULATORY FRAMEWORK

The NRC has established regulatory requirements for nuclear waste repositories in 10 CFR Part 60. This includes requirements in both the procedural and technical rules.

1.2.1 PROCEDURAL RULE, 10 CFR 60

The procedural rule identifies when DOE will submit information on quality assurance to the NRC, and what NRC QA activities would be permitted during site characterization. These requirements are as follows:

Site Characterization Report

60.11a 6iii: provisions to control any adverse, safety-related effects from site characterization, including appropriate quality assurance programs.

60.11a 7: a description of the quality assurance program to be applied to data collection.

60.11g: During site characterization...NRC staff shall be permitted to visit and inspect the site and

observe excavations, borings, and in-situ tests as they are done.

1.2.2 TECHNICAL RULE, 10 CFR 60

The technical rule identifies the scope, applicability, and implementation of a QA program for nuclear waste repositories in Subpart G of 10 CFR 60. These requirements are as follows:

SUBPART G - QUALITY ASSURANCE

§ 60.150 Scope.

As used in this part, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 60.151 Applicability.

The quality assurance program applies to all systems, structures and components important to safety to design and characterization of barriers required to satisfy the performance objectives for the period after permanent closure, and to activities which would prevent or mitigate events that could cause an undue risk to the health and safety of the public. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

§ 60.152 Implementation.

DOE shall implement a quality assurance pgoram based on the criteria of Appendix B of 10 CFR Part 50 as applicable, and appropriately supplemented by additional criteria as required by § 60.151.

QA programs for site characterization activities should be based on Appendix B of 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants". Other documents which may provide additional guidance

for repository siting and design activities are (1) ANSI/ASME NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Power Plants," ANSI/ASME N45.2.20-1979, "Supplementary Quality Assurance Requirement for Subsurface Investigations for Nuclear Power Plants," and (3) Chapter 17 of NUREG-0800, "Standard Review Plan." In addition, U. S. NRC Rgulatory Guide 4.17, "Standard Format and Content of Site Characterization Reports for High-Level Waste Geologic Repositories," states that DOE should present a detailed QA program to allow NRC to make an independent evaluation of the precision, accuracy, reproducibility, analytic sensitivity, and limitation of data acquisition and analysis methods that would be used before and during site characterization.

All the basic requirements of ANSI/ASME NQA-1-1979 and the 18 criteria of 10 CFR 50 Appendix B may not be applicable to all of the geotechnical investigations performed during the site characterization. Thus, only the applicable portions of NQA-1 and the other documents listed above need to be applied to the geotechnical data gathering.

2.0 DISCUSSION

2.1 QA PROGRAM DESCRIPTION

An adequate QA program description, properly implemented with the use of documented procedures, is required to provide confidence in the geotechnical data gathered before and during site characterization. Each QA program description should identify how the 10 CFR 50 Appendix B criteria will be implemented and how compliance with the criteria will be assured. In addition to the DOE QA program, the QA program of the prime contractor/program manager (for example, Rockwell Hanford Operations for the Basalt Waste Isolation Program) should be identified and the interaction of the two programs should be discussed. DOE should also identify the items and activites to be controlled by the QA program, a measure of their required quality levels, and the QA effort necessary to achieve the specified quality requirements.

2.2 UNIQUENESS OF QA PROBLEMS IN REPOSITORY SITE INVESTIGATIONS

The 18 criteria of 10 CFR 50 Appendix B were originally written and applied to evaluation and monitoring of power plant hardware that is critical to public health and safety, or the environment. A hardware-oriented QA program seeks to provide, for example, the inspection of key components at prescribed states of production. Many aspects of this hardware-oriented QA program are easily adaptable to repository site investigations. Such items as document control, instrument

calibration, in-process inspection and testing, etc. which are easily extended to a geotechnical QA program. However, the investigative nature of repository site studies which involve state-of-the-art test procedures, data acquisition, data reduction, and interpretation of results does not lend itself to approaches which are highly prescriptive. Because of this, an essential aspect of the DOE QA program must be an adequate and independent peer review by qualified technical personnel of the procedures/instructions, tests, data acquisition and reductions, analysis, and interpretation of data for each site investigation activity. An essential part of an adequate QA program involves documentation of quality assurances procedures.

It is important to make a distinction between administrative QA procedures and detailed technical or implementing procedures (Figure 1). Administrative procedures are based on the 18 criteria of 10 CFR 50 Appendix B. These are generated by the quality assurance organization and apply across the board to all technical program areas. The detailed technical (implementing) procedures are developed by each technical area following the requirements spelled out in the administrative quality assurance procedures. These contain instruction for actual performance of testing and investigations (e.g., hydrologic pump tests, setting a packer, etc).

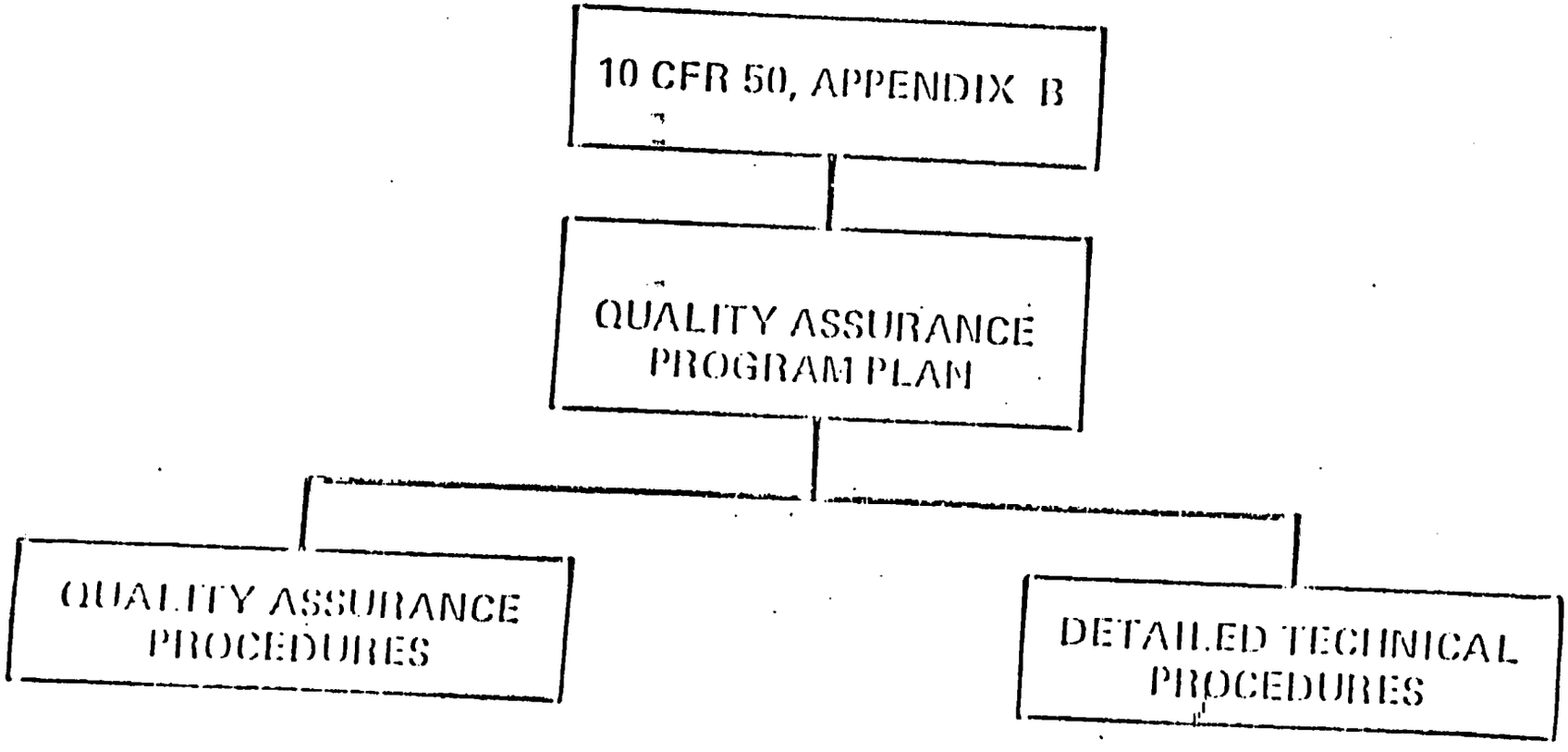
3.0 NRC REVIEW PLAN

The High-Level Waste Technical Development Branch (WMHT) of NRC has the prime responsibility for the review of DOE QA programs for geotechnical investigations for nuclear waste repositories. The review of any QA program for site investigations will involve three phases. Phase one will involve the review of the QA Administrative procedures submitted for each site. This will be the review of the administrative quality assurance procedures of the DOE QA program submitted as required by 10 CFR 60. Review of this document will be conducted by WMHT staff members (with assistance from other groups such as the Quality Assurance Branch, Office of Nuclear Reactor Regulation (NRR)). The document will be reviewed in terms of the points as outlined in Attachment 1. Attachment 1 is comprised of applicable items for QA for geotechnical investigations from Section 17.1 of NUREG-0800.

In parallel, phase two will involve NRC technical staff in various technical program areas (e.g. geochemistry, hydrology, etc.) evaluating the adequacy of selected technical or implementing procedures (see previous section). The program plans of each individual technical program area will describe the approach to be taken by the NRC staff in evaluating the adequacy of the selected technical or implementing procedures.

Phase three will eventually involve NRC surveillance and audit of specific laboratory and field activities (as provided for in 10CFR60 §60.11g) for assurance of implementation of both administrative and technical QA procedures. (This will be covered by later NRC guidance documents). This would include reviewing DOE's technical procedures and plans to determine whether adequate peer review by qualified technical personnel has been performed in each technical work area.

FIGURE 1


10 CFR 50, APPENDIX B
QUALITY ASSURANCE PROGRAM PLAN
QUALITY ASSURANCE PROCEDURES
DETAILED TECHNICAL PROCEDURES

Enclosure

ACCEPTANCE CRITERIA FOR QA PROGRAMS
(GEOTECHNICAL INVESTIGATIONS)

1. The organization elements responsible for the QA program are acceptable if:

   1.1 The responsibility for the overall program is retained and exercised by the DOE.

   1.2 DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.

   1.3 DOE describes how responsibility is exercised for the overall program. The extent of management oversight should be addressed.

   1.4 DOE evaluates the performance of work by its prime contractors/program managers at least annually.

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

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

   1.7 Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program, the lines of responsibility, and a description of the criteria for determining the size of the QA organization including the inspection staff.

   1.8 DOE and its prime contractors/program managers describe the QA responsibilities of each of the organizational elements noted on the organization charts.

   1.9 DOE and its prime contractors/program managers identify a management position that retains overall authority and responsibility for the QA program (normally, this position is the QA Manager) and this position 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, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

* Exceptions and alternatives to these acceptance criteria may be adopted provided adequate justification is given.

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

c. Has responsibility for approval of QA Manual(s).

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

The individual holding this position is qualified to do so based on his management and QA experience and knowledge.

1.10 Verification of conformance to established requirements (except for designs, ref. 3.7) is accomplished by individuals or groups within the QA organization.

1.11 Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a. Identify quality problems.

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

c. Verify implementation of solutions.

d. Stop unsatisfactory work.

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

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

1.13 Designated QA individuals are involved in day-to-day site activities important to safety.

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

1.15 The person at the site responsible for directing and managing the site QA program is identified by position and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to assuring that the QA program at the site is being effectively implemented.

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

2.1 The QA program includes a commitment that items and activities important to safety will be subject to the applicable controls of the QA program. The items and activities covered by the QA program are identified.

2.2 The QA program includes a commitment that any development, control, and/or use of computer programs will be conducted in accordance with the QA program.

2.3 A brief summary of the DOE and prime contractor/program manager QA policies is given.

2.4 a. Provisions are established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and policies and are properly documented, controlled, and made mandatory through a policy statement or equivalent document signed by an identified, responsible official.

b. The QA organization reviews and documents concurrence with these quality-related procedures.

2.5 The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities. This effort involves applying a defined graded approach in accordance with importance to safety and affects such disciplines as design, procurement, document control, inspections, tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

2.6 Existing or proposed QA procedures are identified reflecting that each criterion of 10 CFR Part 50, Appendix B will be met by documented procedures.

2.7 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 preplanned and documented. Corrective action is identified and tracked.

2.8 Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-affecting 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 trained and 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. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified.

e. Certificate of qualifications clearly delineates (a) the specific functions personnel are qualified to perform and (b) the criteria used to qualify personnel in each function.

3. Activities related to Design Control are acceptable if:

3.1 The design control program includes design activities associated with the preparation and review of design documents including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents.

3.2 Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents.

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

3.4 Design interface controls are described.

3.5 Procedures require a documented check to verify the dimensional accuracy and completeness of design drawings.

3.6 Procedures require that design drawings and specifications be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with procedures and that the documents contain the necessary quality assurance requirements.

3.7 Procedures are established and described for design verification activities which assure that the verifier is qualified and is not directly responsible for the design (i.e., neither the performer or his immediate supervisor).

3.8 The responsibilities of the verifier(s), the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

and specification changes, including field changes, are subject to the same design controls that were applicable to the original design.

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

   4.1 Procedures are established for the review of procurement documents by QA personnel to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program.

   4.2 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 if:

   5.1 Organizational responsibilities are described for assuring that activities affecting quality are (1) prescribed by documented instructions, procedures, and drawings and (2) accomplished through implementation of these documents.

   5.2 Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that important activities have been satisfactorily accomplished.

6. Activities related to Document Control are acceptable if:

   6.1 The scope of the document control program is described, and the types of controlled documents are identified.

   6.2 Procedures for the review, approval, issuance and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with regards to QA-related aspects.

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

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

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

7. Activities related to Control of Purchased Material, Equipment, and Services are acceptable if:

7.1 Organizational responsibilities are described for the control of purchased material, equipment, and services.

7.2 The service organization furnishes the following records to the purchaser:

a. Documentation that identifies the purchased service 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."

The review and acceptance of these documents should be described in the purchaser's QA program.

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

8. Activities related to sample Identification and Control are acceptable if:

8.1 Controls are established and described to identify and control samples. The description should include organizational responsibilities.

8.2 Procedures are established which assure that identification is maintained either on the samples or on records traceable to the samples.

8.3 Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, inspection documents, and nonconformance reports.

8.4 Correct identification of samples is verified and documented prior to release.

9. Activities related to control of Special Processes are acceptable 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, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.

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. The QA organization is involved in the qualification activities to assure they are satisfactorily performed.

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

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

10. Activities related to Inspection are acceptable if:

10.1 The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.

10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization.

10.3 A qualification program for inspectors (including NDT personnel) 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 are established to identify mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

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

11. Activities related to Test Control are acceptable if:

11.1 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for determining when a test is required or how and when testing activities are performed. The QA organization participates in these functions.

11.2 Test procedures or instructions provide for the following:

a. The requirements and acceptance limits contained in applicable documents.

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.

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

g. Provisions for assuring test prerequisites have been met.

11.3 Test results are documented, evaluated, and their acceptability determined by a responsible individual or group.

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

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established. This information indicates an effective calibration program has been established.

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) for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.

12.4 Measuring and test equipment is identified and traceable to the calibration test data.

12.5 Measuring and test equipment is labeled or tagged to indicate due date of the next calibration.

12.6 Measuring and test equipment is calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management.

12.7 Calibrating standards have greater accuracy than standards 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 uathorized by responsible management.

12.8 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.

12.9 Measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration when measuring and test equipment is found to be out of calibration. Inspections or tests are repeated on items determined to be suspect.

13. Activities related to Sample Handling, Storage, and Shipping are acceptable if:

13.1 Sample handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

14. Activities related to Inspection and Test Status (17.1.14) are acceptable if:

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

14.2 Procedures are established to control altering the sequence of required inspections and tests.

15. Activities related to Nonconformances are acceptable if:

15.1 Procedures are established for identifying, documenting, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items. The procedures identify individuals authorized to dispose of and close out nonconformances.

15.2 QA responsibilities related to nonconformance control are described.

15.3 Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.

15.4 Nonconformance reports are periodically analyzed by the QA organization to show quality trends, and the significant results are reported to upper management for review and assessment.

16. Activities related to Corrective Action are acceptable if:

16.1 Procedures are established indicating an effective corrective action program has been established. 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 the documented concurrence of the adequacy of the corrective action.

16.3 Followup 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 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition 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 if:

17.1 The scope of the records program is described. QA records include 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; 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 activities related to QA records.

17.3 Inspection and test records contain the following where applicable:

a. A description of the type of observation.

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

c. Information related to conditions adverse to quality.

d. Inspector or data recorder identification.

e. Evidence as to the acceptability of the results.

f. Action taken to resolve any discrepancies noted.

17.4 Suitable facilities for the storage of records are described and utilized.

18. Activities related to Audits are acceptable if:

18.1 Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its prime contractors/program managers.

18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. 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.

18.3 Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.

18.4 Audit data are analyzed by the QA organization and the results are reported to management for review and assessment.

18.5 Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.