ENCLOSURE 1

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U. S. NUCLEAR REGULATORY COMMISSION

NRC REVIEW PLAN:

QUALITY ASSURANCE PROGRAMS

FOR SITE CHARACTERIZATION

OF HIGH LEVEL NUCLEAR WASTE REPOSITORIES

Compiled by
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Office of Nuclear Material Safety and Safeguards

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June 1984

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PDR WASTE
WM-1 PDR

ABSTRACT

Licensing of a geologic repository for high-level waste involves assessing whether the geologic setting and the engineered system will perform in a manner which will meet the performance objectives and requirements of 10 CFR Part 60. Important questions in conducting these licensing assessments will relate to the quality and the assurance of quality of data and analyses used in support of the license application for proposed sites. In addition to questioning the relevance and completeness of data supplied in the license application, the licensing process will address the question of whether data and analyses are of adequate and known quality so that there will be reasonable assurance that operation and long-term disposal of high level waste in the geologic repository will not provide an unreasonable risk to the health and safety of the public. A quality assurance program is therefore necessary to provide confidence in the work performed in development of the repository.

The purpose of this Review Plan is to define the criteria and methods by which the DOE quality assurance program for site characterization activities will be reviewed by the NRC staff during the prelicensing phase. At the same time, the staff positions in this plan provide guidance to DOE for establishing an acceptable program. In particular, it defines how the 18 criteria of Appendix B, 10 CFR Part 50, which were developed for nuclear reactors, can be applied to the site characterization phase of repositories. It also describes the staff review and consultation process with DOE during the site characterization phase.

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1.0 INTRODUCTION AND BACKGROUND

DOE and its contractors are currently involved in performing laboratory and field investigations (site characterization activities) involving various technical areas such as geology, hydrology, seismology, geophysics, geochemistry, and rock mechanics - all of which are generally considered part of geotechnical studies and/or investigations. In addition, waste package testing and conceptual design activities are being performed, including development of performance requirements for repository system components. Information being gathered and data being collected and analyzed will be used by DOE to support license applications to the NRC for the construction and operation of geologic repositories to be used for permanent disposal of high-level nuclear wastes. As part of the regulatory requirements in 10 CFR Part 60, DOE must implement a quality assurance (QA) program to provide confidence in the work performed during development of the repository, including information developed in support of licensing proceedings. 10 CFR Part 60 also requires DOE and NRC to conduct prelicensing consultation prior to submittal of a license application to aid in identification and resolution of issues prior to licensing. This Review Plan presents positions on quality assurance which are acceptable to NRC staff and, if properly carried out by DOE, would be suitable for use in licensing. To give context to these positions, this document also describes generally some of the prelicensing interactions between DOE and NRC through which licensing information needs are established. As these prelicensing consultations progress, and as lessons learned from the application of quality assurance in other programs is assimilated, revisions to this Review Plan may be necessary and appropriate.

It is important to recognize the roles of the DOE and NRC. DOE has overall responsibility for achieving and assuring the quality of high-level waste repositories. Other organizations are responsible to the extent that DOE delegates responsibility. However, ultimate responsibility, even though delegated, is retained by DOE. The role of the NRC in licensing is to exercise sufficient, but limited, oversight to provide reasonable assurance that a license applicant meets all of the applicable requirements. During prelicensing, there is a similar limited function for the NRC. This NRC role does not abrogate DOE's responsibility for assuring that all aspects of a project must be in accordance with NRC requirements. DOE has the burden of proof in licensing proceedings and is responsible for developing information required to make findings in these proceedings. More specifically, DOE is responsible for assuring that information is both complete and of demonstrably adequate quality. The ability to demonstrate quality depends

upon DOE having an adequate quality assurance program during the prelicensing site investigation and design development phase.

2.0 REGULATORY FRAMEWORK

The NRC has established quality assurance requirements for nuclear waste repositories in both the procedural and technical portions of 10 CFR Part 60, as listed below. This summary of quality assurance requirements is not exhaustive. Other sections of 10 CFR Part 60 address quality assurance and information to be submitted throughout the life of the repository.

2.1 PROCEDURAL PROVISIONS (10 CFR Part 60, Subparts A-D)

The procedural rule identifies when DOE will submit information on quality assurance to the NRC, and what NRC monitoring of QA activities will be permitted during site characterization. It also defines the scope of site characterization and the quality assurance program. These requirements* are as follows:

§60.2 Definitions

"Site characterization" means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of a particular site relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic repository, but does not include preliminary borings and geophysical testing needed to decide whether site characterization should be undertaken.

"Important to safety," with reference to structures, systems, and components means those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area of any time until the completion of permanent closure.

"Isolation," means inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

*10 CFR Part 60 is currently being revised to conform to the Nuclear Waste Policy Act of 1982; this Review Plan will be modified as necessary to reflect these rule changes when completed.

§60.11 Site Characterization Report*

a. As early as possible after commencement of planning for a particular geologic repository operations area, and prior to site characterization, the DOE shall submit to the Director a Site Characterization Report*. The report shall include (1) a description of the site to be characterized; (2) the criteria used to conduct site characterization and for which DOE anticipates arrive at the candidate area; (3) the method by which the site was selected for site characterization; (4) identification and location of alternative media and sites at which DOE intends to submitting subsequent Site Characterization Reports; (5) a description of the decision process by which the site was selected for characterization, including the means used to obtain public, Indian tribal and State views during selection; (6) a description of the site characterization program including (i) the extent of planned excavation and plans for in situ testing, (ii) a conceptual design of a repository appropriate to the named site in sufficient detail to allow assessment of the site characterization program with respect to investigation activities which address the ability of the site to host a repository and isolate radioactive waste, or which may affect such ability, and (iii) provisions to control any adverse, safety-related effects from site characterization, including appropriate quality programs; (7) a description of the quality assurance program to be applied to data collection; (emphasis added) and (8) any issues related to the site selection, alternative candidate areas or sites, or design of the geologic repository operations area which the DOE wishes the Commission to review. Also included shall be a description of the research and development activities being conducted by DOE which deal with the waste form and packaging which may be considered appropriate for the site to be characterized, including research planned or underway to evaluate the performance of such waste forms and packaging.

§60.11(g): 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.

*Referred to as "Site Characterization Plan" in the Nuclear Waste Policy Act of 1982

§60.21 Content of Application [i.e., construction authorization application]

(a) An application shall consist of general information and a Safety Analysis Report...

§60.21(c) The Safety Analysis Report shall include:

(1)(ii)(E) An analysis of the performance of the major design structures, systems, and components, both surface and subsurface, to identify those that are important to safety.

(4) A description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation.

§60.31 Construction authorization

Upon review and consideration of an application and environmental report submitted under this part, the Commission may authorize construction if it determines:

(3) The DOE's quality assurance program complies with the requirements of Subpart G.

2.2 TECHNICAL PROVISIONS (10 CFR Part 60, Subparts E-I)

The technical rule identifies the scope, applicability, and implementation of a QA program for nuclear waste repositories in Subpart G of 10 CFR Part 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 important to waste isolation and to activities related thereto. 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 program 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.

2.3 APPLICABLE REGULATORY AND STANDARDS GUIDANCE DOCUMENTS

In addition to the regulations discussed above, NRC Regulatory Guide 4.17, "Standard Format and Content of Site Characterization Reports for High-Level Waste Geologic Repositories," states that DOE should "Describe the quality assurance (QA) programs that have been applied during site exploration activities and that will be applied to data collection during the planned site characterization program. The QA methods should be presented in sufficient detail to allow NRC to make an independent evaluation of the precision, accuracy, reproducibility, analytic sensitivity, and limitation of data acquisition and analysis methods that were used during site exploration and will be used during site characterization."

3.0 DISCUSSION

3.1 QA PROGRAM DESCRIPTION

DOE is required in 10 CFR 60.11 to submit in the Site Characterization Plan (SCP) a description of the quality assurance program to be applied to data collection. An adequate QA program description, properly implemented, is required to provide confidence in the data gathered during site characterization. Each QA program description should identify how the

10 CFR Part 50 Appendix B criteria will be implemented and how compliance with the criteria will be assured. Because design activities will be performed during the site characterization phase, it is important that the overall quality assurance program description, including that for design and design activities, be provided well before licensing, preferably in the Site Characterization Plan. 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 designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analysis activities that are used in supporting design development and verification. They include general plans and detailed procedures for data collection and analysis activities that are used in supporting design development, and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses, such as performance assessments, which integrate many other data and analysis 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.

Appendix A of this Review Plan lists each of the 18 criteria of Appendix B and identifies staff positions and information needs to be addressed in the Site Characterization Plan. A copy of Appendix B, 10 CFR Part 50 is presented in Figure 1. In addition to the DOE QA program, the QA programs of the prime contractor (for example, Rockwell Hanford Operations for the Basalt Waste Isolation Project) and other organizations participating in the project should be described and the interaction of the QA groups including management meetings, audits, inspections, and performance monitoring by DOE should be discussed. DOE should also identify the items and activities important to safety or waste isolation to be controlled by the QA program and the basis for their selection. A list of QA and technical procedures which implement the program description in the Site Characterization Plan should be identified and referenced in the SCP.

3.2 APPLICATION OF QUALITY ASSURANCE TO SITE CHARACTERIZATION ACTIVITIES

A complex, technical program such as site characterization, which includes data gathering and analysis and design development, needs to be based on a systematic approach to planning and controlling the program. The plans outlining the conduct of a data gathering program are of varying levels of detail ranging from identification of general performance objectives and criteria to detailing specific technical procedures (Figure 2). Quality assurance needs to be applied at all levels. As shown in this figure, site characterization planning must start by considering the performance

objectives established in NRC regulations. After considering site specific conditions, specific issues are identified based on these criteria and preliminary evaluations of repository component performance requirements are established. The program can then be divided into program areas related to the technical disciplines of investigations. These program areas then identify information needed to resolve issues in the site characterization program. From these information needs, test plans are developed which identify how testing will be accomplished. As part of the test plans, detailed test procedures and instructions are prepared. Figure 3 illustrates the chronology of events in planning and performing such a testing program and shows how the 18 criteria of Appendix B can be applied. It also shows the involvement of QA throughout the entire process, including how procedures may require review by peer review groups. Peer review groups should be utilized for untried or state-of-the-art testing and analysis procedures, or where detailed technical criteria or requirements do not exist or are under development. Outside consultants are retained when required to obtain needed expertise.

As described above, a QA program for site characterization involves documentation of procedures. It is important to make a distinction between (1) administrative QA procedures and (2) detailed technical or implementing procedures (Figure 4). Quality assurance procedures provide instructions for implementation and application of the 18 criteria of 10 CFR Part 50 Appendix B. These are generated by the quality assurance organization (with assistance from the technical organizations) and apply to all technical program areas (e.g., procedures for test plan development). The detailed technical (implementing) procedures are developed by qualified personnel in accordance with the requirements specified in the administrative quality assurance procedures. These contain instructions for actual performance of testing and investigations (e.g., hydrologic pump tests, setting a packer, etc.).

4.0 NRC REVIEW PLAN

The Repository Projects Branch (WMRP) of NRC has the lead responsibility for reviews of DOE QA programs for site characterization investigations for nuclear waste repositories. Quality assurance specialists from the Office of Inspection and Enforcement, the Policy and Program Control Branch (WMPC) and other branches will provide assistance to WMRP in these reviews. These reviews will involve several activities and will utilize the staff positions presented in Appendix A, which are based on the 18 criteria of Appendix B, 10 CFR Part 50. The first involves the review of the QA program description submitted at the latest in the Site

Characterization Plan (SCP) for each site, as required by 10 CFR 60.11, and other QA program documents and procedures. In addition to the reviews of quality assurance program documents, NRC staff will conduct on-site reviews and meetings with DOE staff and contractors to identify and resolve at an early time potential quality assurance issues which arise in implementation of these programs.

Some of the reviews of the formal quality assurance aspects of DOE progams will occur in connection with the reviews and prelicensing consultations being conducted to establish the technical information needs of licensing. In addition to consultations on potential technical issues and general plans and strategies for resolving these issues, these consultations and reviews deal with specific data collection and analysis procedures. The quality and completeness of data being collected are virtually determined by such plans and procedures. Because all of the procedures that are being used cannot practically be supplied with SCP's or SCP updates, due to their volume, site visits by staff will be necessary. For conducting these visits (as provided for by §60.11(g) of 10 CFR Part 60), the NRC technical staff evaluating data and data collection and analysis procedures may be accompanied by NRC staff QA specialists who are evaluating issues which relate to implementation of the quality assurance program. These visits and reviews are intended to raise issues for consultation and early resolution.

The positions 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 detailed guidance in this Plan may be found acceptable provided the DOE documents and justifies these deviations. A commitment to conform to the guidance in this Plan is considered to be a commitment to implement all staff positions unless exceptions or alternatives are specifically identified.

As discussed in the Introduction and Background section it is important for DOE to recognize the limited role of the NRC in identifying quality-related problems. Deviations from requirements or standards identified by the NRC staff must therefore be carefully examined by DOE to determine a) the root cause of the deficiency and b) if similar deficiencies exist in other areas of the program not reviewed by the NRC staff. The corrective action taken by DOE should be sufficient to assure that similar future deficiencies can be avoided or mitigated.

APPENDIX B QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS AND FUEL REPROCESSING PLANTS

Introduction Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility Every applicant for an operating license is required to include in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public This appendix establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components The pertinent requirements of this appendix apply to all activities affecting the safety related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying

As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component 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

I ORGANIZATION

The applicant[1] shall be responsible for the establishment and execution of the quality assurance program The applicant may delegate to others, such as contractors, agents or consultants the work of establishing and executing the quality assurance program or any part thereof, but shall retain responsibility therefor The authority and duties of persons and organizations performing activities affecting the safety related functions of structures, systems, and components shall be clearly established and delineated in writing These activities include both the performing functions of attaining quality objectives and the quality assurance functions 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 related functions have been correctly performed The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems, to initiate, recommend, or provide solutions, and to verify implementation of solutions Such persons and organizations performing quality assurance functions shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function

II QUALITY ASSURANCE PROGRAM

The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety Activities affecting quality shall 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. The program shall take 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 test. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program. 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.

III. DESIGN CONTROL

Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safely related functions of the structures, systems and components

Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces

for verifying or [illegible] the performance of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization Where a test program is used to verify the adequacy of a specific 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. Design control measures shall be applied to items such as the following reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

IV. PROCUREMENT DOCUMENT CONTROL

Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

VI. DOCUMENT CONTROL

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activi

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[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear power plant or a fuel reprocessing plant These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits and operating licenses

{FIGURE (page 1)}

ties affecting quality These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization

VII. Control of Purchased Material, Equipment, and Services

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear powerplant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services

VIII. Identification and Control of Materials, Parts, and Components

Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components

IX. Control of Special Processes

Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements

X. Inspection

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.

XI. Test Control

A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied

XII. Control of Measuring and Test Equipment

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

XIII. Handling, Storage and Shipping

Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.

XIV. Inspection, Test, and Operating Status

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.

XV. Nonconforming Materials, Parts, or Components

Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

XVI. Corrective Action

Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

XVII. Quality Assurance Records

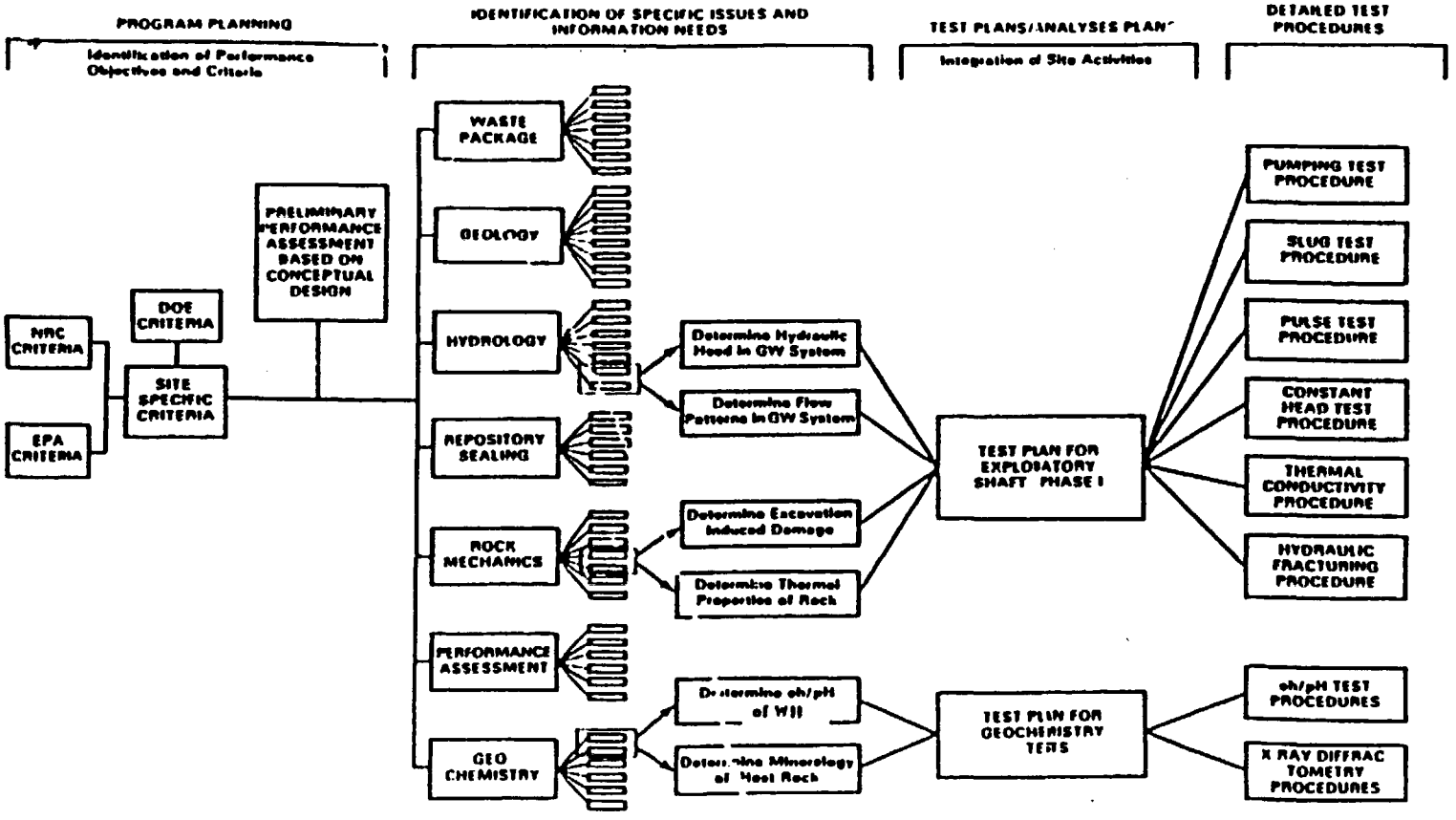
Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

XVIII. Audits

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

[35 FR 10499, June 27, 1970, as amended at 36 FR 18301, Sept. 17, 1971; 40 FR 32101, Jan. 20, 1975]

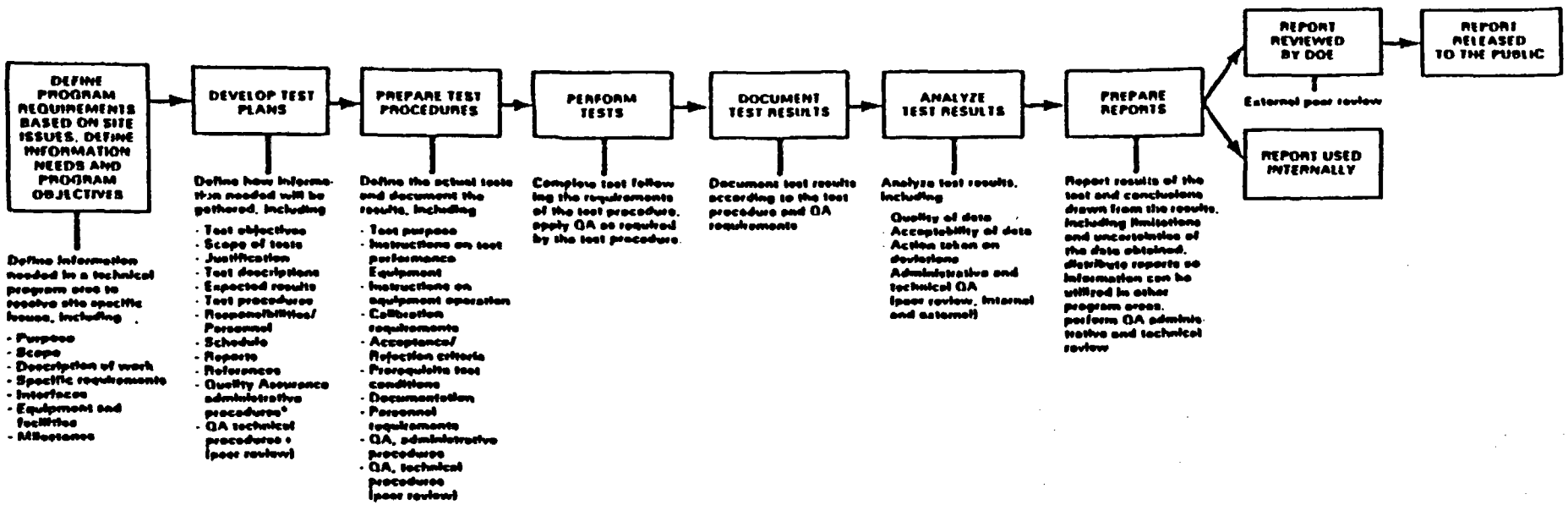
FIGURE 1, page 2



SCOPE OF DIAGRAM
To show levels of detail involved in developing a technical program

PURPOSE OF DIAGRAM
To convey the various levels of detail in planning and controlling a technical program to define lev el of detail necessary in executing a technical program properly

FIGURE 2



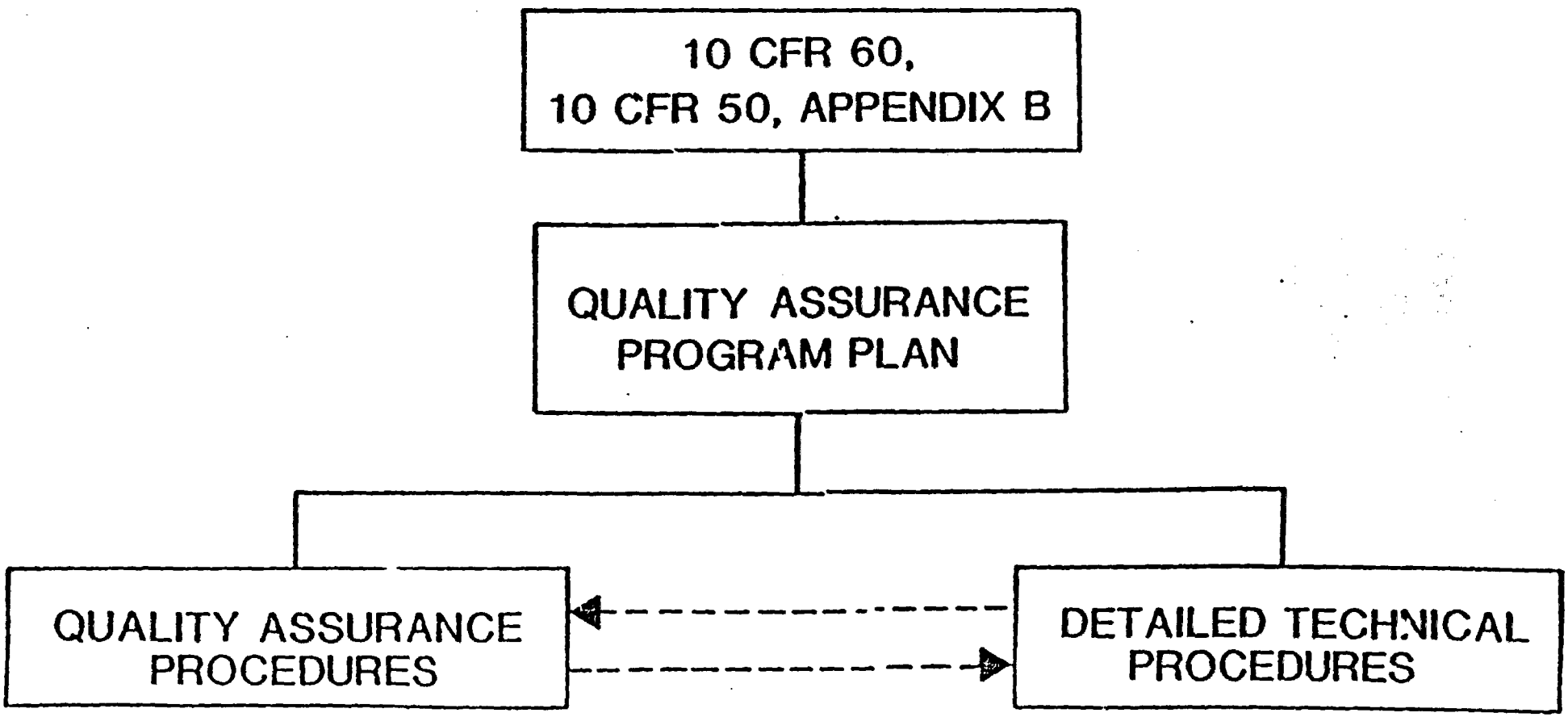
*QA administrative procedures include procedures for: (1) document control, (2) documented instructions, procedures, and drawings; (3) control of materials, equipment, and services, (4) use of qualified personnel; (5) inspections, (6) documented test plans; (7) control of test equipment; (8) control of samples; (9) nonconformance reports; (10) corrective action; (11) peer review (both management and technical); (12) audits

+ QA technical procedures include the actual internal and external peer reviews (both management and technical).

SCOPE OF DIAGRAM:
To show chronology of events in development of a testing program

PURPOSE OF DIAGRAM:
(1) To show a breakdown sequence of development of plans to resolve problem of timely access to data by NRC (2) To show the involvement of QA, both administrative and technical, in each step of program

FIGURE 3



QUALITY ASSURANCE PROGRAM STRUCTURE

APPENDIX A

CRITERIA FOR QA PROGRAM
(HIGH LEVEL WASTE REPOSITORY PROGRAM)

This Appendix is broken down into sections which correspond to each of the 18 criteria of Appendix B to 10 CFR 50. 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. Some individual requirements in Appendix B are not discussed in this Appendix, but should be addressed in the DOE QA program description.

The positions 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 detailed guidance in this Plan may be found acceptable provided these deviations are documented and justified. A commitment to conform to the guidance in this Plan is considered to be a commitment to implement all staff positions unless exceptions or alternatives are specifically identified.

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

1.1 The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.

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 QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.

1.4 DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's* QA program and audits of representative subcontractors, consultants,

* "Contractor" as used in this Appendix refers to all contractors, subcontractors, vendors, consultants, or agents performing work covered by the quality assurance program.

vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.

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 contractors, 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 and the lines of responsibility.

1.8 The QA organization is involved in the aspects 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.

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

1.10 DOE and its prime contractor 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.

1.11 Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for: design, item 3.7; inspections, item 10.2; and test data evaluation, item 11.3 are outlined in these sections.

1.12 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.

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

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

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

1.15 The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.

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

2.1 The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The

rationale should include systems analyses that are used to determine what specific items and activities are covered.

2.2. 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.

2.3 Provisions are established to assure that technical and quality assurance procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official.

2.4 The QA organization reviews and documents concurrence with the quality-related* procedures relative to QA requirements.

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 or waste isolation as defined in 10 CFR Part 60.2 and affects such disciplines as design, data analysis (such as performance assessment), 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 and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met.

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:

*The term "quality-related" refers to the quality of items "important to safety" or "important to waste isolation."

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.

2.8 Indoctrination, training, and qualification programs are established such 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.

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 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 designs 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 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 analysis. Data anlaysis 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 is implemented at the time of submission of the Site Characterization Plan and 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. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.

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

3.4 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.

3.5 Interface controls among organizations or groups involved in design development and other design activities are described.

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

3.7 Procedures are established and described for verification of designs and design activities, the verifier of which is 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.

It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.

3.8 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, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.

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

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

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

4.1 Procedures are established for the review of procurement documents by QA personnel to determine 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 procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants 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 to the NRC staff if:

5.1 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. These documents should be verified and approved as described in Section 3.

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

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.

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 respect to quality-related aspects.

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 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.

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

6.6 When documents which require verification are released prior to verification, they are so identified and controlled.

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

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

7.2 Procedures governing procurement of items or services, including appropriate QA organization participation, provide for: (a) evaluation and selection of suppliers; (b) verification of supplier's activities; and (c) receiving inspections.

7.3 The organization providing materials, equipment, or services 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 procedure for review and acceptance of these documents should be described in the purchaser's QA program.

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

7.5 In developing quality assurance requirements for data collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment.

8. Activities related to sample Identification and Control are acceptable to the NRC staff 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 their containers, or on records traceable thereto.

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

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

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, 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 help 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 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 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. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.

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 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 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how

and when testing activities are performed; and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.

11.2 Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.

11.3 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.

11.4 Test procedures or instructions provide for the following:

a. The requirements and acceptance limits 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 data analysis.

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

h. Provisions for assuring test prerequisites have been met.

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

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

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.

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

13.1 Sampling, 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, 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 on individual items.

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

15.1 Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. 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 to help identify root causes of non-conformances, 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. 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 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 to the NRC staff if:

17.1 The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspections; tests, audits, and material analyses; monitoring of work performance, qualification of personnel, procedures, and equipment; and other cocumentation 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 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 to the NRC staff 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 contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program.

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 responsible management for review, assessment, and appropriate action.

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.

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

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 In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.