

COMPLIANCE DETERMINATION METHOD QUALITY ASSURANCE

3.0 REVIEW PROCEDURES AND ACCEPTANCE CRITERIA

3.1 Acceptance Review:

In conducting the Acceptance Review for docketing, the staff will compare the information in the License Application (LA) concerning quality assurance (QA) with the corresponding section of the FCRG and with the staff's resolution status of objections to LA submittal in the Open Item Tracking System (OITS) and determine if this information meets the following criteria.

(1) The information presented in the LA is clear, is completely documented, consistent with the level of detail presented in the corresponding section of the FCRG, and the references have been provided.

(2) DOE has either resolved, at the staff level, the NRC objections to LA submittal that apply to this regulatory requirement topic, or provided all information requested in Section 1.6 of the FCRG for unresolved objections, namely, DOE has:

- Identified all unresolved objections
- Explained the differences between NRC and DOE positions that have precluded resolution of each objection
- Described all attempts to achieve resolution
- Explained why resolution has not been achieved
- Described the effects of the different positions on demonstrating compliance with 10 CFR Part 60

In addition, unresolved objections, individually or in combination with others, will not prevent the reviewer from conducting a meaningful Compliance Review and the Commission from making a decision regarding construction authorization within the 3-year statutory period.

3.2 Compliance Reviews:

3.2.1 Safety Review of 10 CFR 60.21(c)(4):

The staff will review the QA program descriptions for site characterization, design and construction, operation, and performance confirmation activities, to determine if they meet the applicable criteria which are based on the "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions (NRC, 1989)." This determination will be based on previous reviews of DOE's program descriptions during site characterization, as well as any current reviews deemed necessary. The applicable acceptance criteria are delineated in the following sections:

3.2.1.1 Organization

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 QA program is retained and exercised by that organization or individual responsible for submitting the license application.

1.2 The authorities and duties of persons and organizations performing activities important to safety or waste isolation (e.g., safety 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 QA functions.

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

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

1.6 DOE and major 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 major contractors evaluate the performance of work delegated to other organizations. This shall include audits of the major contractors' QA programs and audits of affected organizations furnishing equipment or services to the major 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 before 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 "onsite" and "offsite" organizational elements that 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 depends on the specific activity, its complexity, and its importance to safety or waste isolation, as defined in 10 CFR 60.2.

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

1.13 DOE and its major 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

1.14 Persons and organizations performing QA functions have sufficient authority and organizational freedom to identify quality problems; initiate, recommend, or provide solutions through designated channels; verify implementation of solutions; 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.

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

1.16 Policies on the implementation of the QA program are documented and made mandatory.

1.17 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).

3.2.1.2 Quality Assurance Program

Activities related to the QA Program are acceptable to the NRC staff if:

2.1 A QA program is established and documented that complies with the QA controls of 10 CFR Part 60, Subpart G; with 10 CFR Part 50, Appendix B; and with other regulatory guidance, as appropriate.

2.2 The QA program provides a commitment to comply with NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities" (ANSI/ASME, 1986) and the following position, relative to the NQA-1 standard: Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," which 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, before initiation of activities.

2.4 Criteria are established and documented for determining and identifying structures, systems, components, software, and activities that are to be controlled by the QA program. Guidance for determining these items and activities is provided in NUREG-1318 (NRC, 1988).

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 that demonstrate, through a matrix system or other means, that each criterion of 10 CFR Part 50, Appendix B, 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 QA program mandatory.

2.9 The QA program includes a commitment that development, control, and/or use of computer programs important to safety and waste isolation will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856 (Silling, 1983). NUREG/CR-4640 (NRC, 1987) may be used as a reference for developing software QA programs.

2.10 Provisions are established to assure that technical and QA 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 that is preplanned and documented, with corrective action identified and tracked

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

2.14 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 manual, 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 at appropriate major milestones, to complement the inspection program.

3.2.1.3 Design Control

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 defined as 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 include the initial step of data reduction, as well as broad-level systems analyses (such as performance assessments) that 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 Section 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: (a) the design of engineered items important to safety or waste isolation; (b) 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 (c) 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 Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.

3.7 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.

3.8 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.

3.9 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 QA requirements and that the appropriate quality standards are specified and included in design documents.

3.10 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.

3.11 Procedures are established to assure that plans for data collection and analyses are completed before performing the data collection and analysis activities.

3.12 Procedures for a design or technical review require, where applicable, the identification of the reviewers, the area or features reviewed, and the resolution methods for resolving comments.

3.13 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 before 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

- (f) The extent of documentation is defined

3.14 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 QA manager

3.15 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 qualification testing of a prototype unit under the most adverse design conditions.

3.16 Peer Reviews, when conducted, comply with the reference commitments in NUREG-1297 (Altman et al., 1988a).

3.17 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 considered and communicated to all affected groups or individuals.

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

3.19 Procedures are established describing methods of reviewing and qualifying data that were gathered without a fully implemented 10 CFR Part 60 QA Program. For guidance, refer to NUREG-1298 (Altman et al., 1988b).

3.20 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.

3.2.1.4 Procurement Document Control

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 QA program commensurate with the scope, complexity, and safety of the activity.

4.3 Organizational responsibilities are described for: (a) procurement planning; (b) the preparation, review, approval, and control of procurement documents; (c) supplier selection; (d) bid evaluations; and (5) review of and concurrence in supplier QA programs before initiation of activities affected by the program. The involvement of the QA organization is described.

3.2.1.5 Instructions, Procedures, and Drawings

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: (a) specified in instructions, procedures, and drawings; and (b) 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.

3.2.1.6 Document Control

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, before 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, before commencing the work.

6.4 Changes to documents are 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 that require verification are released before verification, they are so identified, controlled, and authorized for release through signature approval, with the described bases for release.

3.2.1.7 Control of Purchased Materials, Equipment, Items, and Services

7.1 Measures are established and described to assure that 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 suppliers' activities, items, services and software; and (d) receiving inspections.

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

- (a) Documentation that identifies the procurement and the specific procurement requirements met (e.g., codes, standards, and specifications).
- (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 that assures that the review and acceptance of these documents, before 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, as necessary, and retained in the records storage facilities for retrievability.

7.6 Provisions are established by DOE or its 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 that they are valid and the results documented.

3.2.1.8 Identification and Control of Material, Parts, and Components

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

8.2 Procedures are established that 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 before release for use or analysis.

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

3.2.1.9 Control of Special Processes

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 generally are 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 include: (a) a prototype test to demonstrate that the process maintains quality or produces a quality product; (b) a technical review; or (c) 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.

3.2.1.10 Inspection

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 directly 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 are provided when control is inadequate without both.

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

3.2.1.11 Test Control

11.1 A test program is established to assure that all testing associated with items, software, scientific investigations, and 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 that the test program includes, as appropriate, proof tests before installation, preoperational tests, and operational tests during site characterization, construction, and operation of the high-level waste storage facilities.

11.3 Program procedures for test control 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 Sections 3.15 and 3.17.

11.5 The potential sources of uncertainty and error in test plans, 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, including required levels of precision and accuracy, as appropriate, are 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, 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 are identified, controlled, and ultimately dispositioned, and samples should be archived, as required by procedures.

3.2.1.12 Control of Measuring and Test Equipment

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 are 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 are calibrated at specified intervals, based on required accuracy, precision, purpose, degree of use, stability, characteristics, and other conditions that 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 are 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 they can be shown to be adequate for the requirements and the basis for acceptance is documented and authorized by responsible management. The management authorized to perform this function should be identified.

3.2.1.13 Handling, Storage, and Shipping

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, storing, 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.

3.2.1.14 Inspection, Test, and Operating Status

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

14.2 Procedures are established for the identification of items that 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; for example, 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.

3.2.1.15 Nonconforming Material, Parts, and Components

15.1 Measures are established to control materials, parts, or components that do not conform to requirements, 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 positions 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 and 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.

3.2.1.16 Corrective Action

16.1 Procedures are established indicating that 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, and records are promptly identified and corrected. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated after a nonconformance to preclude recurrence. The QA organization concurs with the corrective action to assure that QA requirements are satisfied.

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 The cause of significant conditions adverse to quality is determined and 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.

3.2.1.17 Quality Assurance Records

17.1 The scope of the records program described 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 defining and implementing 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 the procedure used 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 QA 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 before their being entered and stored in the quality record 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 used to preclude deterioration, damage, loss, and misuse of records.

3.2.1.18 Audits

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 overall QA program and to determine the effectiveness of the program. DOE and its contractors should perform audits of the major contractor and affected organizations.

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 on 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 applicable procedures, instructions, activities, and/or items. As applicable, 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 that 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 that the cause of each finding is also identified, the corrective action for it described, and follow-up action is accomplished to assure proper closeout of deficiencies.

3.2.2 Safety Review of 10 CFR 60.150

10 CFR 60.150 provides a definition for quality assurance which can be reviewed only in the context of quality assurance program descriptions (10 CFR 60.21(c)(4)) and quality assurance program implementation (10 CFR 60.152). Therefore, the Safety Review of this regulatory requirement will be conducted as parts of the Safety Reviews of 10 CFR 60.21(c)(4) and 10 CFR 60.152.

3.2.3 Safety Review of 10 CFR 60.151:

The staff will review the license application to determine if DOE's QA program is applied to the items and activities important to safety as defined in 10 CFR 60.2 and the items and activities subject to 10 CFR Part 60 QA requirements as described in NUREG-1318 (NRC, 1988).

DOE "Q-Lists" (NRC, 1988) will be evaluated by NRC staff associated with the geological setting, the geologic repository operations area, the engineered barrier system, the performance assessment program, and the performance confirmation program. The evaluations will be conducted to determine if the following acceptance criteria are met.

- (a) The Q-Lists identify structures, systems, and components important to safety, barriers important to waste isolation and related activities, and the radiological protection aspects of worker health and safety, as described in 10 CFR 60.131 (a) for each of the elements of the high-level waste program
- (b) The analyses used to develop Q-Lists is consistent with NUREG-1318 (NRC, 1988)

3.2.4 Safety Review 10 CFR 60.152:

The staff will determine whether the DOE QA program for site characterization has been effectively implemented and accepted by the NRC throughout the site characterization period. The determination shall be based on the following evidence of effective implementation: (a) documented results of internal and external DOE audits and surveillances; (b) documented results of NRC audits, surveillances, and observations; (c) reports of NRC onsite representatives; and (d) NRC/DOE interactions.

Criteria for the staff's determination of effective implementation shall include the following:

- (a) Scientific and engineering computer codes used in the period of site characterization have been documented, verified, and validated consistent with the guidance of NUREG-0856 (Silling, 1983).
- (b) Data used, in the period of site characterization, to support the license application, that were not collected under a QA program meeting 10 CFR Part 60, Subpart G, have been qualified in a manner consistent with the guidance of NUREG-1298 (Altman et al., 1988b). General listings by activity are provided of existing data to be qualified during construction and performance confirmation.
- (c) Peer reviews, when applied, have been conducted consistent with the guidance of NUREG-1297 (Altman et al., 1988a).

3.3 Rationale for Review Procedures and Acceptance Criteria:

3.3.1 Rationale for Safety Review of 10 CFR 60.21(c)(4):

Review Procedure Rationale:

The review procedure for determining the acceptability of DOE QA program descriptions is based on the application of QA program criteria from regulations (10 CFR Part 50, Appendix B), NRC technical positions, and QA standards applicable to the high-level waste repository program.

Acceptance Criteria Rationale:

The acceptance criteria for QA program descriptions are based on the "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions" (NRC, 1989). This review plan has been applied throughout site characterization for evaluating the programmatic sufficiency of DOE QA programs. The review plan contains elements from the applicable regulation 10 CFR Part 50, Appendix B, the standard from the American Society of Mechanical Engineers (ASME) NQA-1 (ANSI/ASME, 1986), and NUREGs-0856, -1297, and -1298 (Silling, 1983; Altman et al., 1988a,b).

The NUREGs have been developed to provide guidance to DOE for addressing documentation of scientific and engineering computer codes, conducting peer reviews, and qualifying existing data. For the wide variety of activities anticipated throughout the life cycle of repository planning, design, and operations, the acceptance criteria must be flexibly applied to suit those various activities.

3.3.2 Rationale for Safety Review of 10 CFR 60.150:

Since the Safety Review of 10 CFR 60.150 is conducted as part of the Safety Reviews of 10 CFR 60.21 (c)(4) and 10 CFR 60.152, no rationale is necessary.

3.3.3 Rationale for Safety Review of 10 CFR 60.151:

Review Procedure Rationale:

The evaluation of "Q-Lists" will be performed by the appropriate NRC technical staff because the expertise necessary for determining the adequacy of the "Q-Lists" lies in these disciplines, rather than within the NRC QA staff. "Q-Lists," as described in NUREG-1318, are evaluated because they provide the level of detail necessary to identify the specific items and activities to which the QA program shall apply.

Acceptance Criteria Rationale:

The criteria given in the 10 CFR 60.2 definition of "important to safety," as well as the guidance provided in NUREG-1318, identify the types of items and activities to which a QA program shall apply.

3.3.4 Rationale for Safety Review of 10 CFR 60.152:

Review Procedure Rationale:

DOE QA programs and their implementation have been evaluated throughout the site characterization period and will form the basis for determining if these programs have been effectively implemented. This determination method differs from nuclear power plant experiences of review upon submittal of the license application, but was necessitated by the time constraints imposed on the licensing process. Continuous QA program review and critical evaluation are much more effective and timely than after-the-fact evaluations.

Acceptance Criteria Rationale:

The basis for acceptance of QA program implementation is essentially the same as for QA program descriptions in 10 CFR 60.21(c)(4), but the actions of DOE must also comply with the QA program requirements. As such, the acceptance criteria rationale for the safety review of 10 CFR 60.21(c)(4) (NRC, 1989) apply to the safety review of 10 CFR 60.152 as well.

4.0 IMPLEMENTATION:

4.1 Review Responsibilities:

The review responsibilities for this review plan are as follows:

Lead:	HLPD — QA Section
Support:	HLGE — Materials Section
	HLGE — Geotechnical Engineering Section
	HLGE — Geology — Geophysics Section
	HLHP — Hydraulic Transport Section
	HLHP — Repository Performance Assessment Section

4.2 Interfaces:

4.2.1 Input Information:

Review Plan No.

To be determined.

To be determined.

Note: The main input interfaces for this review plan will be with review plans having key technical uncertainties regarding data qualification or computer code verification and model validation. An interface with the QA review plan should help to reduce those specific uncertainties. Information needed for the QA review is the identification of specific data that DOE is required to qualify and the specific computer codes requiring verification and model validation. The specific interfaces between the QA review plan and other review plans will be identified in the future.

4.2.2 Output Information:

Review Plan No.

To be determined.

To be determined.

Note: The same review plans providing input to the QA review will be provided with data on the qualification of specific data and/or verification and model validation for specific computer codes.

5.0 EXAMPLE EVALUATION FINDINGS:

5.1 Finding for Acceptance Review:

The NRC staff finds that the information presented by DOE on Quality Assurance, as defined in 10 CFR 60.150, is acceptable (not acceptable) for docketing and compliance review.

5.2 Findings for the Compliance Reviews:

5.2.1 Finding for 10 CFR 60.21(c)(4):

The NRC staff finds that the DOE QA program descriptions are (are not) acceptable and that there is reasonable assurance that the regulatory requirements of 10 CFR 60.21(c)(4), including quality assurance as defined in 10 CFR 60.150, will be met for the structures, systems, and activities important to safety and waste isolation.

5.2.2 Finding for 10 CFR 60.150:

Since the Safety Review of 10 CFR 60.150 is conducted as parts of the Safety Reviews of 10 CFR 60.21(c)(4) and 10 CFR 60.152, the finding for 10 CFR 60.150 will be embodied in the findings for 10 CFR 60.21 (c)(4) and 10 CFR 60.152.

5.2.3 Finding for 10 CFR 60.151:

The NRC staff finds that the QA program is (is not) being applied to the items and activities subject to 10 CFR Part 60 QA requirements as described in NUREG-1318 (NRC, 1988) and that there is reasonable

assurance that the regulatory requirement of 10 CFR 60.151 will be met.

5.2.4 Finding for 10 CFR 60.152:

The NRC staff finds that the DOE QA program implementation is (is not) acceptable and that there is (is not) reasonable assurance that the regulatory requirements of 10 CFR 60.152, including quality assurance as defined in 10 CFR 60.150, will be met for the site characterization QA programs. In addition, the NRC staff finds that site characterization data and calculations, and data analysis controls were (were not) found to be sufficient to assure the accuracy and validity of the results.

6.0 REFERENCES:

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