TECHNICAL POSITION
ON
QUALITY ASSURANCE FOR THE
SITE CHARACTERIZATION PHASE OF THE
HIGH-LEVEL NUCLEAR WASTE REPOSITORY

PREFACE

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

The NRC regulations in 10 CFR Part 60 Subpart G require the repository program, including site characterization, to be performed under a quality assurance (QA) program. As required by the regulation, this quality assurance program shall be based on the quality assurance criteria established in 10 CFR Part 50 Appendix B for nuclear power reactors as it applies to the repository program. In addition the regulation requires that the 10 CFR Part 50 Appendix B criteria for quality assurance be supplemented as necessary. In June of 1984 the NRC published the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories." This document outlined the methods by which the NRC staff would oversee the DOE QA program. In addition the document provided in Appendix A the specific QA criteria which the NRC staff would use to review the DOE QA program. Appendix A was based on the Section 17, Quality Assurance, of the NRC Standard Review Plan (SRP) for nuclear power reactors. Some criteria in the SRP were modified and supplemented to address the items and activities in the repository program.

The revision to the NRC Review Plan was undertaken in 1987 to accomplish the following:

* incorporate recommendations (lessons learned) from the power reactor program. The staff issued the 1984 NRC Review Plan shortly after the Ford Amendment Study (NUREG-1055) was published and before many of its recommendations were implemented by the NRC. The Ford Amendment Study was performed at the request of Congress and investigated the

causes of quality and quality assurance problems in nuclear power plants under construction in the late 1970's and early 1980's. The study also provided recommendations for improvements for both utility QA programs and NRC's oversight of those programs.

* endorse for the repository program the use of NQA-1, the industry standard for quality assurance programs for nuclear facilities. NQA-1 provides detailed guidance on quality assurance based on the NRC's quality assurance requirements in 10 CFR Part 50 Appendix B. The NRC staff endorsed the the use of this standard for nuclear power plants in Regulatory Guide 1.28, August 1985.

* reference several generic technical positions issued by the NRC staff in the last year. These positions address peer review, the qualification of existing data, and the identification of items and activities important to safety or waste isolation (Q-List).

* make changes based on 3 years of DOE and NRC staff experience in the use of the 1984 NRC Review Plan.

The revision to the NRC Review Plan incorporates lessons learned such as the use of technical audits and readiness reviews, endorses NQA-1 and where necessary accounts for differences between power reactor projects and the high-level nuclear waste repository program, references the staff's GTP's, and addresses comments received from DOE on improvements that it believes need to be made to the 1984 plan.

In addition, the revision incorporates positions, as applicable, from the draft's of NQA-3, "American National Standard, Quality Assurance Program Requirement Site Characterization of High-Level Nuclear Waste Repositories." This document contains QA guidance specifically for data collection and analysis activities including guidance similar to the generic technical positions referenced by the revision. When published as a final standard the staff will endorse the standard and may eliminate the reference to the technical positions if appropriate.

The revision to the NRC Review Plan has been divided into two documents: The NRC Review Plan for Quality Assurance Programs for the Site Characterization Phase of the High-Level Nuclear Waste Repository and the Technical Position on Quality Assurance for the High-Level Nuclear Waste Repository. The first document outlines the methods that the NRC staff will use to review the DOE QA program. The second document outlines the criteria the NRC staff will use in commenting on the DOE's QA program. These documents are being issued as drafts for public comment. Upon receipt of public comments, the staff will resolve each comment in writing and anticipates meeting with commentors prior to issuing the final document to review the proposed responses to comments and revisions to the draft. In addition, the response to DOE comments and a cross reference between the 1984 NRC Review Plan Appendix A and the 1988 Draft Technical Position on QA is being published concurrently.

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INTRODUCTION

The Department of Energy (DOE) is conducting a site characterization program at the Yucca Mountain site in Nevada. The purpose of this program is to collect and analyze data to determine if natural and engineered barriers can safely isolate high-level nuclear waste from the accessible environment. The information developed during the site characterization phase will be used in an application for a license submitted to the NRC to receive and possess source, special nuclear, or byproduct material.

During the site characterization phase of the repository program the NRC staff is conducting a prelicensing consultation and guidance program with the DOE. The staff will familiarize themselves with the DOE program and identify and resolve issues as early as possible and before a license application is submitted to the NRC. Through these interactions the staff will attempt to gain confidence that the DOE meets all of the applicable regulatory requirements for licensing. The staff, however, does not have the resources to independently evaluate the all or even a major part of the detailed activities associated with siting, designing, constructing, and operating a waste repository prior to a licensing hearing. As a result the NRC regulations specify that the DOE implement a quality assurance (QA) program that will assure quality in the work carried out in the prelicensing phase of the program. The staff will rely on the DOE QA program and the staff's evaluation of that program to generalize the results of the staff's limited review of the work conducted in the repository program. In addition, the documentation produced under the QA program will form the record upon which the suitability of the site will be judged in the NRC licensing process.

As part of the NRC staff's effort in reviewing the overall DOE program, the staff will review and assess the adequacy of the QA program. As described in the NRC Review Plan for Site Characterization Phase of the High Level Nuclear Waste Repository published concurrently with this document, the staff will select and review important aspects of the DOE QA program through such methods as review of DOE QA plans, observation of audits conducted by DOE, and conduct of NRC audits.

Since an effective QA program is of critical importance to the success of the repository in the licensing process, the NRC staff has published this Technical Position (GTP) on quality assurance. The criteria in this TP are acceptable to the NRC staff and if properly carried out by DOE would be suitable for use in licensing.

REGULATORY FRAMEWORK

NRC regulations (10 CFR Part 60, Subpart G) require that DOE implement a QA program that 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. The regulations also identify when the DOE will submit information on quality assurance to the NRC and what NRC monitoring of QA activities will be permitted during site characterization. DOE is required to submit, for NRC review, the Site Characterization Plan, containing a description of the quality assurance plans that will be applied to site characterization activities. With regard to NRC monitoring activities, the regulations state that during site characterization the NRC is permitted to visit and inspect the locations at which activities are carried out and to observe excavations and in situ tests as they are done.

PURPOSE

The purpose of this GTP is to provide DOE with guidance concerning the NRC staff's positions on quality assurance and with specific QA criteria necessary to assure quality and the demonstration of quality in a licensing by the NRC.

NRC staff positions:

- identify 10 CFR Part 50 Appendix B (Ref. 10) quality assurance requirements applicable to the repository program;

- identify NQA-1 Requirements and Supplements (Ref. 5), applicable to the repository program;

- clarify how these requirements and supplements should be applied; and

- provide supplemental guidance for areas particularly important to the success of the repository program, such as control of data collection activities.

SCOPE

The staff positions in this regulatory guide apply to items important to safety or waste isolation and the activities related thereto. DOE will prepare a Q-List and Quality Activities List which will identify the items and activities to which the staff positions apply.

PERIOD OF APPLICABILITY

This document applies during the site characterization phase of the program. A similar document will apply to the construction and operation of the repository.

DOCUMENT ORGANIZATION

This document is organized into nineteen (19) sections, a reference list, a bibliography and an index to definitions. The first section provides general NRC staff positions concerning quality assurance for the high-level nuclear-waste repository. The first section also contains several definitions pertinent to the General NRC Staff Position. The remaining sections, I-XVIII, correspond to the eighteen (18) criteria of 10 CFR Part 50 Appendix B. Each of the remaining 18 sections has three headings: Appendix B, NQA-1, and Supplementary NRC Staff Position. The first heading identifies each Appendix B Requirement. Throughout the document, the Appendix B requirements are in the same order as they appear in 10 CFR Part 50. The NQA-1 heading provides the NQA-1 Basic Requirements and Supplements, or parts thereof, that correspond to the Appendix B requirement. The Supplementary NRC Staff Position has up to 3 subsections: definitions, staff positions, and discussion. The definitions subsection contains particularly important terms used in the Appendix B requirement, the NQA-1 Requirements and Supplements, and the Supplementary NRC Staff Position. The definitions have

several sources, including NQA-1. Typically the definitions will appear only the first time it is used in Appendix B, NQA-1, or the staff position. The Supplementary NRC Staff Positions clarify Appendix B requirements and NQA-1 Requirements and Supplements. The supplementary NRC staff positions also provide additional guidance for areas particularly important to the success of the repository program, such as control of data collection activities. The discussion section elaborates on staff positions.

NOTE ON REFERENCES

References identified for definitions, staff positions, and discussions indicate the document from which the NRC staff derived the definition, staff position, or discussion. The reference does not indicate that the definition or staff position is repeated verbatum from the reference document. Staff positions with reference identified as "NRC STAFF" have been derived through numerous staff discussions within NRC and with DOE staff and its participants, through staff experience with review of DOE QA plans, through NRC audits and audit observations of the DOE QA program, and from numerous drafts of NQA-3, the proposed National Standard for the Quality Assurance Program Requirements for Collection of Scientific Information for Site Characterization of High-Level Nuclear Waste Repositories. This document is not referenced specifically since it exists only in draft form and is currently undergoing frequent revisions.

GENERAL NRC STAFF POSITION

DEFINITIONS

Applicant: the person or organization that submits or will submit a license application for construction authorization of a high-level nuclear waste facility. With respect to the NWPA, 1982, the applicant is the U.S. Department of Energy (DOE). (NRC STAFF)

Quality Assurance (QA): 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. (Ref. 11)

Shall, should and may: The word "shall" is used to denote a regulation; the word "should" to denote a recommendation; and the word "may," to denote permission, neither a requirement nor a recommendation. (Ref. 2)

1. All 10 CFR Part 50 Appendix B requirements apply to the site characterization phase of the high-level waste repository program. The Supplementary NRC Staff Positions clarify, when necessary, how these requirements apply.

2. NQA-1-1986 (exclusive of Addenda to 1986 Version) requirements and supplements should be applied to the repository program. The Supplementary NRC Staff Positions clarify, when necessary, how these requirements and supplements apply.

3. The Supplementary NRC Staff Positions in this document should be applied to the repository program.

4. Alternative solutions and approaches to NQA-1 Requirements and Supplements and Supplementary NRC Staff Positions may be applied to the repository

program, but the alternatives should be identified and adequately justified in the QA Plan (see Criterion II) (Ref. 21).

DISCUSSION

NRC staff recognizes that Appendix B requirements were established explicitly for nuclear power reactors. The requirements, however, were written in general terms with a few exceptions where nuclear plant terminology appears. As a result, the requirements are applicable to many types of projects, including both scientific investigations and engineered design of the repository.

Each of the 18 sections in this document is not meant to be used independently. For example, Criterion III, Design Control, provides requirements and guidance for the control of design. These requirements and guidance, however, are not the only requirements and guidance that shall or should be applied. For example, the qualifications of the designers, the content of design procedures, the control of documents, and audits also apply. These requirements and guidance are contained in other sections of this document.

The requirements, supplements, and staff positions represent good business and scientific practices. If these practices are fully implemented, the license applicant will mitigate problems likely to arise in the licensing process.

I. ORGANIZATION

APPENDIX B

REQUIREMENT 1:
The applicant* shall be responsible for the establishment and execution of the quality assurance program.

*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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

SUPPLEMENT 1S-1

2.0 RESPONSIBILITY

2.2 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefor.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Individual: (also person) position filled with someone who meets the established qualifications of that position. (NRC STAFF)

I.2.1 The applicant may delegate to others, such as contractors, agents, or consultants, the work, or any part thereof, covered by the QA program, but should retain responsibility therefor. (NRC STAFF)

I.2.2 Prior to the initiation of activities, qualified individual(s) or organization(s) should be designated as responsible for the quality of the delegated work. (Ref. 23)

I.2.3 Prior to the initiation of delegated work, the person(s) or organization(s) to which work is delegated should have established and implemented a quality assurance program approved by the delegating organization that meets the guidance in this document. (Ref. 21 and Ref. 23)

I.2.4 The applicant should evaluate the performance of work accomplished by the delegated organizations. The method and frequency of evaluation should be established prior to initiation of activities. These evaluations, at minimum, should be conducted annually. (Ref. 21 and Ref. 23)

APPENDIX B

REQUIREMENT 3:

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.

NQA-1

BASIC REQUIREMENT

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented....

SUPPLEMENT 1S-1

2.0 RESPONSIBILITY

2.1 Purpose

The organizational structure and the responsibility assignments shall be such that:

(a) Quality is achieved and maintained by those who have been assigned responsibility for performing work.

(b) Quality achievement is verified by persons or organizations not directly responsible for performing the work.

2.3 Nonconforming Items

Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing.

3.0 MULTIPLE ORGANIZATIONS

3.1 Responsibility

Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.

3.2 Interface Control

3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

3.2.2 Interface responsibilities shall be defined and documented.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Activities: deeds, actions, work, or performance of a specific function or task. In the HLW geologic repository program, the 10 CFR Part 60, Subpart G, QA program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation (10 CFR 60.151). For example, the pertinent requirements of 10 CFR Part 50, Appendix B apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-List. However, activities related to natural barriers important to waste isolation should be identified and listed on a Quality Activities List. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. For example, site

characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way. (Ref. 32)

Items Important to Safety: 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 at any time until the completion of permanent closure (10 CFR 60.2). (Ref. 32)

Items Important to Waste Isolation: natural and engineered barriers which are relied on for achieving the postclosure performance objectives in 10 CFR 60 Subpart E. (Ref. 32)

Structures, systems, and components (with safety-related functions): items important to safety and barriers (items) important to waste isolation. (Ref. 32)

I.3.1 Each organization should identify a management position responsible for the overall program including ultimate responsibility for the QA program. (Ref. 13)

I.3.2 The applicant and its prime contractors should identify a single QA management position responsible for the establishment and implementation of the QA program. (Ref. 23)

I.3.3 The QA management position should: (Ref. 23)

(a) have appropriate organizational position, at the same or higher organization level as the highest like manager responsible for performing activities affecting quality;

(b) have appropriate QA, management, and technical knowledge and experience;

(c) have knowledge of QA regulations, policies, practices, and standards;

(d) have appropriate authority and responsibility to verify the adequacy and effectiveness of QA plans, requirements, procedures,

and QA program implementation by that organization and its subordinate organizations, contractors, subcontractors, consultants, or agents;

(e) have no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters; (Ref. 13)

(f) be independent of cost and schedule considerations when opposed to safety considerations;

(g) have access to management above the management position in I.3.1 to identify unresolved quality concerns; and

(h) review and approve the QA Program.

I.3.4 The QA manager of a contractor should have access to the management of the contracting organization to identify serious unresolved quality concerns. (NRC STAFF)

I.3.5 Provisions should be established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or from outside the responsible organization(s). (NRC STAFF)

I.3.6 Provisions should be established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel. (Ref. 23)

I.3.7 Quality assurance functions may be part of the line organization but the QA organization should perform sufficient oversight including audits and inspections to confirm that the function is performed in accordance with the QA program. (Ref. 13 and Ref. 24)

DISCUSSION

QA Staff Vs. Technical and Management Staff Responsibilities

QA, technical, and management personnel should implement the QA program. Technical and management personnel should assess the quality of work being performed as a normal part of their everyday activities. QA staff should check

and evaluate the adequacy of technical work on a sampling basis through audits, inspections, and surveillances. The QA staff should utilize technical and management staff, other than those persons responsible for the work, to accomplish this evaluation.

Structures, systems, and components (safety-related functions)

The requirements which apply to protection of public health and safety and the environment from disposal of high-level radioactive waste (HLW) in a geologic repository are defined in 10 CFR Part 60. These requirements address a pre-closure phase, which includes design, construction, waste emplacement, and possible retrieval of waste, and a post-closure phase, which includes containment and long-term isolation of waste. In the pre-closure phase, structures, systems, and components essential to the prevention or mitigation of an accident that could result in an off-site radiation dose of 0.5 rem or greater are termed "important to safety" (10 CFR 60.2). In the post-closure phase, the barriers which contribute to meeting the containment and isolation requirements of 10 CFR Part 60 are defined as "important to waste isolation." These structures, systems, components, and barriers (items), and the activities related to their characterization, design, construction, and operation are required to meet quality assurance (QA) criteria to provide confidence in the performance of the geologic repository. The list of the structure, systems, and components important to safety and engineered barriers important to waste isolation is referred to as a "Q-list" and lies within the scope of the QA program specified in 10 CFR Part 60 Subpart G. (Ref. 32)

APPENDIX B

REQUIREMENT 4:

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.

NQA-1

BASIC REQUIREMENT

...Persons or organizations responsible for assuring that an appropriate quality assurance program is established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.... Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.

SUPPLEMENTARY NRC STAFF POSITION

I.4.1 The authority to stop unsatisfactory work should be assigned to persons and/or organizations who are sufficiently free from direct pressures for cost and schedule. (Ref. 23)

APPENDIX B

REQUIREMENT 5:

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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

I.5.1 Designated QA individuals should be involved in day-to-day activities important to safety or waste isolation (i.e., the QA organization routinely attends and participates in daily work schedule and status meetings to assure they are kept abreast of day-to-day work assignments and that there is adequate implementation of the QA Program). (Ref. 21 and Ref. 24)

APPENDIX B

REQUIREMENT 6:

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.

NQA-1

BASIC REQUIREMENT

...Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected....

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

II. QUALITY ASSURANCE PROGRAM

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof.... The program shall be established at the earliest time consistent with the schedule for accomplishing the activities....

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Item: an all inclusive term used in place of any of the following: appurtenance, assembly, equipment, material, structure, subsystem, system, unit, data or software (Ref. 5).

II.1.1 The QA program for specific items, processes, services or activities should be established prior to use of items, services and processes and prior to initiation of activities. (NRC STAFF)

APPENDIX B

REQUIREMENT 2:
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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Plant life: site characterization phase of the high-level nuclear waste repository program. (NRC STAFF)

II.2.1 The QA program should be documented by a QA Plan, in addition to policies, procedures, or instructions. (NRC STAFF)

II.2.2 The QA Plan should:

(a) identify the the Appendix B requirements, the NQA-1 Requirements and Supplements, and the Supplementary NRC Staff Positions that will be implemented. The plan should provide brief descriptions of how each requirement, supplement, and staff position will be implemented or reference the implementing procedure. Alternative solutions or approaches to NQA-1 Requirements and Supplements and Supplementary NRC Staff Positions should be specifically identified and justified. (Ref. 23)

(b) describe the organization or positions responsible for implementing each Appendix B requirement, NQA-1 Requirements and Supplements, and each Supplementary NRC Staff Position. (Ref. 23)

(c) describe the responsibilities/involvement of the QA organization with regard to each Appendix B requirement, NQA-1 Requirements and Supplements, and each Supplementary NRC Staff Position. (Ref. 23)

II.2.3 The QA Plan should contain a policy statement signed by a top management official rendering the implementation of the QA plan mandatory. (Ref. 23)

II.2.4 Provisions should be established for informing NRC of changes in (1) the QA program, particularly changes in the QA plan and (2) organizational elements. (Note - editorial changes or personnel reassignments of a non-substantive nature should not require informing NRC.) (Ref. 24)

DISCUSSION

QA PLAN CONTENTS

The level of detail that should be provided in the QA plan should be sufficient for the NRC staff to determine that the applicant's QA program description is acceptable under the conditions outlined in this document. A restatement of the requirement, supplement or Supplementary NRC Staff Position does not satisfy the level of detail necessary for NRC staff review.

With regard to II.2.2.a) above, the following is an example of an acceptable approach. Staff position VI.2.8 states:

> "A master list or document control system should be established to identify documents to be controlled and the current revision of documents."

The QA plan should include a description of how the master list will be established or a description of the document control system, including how it will be implemented.

With regard to II.2.2 b) and c) above, the following is an acceptable approach. The QA Plan should contain an organizational chart(s) that identifies the organizations or positions, including the QA organization or positions, responsible for implementing each Criterion in this document. Brief but specific descriptions of the responsibilities of each organization or position with regard to each Appendix B requirement, the NQA-1 Requirements and Supplements, and Supplementary NRC Staff Positions should be included. Particular emphasis should be placed on identifying the organizations and positions performing QA functions and describing the specifics of these functions. For example, the organizational chart(s) should identify the organizations and positions responsible for engineered design. The corresponding description should indicate the responsibilities of these organizations and positions in the preparation, review, approval, and verification of engineered design documents, including changes. The description also should identify the organizations and/or positions that will perform the QA functions, such as review of design documents to assure that they are prepared, reviewed, and approved in accordance with procedures.

APPENDIX B

REQUIREMENT 3:
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.

NQA-1

BASIC REQUIREMENT
... The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality.

SUPPLEMENTARY NRC STAFF POSITION

II.3.1 The identification of safety-related structures, systems, components, and related activities should be in accordance with the Generic Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements. (NRC STAFF and Ref. 32)

APPENDIX B

REQUIREMENT 4:
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.

NQA-1

BASIC REQUIREMENT
The program shall provide control over activities affecting quality to an extent consistent with their importance....

SUPPLEMENTARY NRC STAFF POSITION

II.4.1 The QA organization and the necessary technical organizations should participate early in the QA program definition stage to identify and determine the extent QA controls are to be applied to the Q-LIST items and activities related thereto. (Ref. 23)

II.4.2 The application of graded QA measures should be applied to items and activities important to safety or waste isolation in accordance with guidance in the Generic Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program subject to 10 CFR Part 60 Quality Assurance Requirements. (NRC STAFF and Ref. 32)

II.4.3 Defensible criteria for the application of graded QA measures should be used. If definitive criteria cannot be described, a conservative level of QA should be applied to items and activities in the event that subsequent analyses would show their critical importance in meeting quality objectives. (NRC STAFF)

APPENDIX B

REQUIREMENT 5:

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.

NQA-1

BASIC REQUIREMENT

...The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied....

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 6:

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.

NQA-1

BASIC REQUIREMENT

...The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality....

SUPPLEMENTARY NRC STAFF POSITION

II.6.1 The QA program should take into account the need for verification of quality by processes such as audits and peer review. (Ref. 19)

APPENDIX B

REQUIREMENT 7:

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.

NQA-1

SUPPLEMENT 2S-1

QUALIFICATION OF INSPECTION AND TEST PERSONNEL

1.0 GENERAL

This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirement of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination.

2.0 CERTIFICATION

2.1 Qualification Requirements

The responsible organizations shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities. When a single inspection or test requires implementation by a team, or a group, personnel not meeting the requirements of this Standard may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.

2.2 Personnel Selection

Personnel selection for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.

2.3 Indoctrination

Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed.

2.4 Training

The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests.

2.5 Determination of Initial Capability

The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's eduction, experience, training, and either test results or capability demonstration.

2.6 Evaluation of Performance

The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of 2.5 above. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of one year shall be reevaluated by a determination of required capability in accordance with the requirements of 2.5 above.

2.7 Certificate of Qualification

The qualification of personnel shall be certified in writing in an appropriate form, including the following information:

(a) employer's name;
(b) identification of person being certified
(c) activities certified to perform;
(d) basis used for certification, includes such factors as:

(1) education, experience, indoctrination and training;
(2) test results, where applicable;
(3) results of capability demonstration.

(e) results of periodic evaluation;
(f) results for physical examinations, when required;
(g) signature of employer's designated representative who is responsible for such certification;
(h) date of certification and date of certification expiration.

2.8 Physical

The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

3.0 RECORDS

3.1 Record Files

Records of personnel qualification shall be established and maintained by the employer. These records shall include the information required by 2.7 above.

SUPPLEMENT 2S-2

QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

1.0 GENERAL

This supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NTR),

and leak testing (LT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2.0 CERTIFICATION

2.1 Applicable Documents

The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement.

2.2 Program

The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.

2.3 Records

Records of personnel qualification shall be established and maintained by the employer.

SUPPLEMENT 2S-4

2.0 APPLICABILITY

This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained shall be identified. The extent of indoctrination and training shall be commensurate with the following:

(a) The scope, complexity, and nature of the activity; and
(b) the education, experience, and proficiency of the person.

Activities affecting quality include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

3.0 INDOCTRINATION

Personnel shall be indoctrinated in the following subjects as they relate to a particular function:

(a) general criteria, including applicable codes, standards, and company procedures;
(b) applicable quality assurance program elements; and
(c) job responsibilities and authority.

4.0 TRAINING

Training shall be provided, if needed, to:

(a) achieve initial proficiency;
(b) maintain proficiency; and
(c) adapt to changes in technology, methods, or job responsibilities.

5.0 RECORDS

Records of the implementation of indoctrination and training may take the form of:

(a) attendance sheets;
(b) training logs; or
(c) personnel training records.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Certification: the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures or items in accordance with specified requirements. (Ref. 5)

Qualification (of personnel): the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function. (Ref. 5)

II.7.1 NQA-1, Supplement 2S-1 should be applied to positions performing activities affecting quality. (NRC STAFF)

II.7.2 Each organization should establish position descriptions and minimum qualifications for positions performing activities affecting quality. (NRC STAFF)

II.7.3 Persons should have the minimum qualification prior to performing activities affecting quality or performing QA functions. (NRC STAFF)

II.7.4 The qualifications of persons should include education, experience, indoctrination, training, or a combination of the above. (NRC STAFF and Ref. 23)

II.7.5 The qualifications of persons should be certified. When applicable, the certifications should be in accordance with codes and standards. (Ref. 23)

II.7.6 The certification records should contain information listed in NQA-1, Supplement 2S-1, Section 2.7 a-g and the following, as appropriate:

(a) the bases used for certification, including

(1) indoctrination and on-the-job training, and
(2) professional or vocational certificates; and

(b) the actual examinations used to certify the person(s). (Ref. 19 and NRC STAFF)

II.7.7 (NQA-1, Supplement 2S-1, Section 2.6) A system of annual appraisal and evaluation should be established to monitor the proficiency of persons involved in activities affecting quality. Proficiency should be maintained by retraining, reexamining and/or recertifying, as necessary to maintain quality. (Ref. 21 and Ref. 23)

II.7.8 Indoctrination and training programs should be established to instruct personnel who perform quality-related activities as to the purpose, scope, and implementation of the quality-related manuals, instructions, procedures, and other documents. (Ref. 23)

II.7.9 Documentation of formal indoctrination and training programs should include the:

(a) objective;
(b) program content;
(c) instructor's name;
(d) attendee's names;
(e) dates of attendance; and
(f) results of examination, if applicable. (Ref. 23)

APPENDIX B

REQUIREMENT 8:
The applicant shall regularly review the status and adequacy of the quality assurance program.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

II.8.1 The applicant should review and assess the scope, status, adequacy and compliance of the QA and technical programs to the requirements in this document. This goal should be accomplished by means such as review and approval of plans and procedures, surveillance, inspection, and audit. (Ref. 19, Ref. 21 and Ref. 23)

APPENDIX B

REQUIREMENT 9:

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.

NQA-1

BASIC REQUIREMENT

...Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

III. DESIGN CONTROL

APPENDIX B

REQUIREMENT 1:

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.

NQA-1

BASIC REQUIREMENT

The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis, and correctly translated into design documents....

SUPPLEMENT 3S-1

2.0 DESIGN INPUT

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.

3.0 DESIGN PROCESS

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction and operation....

The final design (approved design output documents and approved changes thereto) shall:

(a) be relatable to the design input by documentation in sufficient detail to permit design verification; and

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

3.1 Design Analyses

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identified by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.

(a) Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

(1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

(2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.

(b) Documentation of design analyses shall include (1) through (6) below:

(1) definition of the objective of the analyses;
(2) definition of design inputs and their sources;
(3) results of literature searches or other applicable background data;
(4) identification of assumptions and indication of those that must be verified as the design proceeds;
(5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem;
(6) review and approval.

7.0 DOCUMENTATION AND RECORDS

Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Standard, shall be collected, stored, and maintained in accordance with documented procedures.

The documentation shall include not only final design documents, such as drawings and specifications and revisions thereto, but also documentation which identifies the important steps, including sources of design inputs, that support the final design.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Conceptual Design: a pictorial and/or narrative description, developed prior to final design, which represents all relevant aspects of structures, systems, or components, the interactions between them, and any internal or external processes which affect their performance, including site-specific requirements. (Ref. 11)

Design: (1) specifications, plans, drawings, blueprints, and other items of like nature; (2) the information contained therein; or (3) the research and development data pertinent to the information contained therein. (Ref. 31) (For the repository program, design includes the description of engineered items and the description of the geologic setting, and the plans for data collection and analyses activities. As a result of this definition, the quality assurance measures for design apply to those aspects of plans such as the site characterization plans, scientific investigation plans, and study plans which will be needed to demonstrate compliance with the 10 CFR Part 60 Performance Objectives.) (NRC STAFF)

Design Basis: information that identifies (1) the specific functions to be performed by the structures, systems, or components of a geologic repository; (2) the assumptions regarding design-controlling parameters; (3) the specific parameter values selected as a basis for the design; (4) the supporting rationale for assumptions and parameter value selection. (Ref. 25)

Design Input: data, criteria, codes and standards, parameters, bases, or requirements including regulatory requirements upon which the design is based. (Ref. 5 and Ref. 17)

Design Output: documents, such as drawings, specifications, and other documents, defining technical requirements of structures, systems, and components. (Ref. 5)

Design Process: an iterative process of developing a geologic repository design from the preliminary stages where the level of uncertainty in design inputs is high, to a final stage where the level of uncertainty is low enough to meet established performance criteria. (Ref. 25)

Measures: policies, plans, procedures, and/or instructions. (NRC STAFF)

Scientific Investigation: an activity that involves one or more of the following: a test, data analysis, interpretation, and conclusion for the purpose of characterizing the natural environment or man-made items. In the repository program, this will include but not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository. (Ref. 18)

III.1.1 Measures should be established to assure that design input as defined in 10 CFR 60; as referenced in 10 CFR 60, such as 40 CFR 191 and 10 CFR 20; and as developed through the site characterization phase activities for those structures, systems and components to which this appendix applies are correctly translated into specifications, drawings, plans, procedures, and instructions. (NRC STAFF and Ref. 23)

III.1.2. The final design should fulfill all of these regulatory requirements. (NRC STAFF)

III.1.3 Design control measures should be applied to the design of engineered items important to safety or waste isolation; the description of the geologic setting; plans for data collection and analysis activities that will generate information pertinent to the repository design and that will be relied on in licensing; and computer codes. The plans should include the Site Characterization Plan, scientific investigation plans, and study plans. (Ref. 23)

III.1.4 Design control measures should be applied to conceptual designs, or parts thereof, which may at a later time become part of the final design. (Ref. 23)

III.1.5 The plans for data collection and analysis activities should assure that the appropriate information for input to the description of the geologic setting and engineered design is provided. (NRC STAFF)

III.1.6 The level of detail necessary for the plans for data collection and analysis activities should be such that the activities are carried out in a correct manner and can be verified as such. (NRC STAFF)

III.1.7 The plans and procedures for data collection and analysis activities should be in accordance with Criteria III, V, and XI. (Ref. 23)

III.1.8 NQA-1 Supplement 3S-1, Section 2.0, Design Input should be applied to inputs to the design of engineered items, the description of the geologic setting, the plans for data collection and analysis activities, and computer codes for design and data analyses. (NRC STAFF)

III.1.9 NQA-1 Supplement 3S-1, Section 2.0, Design Input should be applied to existing data and qualified data prior to their use as inputs to design. (NRC STAFF)

III.1.10 The guidance in the Generic Technical Position on the Qualification of Existing Data for High-Level Nuclear Waste Repository should be

applied to existing data prior to use as inputs to final designs. (NRC STAFF, Ref. 29)

III.1.11 NQA-1 Supplement 3S-2, Section 3.1, Design Analyses should be applied to design and data analyses. (NRC STAFF)

III.1.12 (Supplement 3S-1, 2.0 Design Input) Quality assurance measures for computer software may be in accordance with NUREG/CR-4640 "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry" and should be in accordance with NUREG-0856 "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management." (Refs. 13, 17, 22, and 30)

III.1.13 End-user computer codes, such as word processing, accounting, and data base management, should not require verification and validation unless these codes are supplemented with user-designed programs. (NRC STAFF)

III.1.14 The approval of design output documents should be provided by the organization performing the design. (NRC STAFF)

APPENDIX B

REQUIREMENT 2:
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.

NQA-1

SUPPLEMENT 3S-1
3.0 DESIGN PROCESS

...Appropriate quality standards shall be identified, documented, and their selection reviewed and approved.

Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled....

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Quality Standard: (1) principle characteristic elements of a particular structure, system, or component which will, if applied, produce a product that is consistent with the design objective. (Ref. 16) (2) standard procedures such as for sample collection, data collection, and data analysis. (NRC STAFF)

No additional guidance.

APPENDIX B

REQUIREMENT 3:

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 safety-related functions of the structures, systems and components.

NQA-1

SUPPLEMENT 3S-1

3.0 DESIGN PROCESS

...Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application....

SUPPLEMENTARY NRC STAFF POSITION

III.3.1 Measures should be established for the selection and review for suitability of application of items and services that are essential to the conduct of data collection and analysis activities. (NRC STAFF)

APPENDIX B

REQUIREMENT 4:
Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations.

NQA-1

BASIC REQUIREMENT
....Design interfaces shall be identified and controlled....

SUPPLEMENT 3S-1
6.0 INTERFACE CONTROL
Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations....

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Interface: (1) specifically defined physical, parametric, and/or functional juncture between two or more systems, items of equipment, or between an item of equipment and a structure; (2) relationship between organizations. (Ref. 14 and Ref. 4)

III.4.1 Measures should be established for the identification and control of interfaces and coordination between the organizations responsible for the design of items, the organizations responsible for the plans for data collection and analyses activities, and the organizations conducting data collection and analyses activities. (Ref. 23 and NRC STAFF)

APPENDIX B

REQUIREMENT 5:

These measures (for identification and control of design interfaces) shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

NQA-1

SUPPLEMENT 3S-1

3.0 DESIGN PROCESS

...Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel....

6.0 INTERFACE CONTROL

...Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information document provided and, where necessary, identify incomplete items which require further evaluation, review or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document....

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 6:

The design control measures shall 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.

NQA-1

BASIC REQUIREMENT

....Design adequacy shall be verified by persons other than those who designed the item.

SUPPLEMENT 3S-1

4.0 DESIGN VERIFICATION

....Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated....

....Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, or structure to perform its function....

4.1 Extent of Design Verification

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

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

4.2.1 Design Reviews. These are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable (a) through (f) below shall also be addressed:

(a) Were the design inputs correctly selected?
(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
(c) Was an appropriate design method used?

(d) Were the design inputs correctly incorporated in to the design?
(e) Is the design output reasonable compared to design inputs?
(f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

4.2.2 Alternate Calculations. These are calculations or analyses that are made with alternate methods to verify corrections of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculations methods used shall also be reviewed.

4.2.3 Qualification Tests. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and shall be evaluated by the responsible design organization to assure that test requirements have been met.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested and otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.

7.0 DOCUMENTATION AND RECORDS

Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Standard, shall be collected, stored, and maintained in accordance with documented procedures....

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Validation: In waste management applications, the object of validation is the assurance that the model embodied in a computer program is a correct representation of the process or system for which it is intended. Validation is generally accomplished by using computer programs to simulate field or laboratory experiments. For cases where these experiments are well defined, validation is possible. However, parameters that control experiments involving groundwater flow and contaminant transport, especially in fractured rock, at this stage are too poorly defined to allow for the validation of computer programs. In these cases, the exercise of applying the programs to field experiments is still a valuable test but falls short of "validation." (Ref. 27)

Verification: (1) the act of reviewing, inspecting, testing, checking, auditing or otherwise determining and documenting whether items, processes plans, services, data, models, documents, etc. conform to specified requirements. Verification includes the verification of the items and the completeness of the design. (Reactor SRP) (NQA-1). (2) the documented confirmation of the adequacy (suitability for intended use) of the work, plans, data, items, etc. under review. (draft Peer Review GTP). (3) the process which demonstrates that the software correctly performs its stated capabilities. The verification of software is primarily done through a set of test problems designed to show that the stated equations are solved in a satisfactory manner, but not necessarily indicating that the model is a valid representation of any particular physical system. In addition, these problems can be used for familiarizing users with the function and execution of the computer program and providing a check between standard versions of the program on various computer systems. (Ref. 27)

III.6.1 The verification of design should be performed by design, technical, and/or peer reviews; by the use of alternate or simplified calculation methods; and/or by the performance of a testing program. (Ref. 23 and NRC STAFF)

III.6.2 The verification and validation of computer codes should be performed. Documentation for verification and validation should be in accordance with NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. (Ref. 23)

III.6.3 The verification of plans for data collection and analyses should be completed prior to performing the data collection and analysis activities, respectively. (NRC STAFF)

III.6.4 Documentation of a design or technical review should, as a minimum, identify the reviewers, the area or features reviewed, the comments of the reviewers, and the resolution of the comments. (NRC STAFF)

III.6.5 Peer reviews should be conducted in accordance with the Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories. (NRC STAFF, Ref. 28)

III.6.6 Design verification procedures should assure the following: (Ref. 21)

(a) criteria for determining the method of verification are established;
(b) the persons performing verification and validation are qualified and not directly responsible for the design;
(c) the verification and validation are completed prior to release for procurement, manufacturing, construction, or use;
(d) the responsibilities of the persons performing the verification or validation are defined; (Ref. 23)
(e) the areas and features to be verified are specified; and (Ref. 23)
(f) the extent of documentation is defined. (Ref. 23)

APPENDIX B

REQUIREMENT 7:

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.

NQA-1

SUPPLEMENT 3S-1

4.0 DESIGN VERIFICATION

....Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this Standard....

SUPPLEMENTARY NRC STAFF POSITION

III.7.1 The persons verifying design should be qualified and should not be directly responsible for the design (i.e., neither the performer or his immediate supervisor). In exceptional circumstances, the designer's immediate supervisor may perform the verification provided: (Ref. 23)

(1) the supervisor is the only technically qualified individual;

(2) the need is individually documented and approved in advance by the supervisor's management; and

(3) QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse. (Ref. 21)

DISCUSSION

It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities. (Ref. 23)

APPENDIX B

REQUIREMENT 8:

Where a test program is used to verify the adequacy of a specified 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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

III.8.1 Where a test program is used to verify the result of a data collection or data analysis activity, it should include testing under the most adverse conditions. A prototype unit should be tested, if possible. (NRC STAFF)

APPENDIX B

REQUIREMENT 9:

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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 10:

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

NQA-1

BASIC REQUIREMENT

....Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.

SUPPLEMENT 3S-1

5.0 CHANGE CONTROL

Changes to final designs, field changes, modifications to operating facilities, and nonconforming items disposition use-as-is or repair shall be justified and subjected to design control measures commensurate with those applied to the original design. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the owner or his designee shall designate a new responsible organization which could be the owner's engineering organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

SUPPLEMENTARY NRC STAFF POSITION

III.10.1 Measures should be established to control changes to controlled conceptual designs based on the importance of the change. Criteria should be established to determine significance of changes. (NRC STAFF)

III.10.2 Changes should be analyzed to assure that change is required. (Ref. 23)

III.10.3 Associated changes to procedures and training should be provided as appropriate. (Ref. 23)

IV. PROCUREMENT DOCUMENT CONTROL

APPENDIX B

REQUIREMENT 1

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.

NQA-1

BASIC REQUIREMENT

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.

SUPPLEMENT 4S-1

2.0 CONTENTS OF THE PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.

2.1 Scope of Work

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

2.2 Technical Requirements

Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall

provide for identification of test, inspection, and acceptance requirements of the Purchaser for monitoring and evaluating the Supplier's performance.

2.4 Right of Access

At each tier of a procurement, the procurement document shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative and/or other parties authorized by the Purchaser.

2.5 Documentation Requirements

The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.

2.6 Nonconformances

The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.

2.7 Spare and Replacement Parts

The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies.

3.0 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.

Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations:

(a) appropriate requirements specified in 2.0 of this Supplement;
(b) determination of any additional or modified design criteria;
(c) analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.

Reviews required by this Section shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.0 PROCUREMENT DOCUMENTS CHANGES

Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Material: A substance or combination of substances, such as parts, components consumables, rock samples, and fluid samples. (Ref. 3 and Ref. 23)

IV.1.1 Procurement documents should be reviewed to assure that the procurement requirements are consistent with applicable quality assurance and technical requirements. (Ref. 23)

IV.1.2 NQA-1, Supplement 4S-1, Section 2.7) Procurement requirements for spare and replacement parts should be applied to items such as software in addition to parts and assemblies. (NRC STAFF and Ref. 23)

DISCUSSION

Additional guidance on procurement is in Criterion VII.

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

BASIC REQUIREMENT

To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

SUPPLEMENT 4S-1

2.0 CONTENTS OF THE PROCUREMENT DOCUMENTS

2.3 Quality Assurance Program Requirements

Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard. The extent of the program required shall depend upon the type and use of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures or drawings of a type appropriate to the circumstances.

SUPPLEMENTARY NRC STAFF POSITION

V.1.1 Activities affecting quality should be prescribed and accomplished by documented plans, where appropriate. (NRC STAFF)

V.1.2 Instructions, procedures, drawings, and plans should be sufficiently detailed to permit a qualified individual to repeat the activity described in the procedure. In scientific investigations where the step-by-step methods of performing an investigation are not fully known in advance, a general procedure should be established and actual steps performed should be documented. The general procedure should include the objectives of the investigation, methods that will be applied, and results expected. (NRC STAFF)

V.1.3 Provisions should be established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, drawings, and plans. (Ref. 26)

APPENDIX B

REQUIREMENT 2:
Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

NQA-1

BASIC REQUIREMENT
These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Acceptance Criteria: quantitative or qualitative characteristics of an item, process, or service used to determine if the item, process, or service is fit for use. (NRC STAFF)

V.2.1 Plans, should include or reference appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. (Ref. 19)

V.2.2 Instructions, procedures, drawings, and plans should identify hold points, as appropriate, beyond which work may not proceed until an inspection, audit, design review, technical review, and/or peer review has been conducted and all nonconformances or deficiencies have been resolved. (Ref. 23)

V.2.3 Approval to waive any specified hold or witness points should be documented before work can continue beyond the designated hold or witness point(s). Waivers of designated hold or witness points should be subject to the same provisions as specified for the control of document changes. (Ref. 19 and Ref. 23)

V.2.4 Each instruction, procedure, drawing, or plan should specify the organizations and/or positions responsible for and the organizations and/or positions that will perform the activity controlled by the instruction, procedure, drawing, or plan. (Ref. 23)

V.2.5 Instructions, procedures, drawings, and plans should specify how changes should be controlled and should indicate other work that could be affected by the changes. (DOE comment) Changes to these documents should be controlled in accordance with Criterion VI. (NRC STAFF)

V.2.6 Instruction, procedures, drawings and plans should specify the documentation that should be developed and retained as a result of implementing the procedure. (Ref. 23)

VI. DOCUMENT CONTROL

APPENDIX B

REQUIREMENT 1:
Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality.

NQA-1

BASIC REQUIREMENT
The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed.

SUPPLEMENTARY NRC STAFF POSITION

VI.1.1 Other documents, such as plans, procurement documents, as-built documents, design documents, QA documents, nonconformance reports, and technical reports, including changes thereto, should be subject to document control measures. (Ref. 21)

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

BASIC REQUIREMENT

Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

SUPPLEMENT 6S-1

The control system shall be documented and shall provide for (a) through (c) below:

(a) identification of documents to be controlled;

(b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;

(c) review of documents for adequacy, completeness, and correctness prior to approval and issuance.

SUPPLEMENTARY NRC STAFF POSITION

VI.2.1 Documents should be reviewed and approved to assure that QA and technical requirements have been met, such as (1) the documents should be prepared, reviewed, approved, and revised in accordance with procedures, and (2) the documents should contain the necessary quality assurance requirements; i.e., acceptance criteria, design bases, and quality standards. (Ref. 23 and Ref. 13)

VI.2.2 The QA and technical reviews should be performed by staff who were not responsible for the original work. (NRC STAFF)

VI.2.3 Documents should undergo a peer review when they meet the criteria for peer review established in the Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories. (Ref. 28 and NRC STAFF)

VI.2.4 Document approval and release should be contingent upon the satisfactory resolution of all comments pertaining to the document. (Ref. 18)

VI.2.5 When documents requiring authorization for release are released prior to this authorization, they should be so identified and controlled to prevent inadvertent use. (Ref. 23 and NRC STAFF)

VI.2.6 Prior to commencing the work, current applicable documents should be available at the location where the activity will be performed. (Ref. 23)

VI.2.7 Obsolete or superseded documents should be removed and replaced by applicable revisions at work areas in a timely manner. (Ref. 23)

VI.2.8 A master list or equivalent document control system should be established to identify documents to be controlled and the current revision of documents. (Ref. 23)

APPENDIX B

REQUIREMENT 3:

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.

NQA-1

SUPPLEMENT 6S-1

3.0 DOCUMENT CHANGES

3.1 Major Changes

Changes to documents, other than those defined as minor changes in 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organizations shall have access to pertinent background data or information upon which to base their approval.

3.2 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

VII. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
The procurement of items and services shall be controlled to assure conformance with specified requirements.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Commercial Grade item: An item which is 1) not subject to design or specification requirements that are unique to facilities or activities licensed by the NRC, and 2) used in applications other than facilities or activities licensed by the NRC, and 3) ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description, such as a catalogue. The term "commercial grade item" includes items about which a range of technical information is available from the vendor. This information can be as little as the unique identifier (e.g. part number, model) given the item or a listing of specifications (e.g., material qualification and testing, reliability and service life, range of environmental operating conditions, operating characteristics and data, functional testing). (Ref. 9 and NRC STAFF)

VII.1.1 Purchased data and software should conform to procurement requirements. (NRC STAFF)

DISCUSSION

Purchased data may include maps; geological, geophysical, geochemical, and hydrological data bases; seismic lines; data analyses; etc. Some data such as topographic maps and geological maps may be considered commercial grade items.

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

BASIC REQUIREMENT

Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or service upon delivery or completion.

SUPPLEMENT 7S-1

2.0 PROCUREMENT PLANNING

Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities.

Planning shall determine the following:

(a) what is to be accomplished;
(b) who is to accomplish it;
(c) how it is to be accomplished;
(d) when it is to be accomplished.

Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.

Planning shall result in the documented identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning shall provide for the integration of (a) through (i) below:

(a) procurement document preparation, review and change control;
(b) selection of procurement sources;
(c) bid evaluation and award;
(d) Purchaser control of Supplier performance;
(e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points:
(f) control of nonconformances;
(g) corrective action;
(h) acceptance of item or service;
(i) quality assurance records.

3.0 SUPPLIER SELECTION

3.1 Source Evaluation and Selection

The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.

Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability. Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more of (a) through (c) below:

(a) evaluation of the Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The Supplier's history shall reflect current capability;
(b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated;

(c) Supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.

4.0 BID EVALUATION

Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

(a) technical considerations;
(b) quality assurance requirements;
(c) Supplier's personnel;
(d) Supplier's production capability;
(e) Supplier's past performance;
(f) alternates;
(g) exceptions.

Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation.

5.0 SUPPLIER PERFORMANCE EVALUATION

The Purchaser of items and service shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f) below:

(a) establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents;
(b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements;
(c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements;
(d) identifying and processing necessary change information;

(e) establishing method of document information exchange between Purchaser and Supplier;

(f) establishing the extent of source surveillance and inspection activities.

These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for verification of quality requirements.

5.1 Extent of Activities

The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the items or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of Suppliers.

5.2 Records

Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented.

The Purchaser shall assure that this documentation is evaluated to determine the Supplier's quality assurance program effectiveness.

6.0 CONTROL OF SUPPLIER GENERATED DOCUMENTS

Supplier generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to assure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

7.0 CONTROL OF CHANGES IN ITEMS OR SERVICES

The Purchaser and Supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented and are in accordance with this Standard.

8.0 ACCEPTANCE OF ITEM OR SERVICE

8.1 General

Methods shall be established for the acceptance of an item or service being furnished by the Supplier. Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements.

8.2 Methods of Acceptance

Purchaser methods used to accept an item or related service from a Supplier shall be Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site, or a combination thereof.

8.2.1 Certificate of Conformance. When a Certificate of Conformance is used, the minimum criteria of (a) through (f) below shall be met.

(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.

(b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.

(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.

(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

8.2.2 Source Verification. When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

8.2.3 Receiving Inspection. When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall be performed in accordance with established procedures and inspection instructions, to verify by objective evidence such features as proper configuration;

identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

8.2.4 Post-Installation Testing. When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.

8.3 Acceptance of Service Only

In certain cases involving procurement of services only, such as third party inspection, engineering and consulting services; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:

(a) technical verification of data produced;
(b) surveillance and/or audit of the activity;
(c) review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.

9.0 CONTROL OF SUPPLIER NONCONFORMANCES

The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement document requirements.

These methods shall contain provisions for (a) through (e) below:

(a) Evaluation of nonconforming items.
(b) Submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents which consist of one or more of the following shall be submitted to the Purchaser for approval of the recommended disposition:
(1) technical or material requirement is violated;

(2) requirement in Supplier documents, which have been approved by the Purchaser, is violated;

(3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework;

(4) the item does not conform to the original requirement event though the item can be restored to a condition such that the capability of the item to function is unimpaired.

(c) Purchaser disposition of Supplier recommendation.

(d) Verification of the implementation of the disposition.

(e) Maintenance of records of Supplier-submitted nonconformances.

10.0 COMMERCIAL GRADE ITEMS

Where the design utilizes commercial grade items, the following requirements are an acceptable alternate to other requirements of this Supplement, except as noted in (b) below and the requirements of Supplement 4S-1.

(a) The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.

(b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with paragraph 3.1 of this Supplement.

(c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number).

(d) After receipt of a commercial grade item, the Purchaser shall determine that:

(1) damage was not sustained during shipment;

(2) the item received was the item ordered;

(3) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements;

(4) documentation, as applicable to the item, was received and is acceptable.

DEFINITIONS

Nuclear Power Plant, Fuel Reprocessing Plant and other like terms: (1) high-level waste repository site; (2) an appropriate location. (NRC STAFF)

SUPPLEMENTARY NRC STAFF POSITION

VII.2.1 Both QA and technical staff, where appropriate, should participate in procurement of items and services. (Ref. 21)

VII.2.2 (NQA-1, Supplement 7S-1, 8.21) Criteria for certificate of conformance should be applied to items other than material and equipment as appropriate. (NRC STAFF)

APPENDIX B

REQUIREMENT 3:

Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment.

NQA-1

Supplement 7S-1

8.0 ACCEPTANCE OF ITEM OR SERVICE

8.1 General

Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use.

SUPPLEMENTARY NRC STAFF POSITION

VII.3.1 Documentary evidence that services conform to procurement documents should be available at an appropriate location. (NRC STAFF)

APPENDIX B

REQUIREMENT 4:

This documentary evidence shall be retained at the nuclear power plant 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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 5:

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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

APPENDIX B

REQUIREMENT 1:
Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies.

NQA-1

SUPPLEMENT 8S-1

2.0 IDENTIFICATION METHODS

2.1 Item Identification

Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

3.0 SPECIFIC REQUIREMENTS

3.1 Identification and Traceability of Items

When specified by codes, standards, or specifications that include specific identification or traceability requirements, such as identification or traceability of the item to applicable specification and grade of material, heat, batch, lot, part, or serial number; or specified inspection, test, or other records, the program shall be designed to provide such identification and traceability control.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Material: A substance or combination of substances, such as parts, components consumables, rock samples, and fluid samples. (Ref. 3 and Ref. 23)

VIII.1.1 Measures should be established for the identification and control of items. (NRC STAFF)

VIII.1.2 Correct identification of items should be verified and documented prior to release for use, installation, or analysis. (Ref. 23 and Ref. 21, NRC STAFF)

VIII.1.3 (NQA-1, Supplement 8S-1, 2.1 Item Identification) Items should be identified from the initial receipt or collection. These items should be identifiable throughout the lifetime of the items. The identification should relate the item to its source, such as well bore and depth, and applicable documents, including design documents, plans, test records, and technical reports. (NRC STAFF, Ref. 21 and Ref. 23)

VIII.1.4 Procedures should be developed and implemented to assure that a representative archival sample is maintained from difficult to repeat sample collection activities, such as principle bore hole coring. (NRC STAFF)

VIII.1.5 Provisions should be made for documenting the installation, consumption, or other use of items. (Ref. 18)

APPENDIX B

REQUIREMENT 2:

These measures shall assure that identification of the items 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.

NQA-1

BASIC REQUIREMENT

Identification shall be maintained on the items or in documents traceable to the items, or in a manner which assures that identification is established and maintained.

SUPPLEMENT 8S-1

2.0 IDENTIFICATION METHODS

2.2 Physical Identification

Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.

2.3 Markings

Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified items when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

3.0 SPECIFIC REQUIREMENTS

3.3 Maintaining Identification of Stored Items

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identifications on items subject to excessive deterioration due to environmental exposure; and (3) provisions for updating existing plant records.

SUPPLEMENTARY NRC STAFF POSITION

VIII.2.1 (NQA-1, Supplement 8S-1, 2.3 Markings) Identification markings should be applied with materials and methods which do not detrimentally effect or change the physical or chemical properties of items. (NRC STAFF)

APPENDIX B

REQUIREMENT 3:
These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.

NQA-1

BASIC REQUIREMENT
Controls shall be established to assure that only correct and accepted items are used or installed.

SUPPLEMENT 8S-1
3.0 SPECIFIC REQUIREMENTS
3.2 Limited Life Items
Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose life or operating life has expired.

SUPPLEMENTARY NRC STAFF POSITION

VIII.3.1 These identification and control measures should be designed to prevent the use of incorrect or defective items. (Ref. 23 and Ref. 19)

IX. CONTROL OF SPECIAL PROCESSES

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

SUPPLEMENT 9S-1

2.0 PROCESS CONTROL

Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained.

3.0 SPECIAL PROCESSES

Each special process shall be performed in accordance with appropriate instructions which include or reference procedure, personnel, and equipment qualification requirements.

3.1 Responsibility

It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.

3.1.1 Qualification of personnel, procedures, and equipment shall comply with specified requirements.

3.1.2 Conditions necessary for accomplishment of the process shall be included in procedures or instructions. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements.

3.2 Acceptance Criteria

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions.

3.3 Records

Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

3.4 Special Requirements

For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications for personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Special Process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. (Ref. 5)

Qualified Procedure: an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose. (Ref. 5)

IX.1.1 Criteria should be established to determine processes that should be controlled as a special process. (Ref. 23)

IX.1.2 A procedure for a special process should be qualified by: (NRC STAFF)

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

(2) a technical review; or

(3) a peer review; and

(4) review and approval in accordance with Criterion VI.

IX.1.3 When a demonstration test is used, the test should be conducted under the most adverse conditions. (NRC STAFF)

IX.1.4 A peer review should be used when the process meets the requirements for peer review. The peer review should be conducted in accordance with the Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories. (NRC STAFF)

IX.1.5 A technical review should be conducted in accordance with Supplementary NRC Staff Position III.6.4. (NRC STAFF)

IX.1.6 Procedures for special processes should be subject to the provisions in Criterion V and VI. (NRC STAFF)

DISCUSSION

In the site characterization phase of the repository program, numerous activities meet the definition of special processes. For example, many data collection activities should be special processes since the quality of the data cannot be determined by direct inspection or test. Procedures for performing these activities should be qualified by the above methods. For example, the grouting

of piezometer tubes may be considered a special process since the grout cannot be inspected in place. To qualify the procedure for this process, a prototype test may be conducted. The prototype test should simulate borehole conditions such as irregular borehole surfaces, borehole temperatures and pressures, rock type, and casing type.

X. INSPECTION

APPENDIX B

REQUIREMENT 1:
A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformances with the documented instructions, procedures, and drawings for accomplishing the activity.

NQA-1

BASIC REQUIREMENT
Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented.

SUPPLEMENT 10S-1

4.0 INSPECTION PLANNING

4.1 Planning

Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.

4.2 Sampling

Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.

6.0 FINAL INSPECTIONS

6.1 Resolution of Nonconformances

Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

6.2 Inspection Requirements

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformances of the item to specified requirements. Quality records shall be examined for adequacy and completeness if not previously so examined.

6.3 Acceptance

The acceptance of the item shall be documented and approved by authorized personnel.

6.4 Modifications, Repairs, or Replacements

Modification, repair, or replacement of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

7.0 INSERVICE INSPECTION

7.1 Planning and Performance

Required inservice inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.

7.2 Methods

Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

8.0 RECORDS

Records shall, as a minimum, identify (a) through (f) below:

(a) item inspected;
(b) date of inspection;
(c) inspector;
(d) types of observation;
(e) results or acceptability; and
(f) reference to information on action taken in connection with non-conformances.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Inspection: Examination or measurement to verify conformance to specified requirements. (Ref. 5)

Readiness Review: An assessment of readiness to proceed to the next critical phase of a project, for example planning to construction and construction to pre-op testing. (Ref. 24)

Surveillance: The act of monitoring, observing, or examining work that is in progress to verify whether an item or activity conforms to specified requirements. (Ref. 5 and Ref. 18)

X.1.1 A program for inspection should be established and executed to verify that reports, quality assurance records, processes and services conform to documented instructions, procedures, drawings, specifications or other documents. (Ref. 10 and Ref. 12)

X.1.2 Inspection procedures should provide criteria for determining when inspections are required or define how and when inspections are performed. (Ref. 23)

X.1.3 (NQA-1, Supplement 10S-1, 6.4 Modifications, Repairs, or Replacements) Reinspection should be performed in accordance with original or revised requirements. (Ref. 17)

X.1.4 (NQA-1, Supplement 10S-1, 8.0 Records) Inspection records should include a-f and:

(a) inspection procedure;
(b) characteristics to be inspected;
(c) inspection criteria or reference to documents such as instructions procedures, specifications, drawings or other documents that were used to determine acceptance; (Ref. 19)
(d) equipment used during the inspection; (Ref. 19)
(e) special expertise required for inspection; and
(f) signature of inspector. (Ref. 7)

X.1.5 Surveillances may be used to complement the inspection program. For example, evaluations of surveillance results may be used to indicate that scheduled inspections should be rescheduled, that scheduled inspections should have their scope or direction changed, or that additional inspections should be scheduled. (NRC STAFF)

X.1.6 A program of readiness reviews may be established to complement the inspection program. Readiness reviews may be conducted prior to initiation of activities and at designated hold points. (Ref. 24)

X.1.7 A readiness review may include:
(NRC STAFF)

(a) identification of individual work process;
(b) in-depth self-assessment by the organization that will perform the work process;
(c) senior management overview;

(d) planned and systematic NRC involvement;

(e) early resolution of issues; and

(f) incremental acceptance.

X.1.8 Inspection results should be evaluated and the acceptability should be determined by a responsible individual. (Ref. 23)

APPENDIX B

REQUIREMENT 2:
Such inspection shall be performed by individuals other than those who performed the activity being inspected.

NQA-1

BASIC REQUIREMENT
Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

SUPPLEMENT 10S-1

2.0 PERSONNEL

2.1 Reporting Independence

Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

2.2 Qualification

Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.

Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.

SUPPLEMENTARY NRC STAFF POSITION

DISCUSSION

It would be desirable to have inspections, surveillances, and readiness reviews performed periodically by personnel knowledgeable or formally trained in the areas inspected, surveilled, or readiness reviewed. These personnel, however, shall meet the independence requirement in Appendix B and should meet the independence requirements in NQA-1.

APPENDIX B

REQUIREMENT 3:
Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY STAFF POSITION

X.3.1 Examinations, measurements or tests of items should be performed for each work operation when necessary to assure quality. (NRC STAFF)

APPENDIX B

REQUIREMENT 4:

If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided.

NQA-1

SUPPLEMENT 10S-1

5.0 IN-PROCESS INSPECTION

5.1 Inspection

Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

SUPPLEMENTARY NRC STAFF POSITION

X.4.1 In-process inspections should be performed of activities, service, and processes, especially when the quality of the data cannot be determined by examining the data. (NRC STAFF)

APPENDIX B

REQUIREMENT 5:

Both inspection and process monitoring shall be provided when control is inadequate without both.

NQA-1

SUPPLEMENT 10S-1

5.0 IN-PROCESS INSPECTION

5.1 Inspection

Both inspection and process monitoring shall be provided when control is inadequate without both.

5.2 Combined Inspection and Monitoring

5.2.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

5.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 6:

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.

NQA-1

SUPPLEMENT 10S-1

3.0 INSPECTION HOLD POINTS

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

DISCUSSION

Criterion X identifies requirements and guidance for several methods which shall, or may, be used to verify quality. These methods are:

(1) inspection of processed or completed items, activites, processes and services;
(2) in-process inspection of items, activities, processes and services;
(3) process monitoring;
(4) surveillance; and
(5) readiness review.

Although not specifically required by the Appendix B requirements, the NRC staff encourages the use of plans, procedures, and recordkeeping controls for process monitoring, surveillance, and readiness reviews.

XI. TEST CONTROL

APPENDIX B

REQUIREMENT 1:

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.

NQA-1

BASIC REQUIREMENT

Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified.

Tests required to collect data, such as for siting or design input shall be planned, executed, documented, and evaluated.

SUPPLEMENT 11S-1

2.0 TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to

installation, construction tests, preoperational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITIONS

Acceptance Criteria: quantitative or qualitative characteristics of an item, data, process, or service used to determine if the item, data, process, or service is fit for use. (NRC STAFF)

Scientific Investigation: an activity that involves one or more of the following: a test, data analysis, interpretation, and conclusion for the purpose of characterizing the natural environment or man-made items. In the repository program, this will include but not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository. (Ref. 19)

Test: 1. a data collection activity (i.e. an experiment conducted in the field or laboratory that (a) measures physical, chemical, hydrologic, geologic, geochemical parameters or processes; (b) provides engineering and process evaluation; (c) simulates environmental events; or (d) measures radionuclide transport. (e.g. that part of a scientific investigation that involves the collection of data). 2. an operation, series of actions or process by which an item is shown to perform satisfactorily in service (qualification test) or by which an item is shown to comply with specified requirements (certification test). (NRC STAFF and Ref. 15)

STAFF POSITION

XI.1.1 When a scientific investigation includes a test, the test should be controlled in accordance with Criterion XI. Other activities of the scientific investigation, such as data analysis, should be controlled in accordance with Criterion III. (NRC STAFF)

XI.1.2 The test program should include scientific investigations. (NRC STAFF)

XI.1.3 The test plans and procedures should ensure that the precision, accuracy and inherent uncertainty of data will be suitable for the intended use of that data, such as in computer models and performance assessments. (Ref. 18)

XI.1.4 Potential sources of uncertainty and error in test plans, procedures and parameters that affect data quality should be identified. (Ref. 23)

DISCUSSION

For data collection activities, acceptance limits refer to acceptance criteria for data. The acceptance criteria may be an acceptable range of values within which a data point should fall or an acceptable uncertainty in a measurement. Applicable design documents refer to plans, procedures, or other documents for the conduct of the activity.

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

SUPPLEMENT 11S-1

3.0 TEST PROCEDURES

Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.

In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.

SUPPLEMENTARY NRC STAFF POSITION

XI.2.1 Test procedures and plans for data collection and analysis activities should consider but should not be limited to the following. (Ref. 15)

(a) a descriptive title;

(b) statement of purpose;

(c) objective(s) of the test and its relationship to the overall site characterization program;
(d) method of conduct of the test;
(e) the proposed starting and completion dates;
(f) methods for control of statistical bias;
(g) the type, frequency, and number of tests, analyses, and measurements to be made;
(h) the technical and QA procedures to be used in the conduct of the test. Standard test procedures, such as ASTM, API, or EPA, require documentation by reference only;
(i) technical and programmatic requirements and constraints;
(j) background or supporting professional work or papers;
(k) documenting and reporting requirements;
(l) assumptions, requirements, regulations, and key issues;
(m) acceptance criteria or other requirements for the use of the item tested or the retention of data collected;
(n) identification of all documents by number and title expected to be produced as a result of the test;
(o) identification of features, items, and processes to be tested;
(p) the method, such as nonconformance report, for controlling and documenting unexpected results of tests or test failure. (Ref. 8)
(q) identification of test equipment;
(r) identification of hold points for quality control checks, inspection, audit, and/or review; (Ref. 23, NRC STAFF)
(s) provisions for readiness reviews prior to initiation of the test; (Ref. 24)
(t) provisions for reviews at the completion of the test;
(u) identification of methods for documenting or recording data and/or results; (Ref. 23)
(v) instructions for performing the test; (Ref. 23)

(w) identify and provide means for control of potential sources of uncertainty and error in test results; (Ref. 23)

(x) identification of the principal investigators, technicians, and supervisors who are responsible for the test;

(y) identification of interfaces and interaction with other personnel, including personnel whose tests may be effected by a test result or by a change in the test;

(z) identification of computer codes used in the collection or storage of data; and

(aa) provisions that establish the extent and method of control of changes to the test.

XI.2.2 Items to be tested should be identified, controlled, and ultimately dispositioned or archived. (NRC STAFF)

XI.2.3 When failure or malfunction of equipment is not detectable either during data collection or by examination of the data, technical and quality procurement requirements and test procedures should include specifications to minimize the likelihood for undetectable failure or malfunction of equipment. (Ref. 18)

APPENDIX B

REQUIREMENT 3:
Test results shall be documented and evaluated to assure that test requirements have been satisfied.

NQA-1

BASIC REQUIREMENT
Test results shall be documented and their conformance with acceptance criteria shall be evaluated.

SUPPLEMENT 11S-1

4.0 TEST RESULTS

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

5.0 TEST RECORDS

Test records shall, as a minimum, identify (a) through (g) below:

(a) item tested;
(b) date of test;
(c) tester or data recorder;
(d) type of observation;
(e) results and acceptability;
(f) action taken in connection with any deviations noted;
(g) person evaluating test results.

SUPPLEMENTARY NRC STAFF POSITION

XI.3.1 Test records shall include, as applicable: (Ref. 15 and NRC STAFF)

(a) test plans and procedures;

(b) test review documents;

(c) field and laboratory notebooks and logs;

(d) evaluation or analyses of test results;

(e) test reports; and

(f) magnetic tapes or diskettes.

XII. CONTROL OF MEASURING AND TEST EQUIPMENT

APPENDIX B

REQUIREMENT 1:

Measures shall be established to assure that tools, gauges, 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.

NQA-1

BASIC REQUIREMENT

Tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

SUPPLEMENT 12S-1

2.0 SELECTION

Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

3.0 CALIBRATION AND CONTROL

3.1 Calibration

Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

3.2 Control

The method and interval of calibration for each item shall be defined, based on the type of equipment stability, characteristics, required accuracy, intended use, and other conditions affecting measurement control. When measuring and test equipment is found to be out-of-calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out-of-calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspected.

3.3 Commercial Devices

Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices if normal commercial equipment provide adequate accuracy.

4.0 HANDLING AND STORAGE

Measuring and test equipment shall be properly handled and stored to maintain accuracy.

5.0 RECORDS

Records shall be maintained and equipment shall be suitably marked to indicate calibration status.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Measuring and Test Equipment: Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or to acquire data to verify conformance to specified requirements or to collect data for input to design. (NQA-1). This equipment includes instruments, tools, gauges, fixtures, reference and transfer standards and nondestructive test equipment used for measurement, inspection, and monitoring. (Ref. 23)

XII.1.1 Procedures for control of measuring and test equipment should include the following (Ref. 16):

(a) provisions for maintaining a list of equipment requiring calibration and the calibration dates or interval;
(b) provisions for identifying the latest and next calibration dates on the device or record(s) traceable to the device;
(c) provisions for assuring that each device is calibrated and adjusted on or before the date required, based on the defined frequency;
(d) provisions for the use of methods and materials in the calibration or adjustment; (Ref. 15) and
(e) provision for the traceability of equipment to calibration data. (Ref. 23)

XII.1.2 The method and interval of calibration for each item should be based on the type of equipment, stability, characteristics, required accuracy and precision, purpose, and other conditions that affect measurement control. (Ref. 19 and Ref. 23)

XII.1.3 When environmental conditions, operator error, or systematic error may adversely affect the calibration of certain equipment, instruction for the operation of this equipment and corrections to resulting data should be documented and used. (Ref. 7 and Ref. 12)

XII.1.4 Calibrating standards should have a greater accuracy than the equipment being calibrated. (Ref. 21 and NRC STAFF)

XII.1.5 Measuring and test equipment should be calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. (Ref. 23)

XII.1.6 Calibrating standards should have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function should be identified. (Ref. 21)

XII.1.7 Equipment that is out of calibration should be tagged or segregated and should not be used until it has been recalibrated. (Ref. 19)

XII.1.8 When methods being employed for calibration meet the applicability requirements for peer review, the guidance in the Generic Technical Position for Peer Review for High-Level Nuclear Waste Repositories should be used. (Ref. 23)

XII.1.9 (NQA-1, Supplement 12S-1, 2.0 SELECTION) Selection of measuring and test equipment should be controlled to assure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the intended function. (NRC STAFF)

XII.1.10 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 repreated on items, such as materials, parts, components and data determined to be suspect. (Ref. 23)

XIII. HANDLING, STORAGE, AND SHIPPING

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

SUPPLEMENT 13S-1

2.0 INSTRUCTION

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

3.0 REQUIREMENTS

3.2 Procedures

When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

3.3 Tools and Equipment

Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures

and at specified time intervals to verify that the tools and equipment are adequately maintained.

3.4 Operators

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

4.0 MARKING

Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Material: A substance or combination of substances, such as parts, components consumables, rock samples, and fluid samples. (Ref. 3 and Ref. 23)

STAFF POSITION

XIII.1.1 Measures should be established to control the storage of documentation and draft and final reports and the cleaning of items. (Ref. 10 and Ref. 15)

XIII.1.2 These measures should prevent contamination of items and damage or deterioration of identification markings thereon. (Ref. 10, Ref. 23, Ref. 5 and NRC STAFF)

XIII.1.3 These measures should be in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, manufacturer's instructions or recommendations, and other pertinent documents or procedures. (Ref. 17)

XIII.1.4 These measures should take into consideration limited life expectancy of items. (NRC STAFF)

XIII.1.5 Handling procedures should include, as applicable: (Ref. 16)

(1) handling method or technique for each items or generic classification from receipt to storage and storage to use; and
(2) storage locations.

XIII.1.6 Storage procedures should include, as applicable, the following during storage and after installation but prior to use: (Ref. 16)

(1) storage method or technique;
(2) special precautions or requirements; and
(3) manufacturer's instructions/recommendations.

XIII.1.7 Cleaning procedures should include, as applicable, the state or level of cleanliness which must be maintained during storage, installation and use. (Ref. 16)

XIII.1.8 Shipping procedures should include, as applicable: (Ref. 16)

(1) manufacturer's recommendations; and
(2) special precautions or techniques.

XIII.1.9 Controls should be established to assure data transfer is error free (or within a prescribed permissible error rate) to assure no information is lost in transfer and that the input is completely recoverable from the output. Examples of data transfer include: copying data from a notebook onto a data form for data entry or copying from computer tape to disk. (NRC STAFF)

XIII.1.10 All processes which change either the form of expression or quantity of data, values, or number of data items (data reduction) should be controlled by prescribed methods which allow for the validation of the conversion process. (NRC STAFF)

XIII.1.11 The method of data recording (e.g., laboratory and field notebooks, log books, data sheets, computerized instrumentation systems, etc. should be controlled to avoid loss and permit retrievability. (NRC STAFF)

XIII.1.12 At each stage of data processing where data is stored, controls should be established to assure data integrity and security is maintained. (NRC STAFF)

XIII.1.13 Controls should prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, and access. (NRC STAFF)

XIII.1.14 Data should be suitably protected from damage and unintentional destruction during their prescribed lifetime and readily retrievable from wherever stored. (NRC STAFF)

XIII.1.15 Samples should be physically separated from like samples to preclude mixing. (NRC STAFF)

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

SUPPLEMENT 13S-1

3.0 REQUIREMENTS

3.1 General

When required for particular items, special equipment, such as containers, shock absorbers, and accelerometers, and special protective environments, such as inert gas atmosphere, specific moisture content level, and temperature levels shall be specified, provided, and their existence verified.

SUPPLEMENTARY NRC STAFF POSITION

XIII.2.1 For critical, sensitive or perishable items, specific procedures for handling, storage, packaging, shipping, and preservation should be used. (Ref. 2)

XIV. INSPECTION, TEST, AND OPERATING STATUS

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Status shall be maintained through indicators such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified.

SUPPLEMENTARY NRC STAFF POSITION

XIV.1.1 Measures shall be establised to indicate the status of inspections and tests either on the items or in documents traceable to the items. (Ref. 10 and Ref. 13)

XIV.1.2 These measures should control the alteration of sequences of required tests, inspections, and other operations important to safety or waste isolation. Such actions should be subject to the same controls as the original review and approval. (Ref. 21)

XIV.1.3 These measures should prevent the inadvertent use of nonconforming, inoperative, or malfunctioning items. (Ref. 21)

APPENDIX B

REQUIREMENT 2:

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.

NQA-1 Interpretation

No additional guidance provided by NQA-1.

Supplementary NRC Staff Position

No additional guidance.

APPENDIX B

REQUIREMENT 3:
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.

NQA-1

BASIC REQUIREMENT
The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and test are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

Supplementary NRC Staff Position

XIV.3.1 Measures shall be established for indicating the operating status of engineered structures, systems, and components where it is necessary to assure these items are not inadvertently installed, used, or operated prior to the successful completion of required inspections and tests. (Ref. 19)

XIV.3.2 These measures should include the use of special tags or other special means, where possible, that prevent inadvertent operation. (Ref. 17)

XV. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.

SUPPLEMENTARY NRC STAFF POSITION

XV.1.1 Measures for control of nonconformances should be applied to procedures, plans, instructions, activities which do not conform to requirements. (Refs. 12, 13 and 21)

XV.1.2 Nonconformance reports should be periodically analyzed to show quality trends, and significant results should be reported to upper management for review and assessment. (Refs. 21 and 23)

XV.1.3 When repetitive or recurring conditions are identified, an evaluation should be made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action shall be beyond the scope of action taken for the disposition on existing NCRs, should identify root causes and should be processed in accordance with corrective action procedures. (Ref. 16)

DISCUSSION

Lack of required documentation can be a nonconformance of equal magnitude to a physical defect or failure to meet performance objectives. (Ref. 16)

APPENDIX B

REQUIREMENT 2:
These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

NQA-1

BASIC REQUIREMENT
Controls shall provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations.

SUPPLEMENT 15S-1
2.0 IDENTIFICATION

(a) Identification of nonconforming items shall be by marking, tagging, or other methods, which shall not adversely affect the end use of the item. The identification shall be legible and easily recognizable.
(b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

3.0 SEGREGATION

(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.
(b) When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

SUPPLEMENTARY NRC STAFF POSITION

XV.2.1 Measures to control nonconformances should include, as appropriate, tracking and review of nonconformances.

XV.2.2 Measures to control nonconformances should provide authorized positions for identification of independent review of nonconformances, including disposition and closeout. (Refs. 21 and 23)

XV.2.3 Documentation should:
(Ref. 23 and Ref. 21)

(a) identify the nonconforming items;
(b) describe the nonconformance, the dispostion of the nonconformance, and the inspection requirements;
(c) identify the significance and impact of the nonconformance; (NRC STAFF)
(d) justify the disposition as required by NQA-1, Supplement 15S-1, Section 4.4; (Ref. 19)
(e) reference any approved design documents, procedures, plans, work orders, etc., that are to be used for the correction of the nonconforming condition, (Ref. 19) and
(f) include the signature approval of the disposition.

APPENDIX B

REQUIREMENT 3:
Non-conforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

NQA-1

SUPPLEMENT 15S-1

4.0 DISPOSITION

4.1 Control

Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.

4.2 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.

4.3 Personnel

Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

4.4 Disposition

The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.

Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented. Nonconformances to design requirements dispositioned user-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviations.

4.5 Repaired or Reworked Items

Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

SUPPLEMENTARY NRC STAFF POSITION

XV.3.1 NQA-1, Supplement 15S-1, Section 4.5 should be applied to replacement items as well as repaired or reworked items. (NRC STAFF)

XVI. CORRECTIVE ACTION

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Conditions adverse to quality shall be identified promptly and corrected as soon as practical.

SUPPLEMENTARY NRC STAFF POSITION

XVI.1.1 The QA organization should concur on the adequacy of the corrective action. (Ref. 21 and Ref. 23)

XVI.1.2 Corrective action should be closed out in a timely manner. (Ref. 23)

APPENDIX B

REQUIREMENT 2:

In the case of significant conditions adverse to quality, the measures shall assure that the cause of the conditions is determined and corrective action taken to preclude repetition.

NQA-1

BASIC REQUIREMENT

In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance.

APPENDIX B

REQUIREMENT 3:
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.

NQA-1

BASIC REQUIREMENT
The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of corrective action.

SUPPLEMENTARY NRC STAFF POSITION

XVI.3.1 Corrective action should be documented and reported to appropriate level of management for review and assessment. (Ref. 23)

XVII. QUALITY ASSURANCE RECORDS

APPENDIX B

REQUIREMENT 1:
Sufficient records shall be maintained to furnish evidence of activities affecting quality.

NQA-1

BASIC REQUIREMENT
Records that furnish documentary evidence of quality shall be specified, prepared, and maintained.

SUPPLEMENT 17S-1

2.0 RECORDS ADMINISTRATION

2.1 Records System

Records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

2.2 Generation of Records

The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the owner.

2.3 Record Validation

Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies.

2.9 Corrected Information in Records

Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.

3.0 RECEIPT

3.1 Responsibility

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

3.2 Receipt Control

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage. As a minimum, a receipt control system shall include the following:

(a) a method for designating the required records;
(b) a method for identifying records received;
(c) procedures for receipt and inspection of incoming records.

3.3 Status

Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

SUPPLEMENTARY NRC STAFF POSITION

XVII.1.1 Measures should be established to enter records into the records system, including the frequency which records will be entered. Measures should be established to enter all copies of the completed part of records that develop over long periods of time, such as test records for long-term experiments. (NRC STAFF)

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

XVII.2.1 (Appendix B Requirement 2) The records should include operating logs, geotechnical samples, data, and documentation resulting from the implementation of the requirements in this document, such as results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses; work performance documentation; personnel qualification records, procedures; equipment records; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, nonconformance reports, and corrective action reports. (Ref. 23)

APPENDIX B

REQUIREMENT 3:
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.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

No additional guidance. (See Criteria X and XI.)

APPENDIX B

REQUIREMENT 4:
Records shall be identifiable and retrievable.

NQA-1

BASIC REQUIREMENT
Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

SUPPLEMENT 17S-1
2.0 RECORDS ADMINISTRATION
2.2 Generation of Records
Documents that are designated records shall be legible, accurate, and completed appropriate to the work accomplished.

2.4 Index
The records shall be indexed. The indexing system shall include, as a minimum, record retention times and the locations of the record within the record system.

2.5 Distribution
The records shall be distributed, handled, and controlled in accordance with written procedures.

2.6 Identification
Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.

5.0 RETRIEVAL

Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type.

A list shall be maintained designating those personnel who shall access to the files.

Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the owner.

6.0 DISPOSITION

Records accumulated at various locations, prior to transfer, shall be made accessible to the owner directly or through the procuring organization.

The custodian shall inventory the submittals, acknowledge receipt and process these records in accordance with this Standard.

Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition.

The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied:

(a) Items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed.
(b) Regulatory requirements are satisfied.
(c) Operational status permits.
(d) Warranty consideration is satisfied.
(e) Purchaser's requirements are satisfied.

SUPPLEMENTARY NRC STAFF POSITION

XVII.4.1 Records shall be accurate, complete, reproducible, and appropriate to the work accomplished. (Ref. 19)

XVII.4.2 (2.7 Classification) Retention periods for records should be defined and designated. (NRC STAFF)

APPENDIX B

REQUIREMENT 5:
Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

NQA-1

SUPPLEMENT 17S-1
2.0 RECORDS ADMINISTRATION

2.7 Classification
Records shall be classified as Lifetime or Nonpermanent by the owner, or his agent when authorized, in accordance with the criteria given in 2.7.1 and 2.7.2 below.

2.7.1 Lifetime Records. Lifetime records are those that meet one or more of the following criteria:

(a) those which would be of significant value in demonstrating capability for safe operation;
(b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;
(c) those which would be of significant value in determining the cause of an accident or malfunction of an item;
(d) those which provide required baseline data for inservice inspections.

Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.

2.7.2 Nonpermanent Records. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

2.8 Retention of Records

Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing.

4.0 STORAGE, PRESERVATION, AND SAFEKEEPING

4.1 Storage

The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies. Prior to storage of records, a written storage procedures shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum, (a) through (g) below:

(a) a description of the storage facility;
(b) the filing system to be used;
(c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible;
(d) a method of verifying that the records are those designated (see 3.2 above);
(e) the rules governing access to and control of the files;
(f) a method for maintaining control of accountability for records removed from the storage facility;
(g) a method for filing supplemental information (see 2.9 above) and disposing of superseded records.

4.2 Preservation

Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records the requirements of (a) through (c) below apply.

(a) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.
(b) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.

(c) Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

4.3 Safekeeping

Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.

Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.

4.4 Facility

Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

(a) natural disasters such as winds, floods, or fires;
(b) environmental conditions such as high and low temperatures and humidity;
(c) infestation of insects, mold, or rodents.

There are two satisfactory methods of providing storage facilities, single or dual.

4.4.1 Single Facility. Design and construction of a single record storage facility shall meet the following criteria of (a) through (i):

(a) reinforced concrete, concrete block, masonry, or equal construction;
(b) a floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included;
(c) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating;
(d) sealant applied over walls as a moisture or condensation barrier;

(e) surface sealant on floor providing a hard wear surface to minimize concrete dusting;
(f) foundation sealant and provisions for drainage;
(g) forced air circulation with filter system;
(h) fire protection system;
(i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating.

The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.

If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.

4.4.2 Alternate Single Facilities. The following are acceptable alternatives to the criteria of 4.4.1 above for a single facility:

(a) 2 hr fire rated vault meeting the requirements of NFPA 232-1975;
(b) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1975[1]; or
(c) 2 hr fire rated file room meeting the requirements of NFPA 232-1975[1] with the following additional provisions:
    (1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station;
    (2) records storage in fully enclosed metal cabinets;
    (3) adequate access and aisle ways;
    (4) prohibition in the room of work not directly associated with record storage or retrieval;
    (5) prohibition in the room of smoking, eating, or drinking;
    (6) 2 hr fire rated dampers or doors in all boundary penetrations.

4.4.3 Dual Facilities. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either 4.4.1 or 4.4.2 above, but shall meet the other requirements of this Standard.

SUPPLEMENTARY NRC STAFF POSITION

XVII.5.1 Geotechnical samples should be afforded archival controls and protection for the period during which additional examination or analysis by the U.S. Department of Energy or the U.S. Nuclear Regulatory Commission may be needed, or during which natural, time-dependent deterioration processes inherent to the sample materials have not destroyed or substantially changed sample properties. When necessary storage facilities for geotechnical samples should be established to prevent or mitigate this natural time-dependent deterioration. In those cases for geotechnical samples that natural time-dependent deterioration will preclude archival controls and no provisions are established to prevent or mitigate deterioration, justification should be documented. (Ref. 18)

XVIII. AUDITS

APPENDIX B

REQUIREMENT 1:
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.

NQA-1

BASIC REQUIREMENT
Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness.

SUPPLEMENT 18S-1

2.0 SCHEDULING

Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

3.0 PREPARATION

3.1 Audit Plan

The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

3.2 Personnel

The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

3.3 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit.

SUPPLEMENTARY NRC STAFF POSITION

XVIII.1.1 Audits should be initiated early enough to assure effective quality assurance and should be conducted periodically to assure maintenance of effective quality assurance during design, procurement, manufacturing, construction, installation, inspection and testing. (Ref. 23)

XVIII.1.2 The frequency, scope, and depth of audits should consider alternative oversight mechanisms, such as inspections and surveillances. (NRC STAFF)

XVIII.1.3 Audits should include both technical and programmatic aspects of the repository program by:

(a) comprehensive, independent evaluation of quality-related practices, procedures, instructions, activities, and items and the verification that these practices, procedures, instructions,

activities and items conform to specified requirements; (Ref. 23 and Ref. 17)

(b) reviews of documents and records to ensure that the QA program is established; (Ref. 23 and Ref. 7)

(c) assessment of the effectiveness and proper implementation of the QA program; (Ref. 17)

(d) assessment of the technical adequacy of the activities being conducted, and

(e) evaluation of suppliers' QA programs, procedures, and activities and verification that the programs conform to specified requirements. (Ref. 26 and Ref. 17)

XVIII.1.4 In the event that a participant's program or organization undergoes a major change or major areas of concern are discovered, the schedule of audits should be revised. (Ref. 18)

XVIII.1.5 For internal audits, applicable elements of an organization's quality assurance program should be audited at least once each year or at least once during the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the activity being audited may be useful. The evaluation may include results of previous quality assurance program audits and the results of audits from other sources, including the nature and frequency of identified deficiencies and any significant changes in personnel, organization, or quality assurance program. (Ref. 20)

XVIII.1.6 After the award of a contract, the applicant or licensee may determine, based on the evaluation conducted in accordance with Section 5.1 of Appendix 4A-1 (NQA-1-1986), that external audits are not necessary for procuring items that are (1) relatively simple and standard in design, manufacturing, and testing and (2) adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. (Ref. 20)

For other procurement actions not covered by the above exceptions, audits should be conducted as described below. (Ref. 20)

(a) The applicant or licensee should either audit its supplier's quality assurance program on a triennial basis or arrange for such audit. In either case, the audit should be implemented in accordance with Supplement 18S-1 of ANSI/ASME NQA-1-1986. The triennial period begins when an audit is performed. An audit may be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a quality assurance program that has the required scope for purchases placed during the triennial period. If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements should be conducted, thus starting a new triennial period. If the supplier is implementing the same quality assurance program for other customers that is proposed for use on the auditing party's contract, the pre-award survey may serve as the first triennial audit if conducted in accordance with the requirements of ANSI/ASME NQA-1-1986. Therefore, when such pre-award surveys are employed as the first triennial audits, they should satisfy the same audit elements and criteria as those used on other triennial audits.

(b) The applicant or licensee should perform or arrange for annual evaluations of suppliers. This evaluation should be documented and should take into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

(c) If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all the purchasers, and the audit report should be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

APPENDIX B

REQUIREMENT 2:

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.

NQA-1

BASIC REQUIREMENT

These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

SUPPLEMENT 18S-1

4.0 PERFORMANCE

Audits shall be performed in accordance with written procedures or checklists. Audits shall begin as early in the life of the activity as practicable and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

SUPPLEMENT 2S-3

QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1.0 GENERAL

This Supplement provides amplified requirements for the qualifications of audit team leaders, henceforth identified as Lead Auditors, who organize and direct audits, report audit findings, and evaluate corrective action. This Supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate

in an audit, such as technical specialists, management representatives, and auditors-in-training. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

See NQA-1-1983, Appendix 2A-3 for nonmandatory guidance on the education and experience of Lead Auditors.

2.0 QUALIFICATION OF AUDITORS

2.1 Responsibility of Auditors Organization

The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel of performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below:

(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results;

(b) training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings;

(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

3.0 QUALIFICATION OF LEAD AUDITORS

An individual shall meet the requirements of 3.1 through 3.4 below prior to being designated a Lead Auditor.

3.1 Communication Skills

The prospective Lead Auditors shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

3.2 Training

Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.

3.2.1 Knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.

3.2.2 General structure of quality assurance programs as a whole and applicable elements as defined in this Standard.

3.2.3 Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.

3.2.4 Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.

3.2.5 On-the-job training to include applicable elements of the audit program.

3.3 Audit Participation

The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall

be a nuclear quality assurance audit within the year prior to his qualification.

3.4 Examination

The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply to body of knowledge identified in 3.2 above. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with 5.0 of this Supplement.

4.0 MAINTENANCE OF QUALIFICATION

4.1 Maintenance of Proficiency

Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participating in training programs. Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.

4.2 Requalification

Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of 3.2 above, reexamination in accordance with 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit.

5.0 ADMINISTRATION

5.1 Organizational Responsibility

Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

5.2 Qualification Examination

The development and administration of the examination for Lead Auditor required by 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to this Standard. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files, and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of 6.0 below.

6.0 RECORDS

6.1 General

Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer.

6.2 Certification and Qualification

Each Lead Auditor shall be certified by this employer as being qualified to lead audits. This certification shall, as a minimum, document the following:

(a) employer's name
(b) Lead Auditor's name
(c) date of certification or recertification
(d) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.);
(e) signature of employer's designated representative who is responsible for such certification.

6.3 Updating of Lead Auditor's Records

Records for each Lead Auditor shall be maintained and updated annually.

SUPPLEMENTARY NRC STAFF POSITION

XVIII.2.1 The audit team membership should include QA and technical personnel having expertise which encompasses the areas being audited. (Ref. 26)

XVIII.2.2 The audit procedures should: (Ref. 16)

(a) assign responsibility for the audit program;
(b) establish the frequency for the audits; (Ref. 23)
(c) provide the mechanism and establish a requirement for development, review and approval of the procedures/check lists;
(d) provide minimum qualifications for auditors and for their independence from the area being audited; (Ref. 23)
(e) prescribe the format for documenting the results;
(f) prescribe the mechanism for submission of audit results to appropriate management personnel and the criterion for follow-up action in deficient areas. (Ref. 23)

APPENDIX B

REQUIREMENT 3:
Audit results shall be documented and reviewed by management having responsibility in the area audited.

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BASIC REQUIREMENT
Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

SUPPLEMENT 18S-1

5.0 REPORTING

The audit report shall be signed by the audit team leader and issued and shall include the following information, as appropriate:

(a) description of the audit scope;
(b) identification of the auditors;
(c) identification of persons contacted during audit activities;
(d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited;
(e) description of each reported adverse audit finding in sufficient detail to enable corrective actions to be taken by the audited organization.

6.0 RESPONSE

Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

8.0 RECORDS

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

SUPPLEMENTARY NRC STAFF POSITION

XVIII.3.1 Audit results should be prioritized based on their importance to safety and to respository performance. (NRC STAFF)

XVIII.3.2 A tracking system for audit results should be established to help assure that all results are appropriately dispositioned, to trend audit results and to assess root causes. (Ref. 23)

APPENDIX B

REQUIREMENT 4:
Followup action, including reaudit of deficient areas, shall be taken where indicated.

NQA-1

SUPPLEMENT 18S-1
7.0 FOLLOW-UP ACTION
Follow-up action shall be taken to verify whether corrective action is accomplished as scheduled.

SUPPLEMENTARY NRC STAFF POSITION

XVIII.4.1 The audited organization should describe in a formal report the corrective action to be taken to address audit results. This report should be submitted to the auditing organization by the responsible management of the audited organization. (Ref. 23 and Ref. 13)

XVIII.4.2 In the resolution of results, the root cause of each significant result should be identified and corrective action for it described. (Ref. 23)

REFERENCES

1. American Nuclear Society (ANS) 1972. Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants (During the Construction Phase), ANSI N45.2.2, American Society of Mechanical Engineers, New York, NY.

2. American Nuclear Society (ANS) 1976. American National Standard Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants, ANSI N18.7, Hindsdale, IL 60521.

3. American Society of Mechanical Engineers (ASME). 1973. Quality Assurance Terms and Definitions, ANSI, N45.2.10, New York, NY.

4. American Society of Mechanical Engineers (ASME). 1974. American National Standard, Reactor Plants and Their Maintenance, Quality Assurance Requirements for the Design of Nuclear Power Plants, ANSI, N45.2.11, New York, NY.

5. American Society of Mechanical Engineers (ASME). 1986. NQA-1, American National Standard Quality Assurance Program Requirements for Nuclear Facilities, New York, NY.

6. American Society for Nondestructive Testing. August 1984. Recommended Practice No. SNT-TC-1A, Personnel Qualification and Certification in Non-Destructive Testing.

7. American Society for Quality Control (ASQC) Energy Division. 1987. Draft ASQC Quality Assurance Guidelines Document, Milwaukee, WI.

8. Arter, D. R. 1986. Why NQA-1 Will Not Work for Research, Proceedings of the Thirteenth National Energy Division Conference, American Society for Quality Control, Milwaukee, WI.

9. Code of Federal Regulations, Title 10, "Energy." Part 21, "Reporting of Defects and Noncompliance," U.S. Government Printing Office, Washington, DC.

10. Code of Federal Regulations, Title 10, "Energy." Part 50, "Domestic Licensing of Production and Utilization Facilities." Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," U.S. Government Printing Office, Washington, DC.

11. Code of Federal Regulations, Title 10, "Energy." Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," U.S. Government Printing Office, Washington, DC.

12. Henderson, J. T., August, 1982. Applying QA to Geoscience Investigations, Quality Progress.

13. Knight, J. P. to Browning, R.. September 5, 1986. Proposed Changes/ Clarifications to the NRC Review Plan: "Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories," Department of Energy, Washington, DC.

14. Letter from American Society of Mechanical Engineers (ASME) Committee on Nuclear Quality Assurance to Mr. Allen Breed, Subject: Action Item No. 81-12 - Configuration Management, dated June 22, 1981.

15. Memorandum from J. J. Surmeier, NRC, to those on Attached List, NRC, dated December 22, 1983, Subject: Strawman Quality Assurance Amendment to 10 CFR Part 60 for Pre-Licensing Site Characterization Activities, Nuclear Regulatory Commission (NRC), Washington, DC.

16. Quality Control Bulletin. 1973. AEC Interpretation of the 18 Criteria of Quality Assurance of 10 CFR 50, Appendix B, issued by Reliability and Quality Assurance Division of United Engineers and Constructors, Inc., Philadelphia, PA.

17. U.S. Department of Energy (DOE), Salt Repository Project Office. 1985. Salt Repository Project Office Quality Assurance Plan, Revision 0, Hereford, TX.

18. U.S. Department of Energy (DOE), Basalt Waste Isolation Project Office. 1987. Basalt Waste Isolation Quality Assurance Plan, Revision 2, Hanford, WA.

19. U.S. Department of Energy (DOE), Nevada Operations Office. 1987. Nevada Nuclear Waste Storage Investigation Project Quality Assurance Plan, NVO-196-17, Revision 5, Las Vegas, NV.

20. U.S. Nuclear Regulatory Commission (NRC). 1985. Quality Assurance Program Requirements (Design and Construction), Regulatory Guide 1.28, Washington, DC.

21. U.S. Nuclear Regulatory Commission (NRC). July 1981. Standard Review Plan, NUREG-0800, Washington, DC.

22. U.S. Nuclear Regulatory Commission (NRC). 1983. Final Technical Position on Documentation of Computer Codes for High-Level Waste Management, NUREG-0856-F, Washington, DC.

23. U.S. Nuclear Regulatory Commission (NRC). June, 1984. NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories, Washington, DC.

24. U.S. Nuclear Regulatory Commission (NRC). 1984. Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants, NUREG-1055, Washington, DC.

25. U.S. Nuclear Regulatory Commission (NRC). 1985. Generic Technical Position on Design Information Needs in the Site Characterization Plan, Washington, DC.

26. U.S. Nuclear Regulatory Commission (NRC). June, 1986. Standard Review Plan for Quality Assurance Programs for an Independent Spent Fuel Storage Installation (ISFSI) 10 CFR 72, Washington, DC.

27. U.S. Nuclear Regulatory Commission (NRC). 1986. Quality Assurance (QA) Plan for Computer Software Supporting the U.S. Nuclear Regulatory Commission's High-Level Waste Management Program, NUREG/CR-4369, Washington, DC.

28. U.S. Nuclear Regulatory Commission (NRC), 1987. "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," Federal Register, Vol. 52, No. 131, July 9, 1987, 25932-25933.

29. U.S. Nuclear Regulatory Commission (NRC), 1987. "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," Federal Register, Vol. 52, No. 131, July 9, 1987, 25932-25933.

30. U.S. Nuclear Regulatory Commission (NRC), 1987. Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry, NUREG/CR-4640, Washington, DC.

31. U.S. Nuclear Regulatory Commission (NRC), 1987. Nuclear Regulatory Legislation, "Atomic Energy Act of 1957," NUREG-0980, Washington, DC.

32. U.S. Nuclear Regulatory Commission (NRC), 1988. "Generic Technical Position on Items and Activities in the High-Level Nuclear Waste Repository Program Subject to Quality Assurance Requirements, Washington, DC.

INDEX TO DEFINITIONS

INDEX TO DEFINITIONS (Continued)

CROSS REFERENCE:
1984 NRC REVIEW PLAN APPENDIX A
TO
1988 DRAFT TECHNICAL POSITION ON
QUALITY ASSURANCE

Cross Reference for the disposition of positions from the 1984 NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories Appendix A to the revised draft version: Technical Position on Quality Assurance for the Site Characterization Phase of a High-Level Nuclear Waste Repository

1984	1988 QA Draft TP
1.1	Criterion I Appendix B Requirement 1 and 3, NQA-1 Supplement 1S-1 2.1, I.3.7, II.2.2 (b) and (c).
1.2	Criterion I Appendix B Requirement 2, II.2.2.
1.3	Criterion I Appendix B Requirement 3, NQA-1 Supplement 1S-1, I.3.1, I.3.2, I.3.3 (Appendix B, Requirement 3 includes but is not limited to "the extent of management responsibility and authority from DOE Headquarters and from the field office."
1.4	I.2.4, Criterion XVIII.
1.5	I.2.2, II.2.2(b) and (c).
1.6	NQA-1 1.0 Basic Requirement, NQA-1 Supplement 1S-1 3.0 Multiple Organizations.
1.7	II.2.2(b) and (c), Discussion p. II-4.
1.8	II.2.2(c), II.4.1, II.4.2
1.9	II.2.2(b) and (c), Discussion p. II-4.
1.10	I.3.1, I.3.2, I.3.3.
1.11	NQA-1 Supplement 1S-1 2.1 Purpose, I.3.7, VI.2.1 (These positions allow for the verification of conformance to established requirements to be performed by personnel outside of the QA organization.)
1.12	Criterion I Appendix B Requirement 4, NQA-1 1.0 Basic Requirement, I.4.1, II.2.2(b) and (c).
1.13	I.3.6.
1.14	II.2.3.
1.15	I.3.1, I.3.2, I.3.3, II.2.2(b) and (c).

2.1 Criterion II Appendix B Requirement 3 and 4, II.3.1.

2.2 NQA-1 Supplement 3S-1 3.1 Design Analysis, III.1.12.

2.3 Criterion II Appendix B Requirement 1 and 2, NQA-1 2.0 Basic Requirement, II.2.1, II.2.3, VI.2.1.

2.4 II.2.2(b) and (c), Discussion p.II-4, VI.2.1, VI.2.2.

2.5 II.4.1, II.4.2.

2.6 II.2.2(a).

2.7 Criterion II Appendix B Requirement 8 and 9, NQA-1 2.0 Basic Requirement, II.8.1, I.2.4, I.5.1.

2.8 Criterion II Appendix B Requirement 7, NQA-1 Supplement 2S-1 and 2S-2, II.7.1, II.7.5, II.7.7, II.7.8.

3.1 Definitions p. III-4 and III-5. (The definitions for design information and design activities have not been retained in the revision. Design information is included in the definition of design as outlined in the AEA, 1954. The definition of design activities has been replaced by the definitions of design process and scientific investigations. Plans for data collection and analysis and related information are covered by the definition of design. The definition of data analysis was not retained due to its broad and ubiquitous use).

3.2 II.1.1, III.1.1, III.1.3, II.3.1.

3.3 II.2.2(b) and (c).

3.4 Criterion XV and XVI.

3.5 Criterion III Appendix B Requirement 4, NQA-1 3.0 Basic Requirement and Supplement 3S-1, III.4.1.

3.6 Criterion III Appendix B Requirement 6, II.2.2(b) and (c), VI.2.1, VI.2.2.

3.7 Criterion III Appendix B Requirement 6 and 7, NQA-1 3.0 Design Control and Supplement 3S-1, III.6.1, III.6.6, III.7.1, and Discussion p. III-18.

3.8 III.6.1, III.6.5.

3.9 III.6.6, II.2.2(b) and (c).

3.10	Criterion III Appendix B Requirement 4 and 10, NQA-1 3.0 Basic Requirement and Supplement 3S-1, II.1.1, Appendix B Requirement 4, NQA-1 3.0 Basic Requirement and Supplement 3S-1, III.4.1, III.10.2, III.10.3, III.4.1.
4.1	Criterion IV Appendix B Requirement 1 and 2, NQA-1 4.0 Basic Requirement and Supplement 4S-1, II.2.2(b) and (c), VI.2.1. (Rejection criteria are considered the same as acceptance criteria.)
4.2	II.2.2(b) and (c), NQA-1 Supplement 4S-1 and 7S-1, Criterion VI, II.1.1.
5.1	II.2.2(b) and (c), Criterion V Appendix B Requirement 1. (This staff position also states that these documents should be verified and approved as described in Section 3. This position has not been retained in the revision. Documents concerning design should be verified and approved in accordance with this criterion and with Criterion VI, Document Control, as well as with any other criterion that applies.)
5.2	Criterion V Appendix B Requirement 2.
6.1	Criterion VI Appendix B Requirement 1, NQA-1 Supplement 6S-1.
6.2	Criterion VI Appendix B Requirement 2, VI.2.1, VI.2.4, VI.2.5, II.2.2(b) and (c).
6.3	Criterion VI Appendix B Requirement 2, VI.2.6.
6.4	VI.2.7.
6.5	VI.2.8.
6.6	VI.2.5.
7.1	II.2.2(b) and (c).
7.2	Criterion VII Appendix B Requirement 2, NQA-1 7.0 Basic Requirement and Supplement 7S-1, II.2.2(b) and (c).
7.3	NQA-1 Supplement 7S-1.

7.4 Criteria X, XI, XVIII.

7.5 This position has been rewritten in XI.2.3.

8.1 Criterion VIII Appendix B Requirement 1, Definitions p. VIII-2, II.2.2(b) and (c). (The definition of material has been expanded to include samples; the definition of items includes materials.)

8.2 NQA-1 8.0 Basic Requirement and Supplement 8S-1.

8.3 VIII.1.3.

8.4 Criterion VIII Appendix B Requirement 3, NQA-1 8.0 Basic Requirement and Supplement 8S-1, VIII.3.1.

9.1 Criterion XI Appendix B Requirement 1, Discussion p. IX-3. (As noted in Discussion p. IX-3, the site characterization phase of the repository program has numerous activities that are special processes by definition. The staff position on the establishment of criteria for determining what processes are "special" has been retained but the staff position for a list of special processes has not been retained in the revision).

9.2 II.2.2(b) and (c).

9.3 Criterion IX Appendix B Requirement 1, NQA-1 Supplement 9S-1, IX.1.2, II.2.2(b) and (c).

9.4 Criterion IX Appendix B Requirement 1, Criterion V Appendix B Requirement 2, NQA-1 Supplement 9S-1, V.2.6.

9.5 NQA-1 Supplement 9S-1.

10.1 Criterion X Appendix B Requirement 1, II.2.2(b) and (c), X.1.2.

10.2 II.2.2(b) and (c), NQA-1 Supplement 10S-1, Discussion p. X-5. (The position that persons performing inspections are part of the QA organization has not been retained in the revision. The NRC staff position is that these persons may be from any organization as long as they are qualified and they did not perform or supervise the work being inspected.)

10.3 NQA-1 Supplement 10S-1, Criterion II.

10.4 NQA-1 Supplement 10S-1, V.2.4.

10.5 V.2.2.

10.6 NQA-1 Supplement 10S-1, X.1.8.

11.1 Criterion XI Appendix B Requirement 1, Criterion II, II.2.2(b) and (c), Criterion VIII.

11.2 VI.2.1.

11.3 XI.1.3, XI.1.4.

11.4 Criterion XI Appendix B Requirement 2, NQA-1 Supplement 11S-1, XI.2.1, V.2.2. (The position that methods of data analysis be contained in test procedures was not retained in the revision. The methods of data analysis do not necessarily have to be contained in the test procedure; they may be contained in other documentation such as the site characterization plan.)

11.5 Criterion XI Appendix B Requirement 3, NQA-1 11.0 Basic Requirement and Supplement 11S-1, XI.3.1.

12.1 Criterion XII Appendix B Requirement 1, NQA-1 12.0 Basic Requirement and Supplement 12S-1, XII.1.1.

12.2 Criterion I Appendix B Requirement 3, II.2.2(b) and (c).

12.3 Criterion XII Appendix B Requirement 1, NQA-1 Basic Requirement and Supplement 12S-1, Definition p. XII-2, Criterion VI.

12.4 XII.1.1(b) and (e).

12.5 XII.1.5.

12.6 NQA-1 Supplement 12S-1 3.1 Calibration.

12.7 NQA-1 Supplement 12S-1 3.2 Control, XII.1.10.

13.1 Criterion XIII Appendix B, NQA-1 13.0 Basic Requirement and Supplement 13S-1, II.7.1, II.7.2, II.7.3.

13.2 Criterion XIII Appendix B Requirement 1, NQA-1 13.0 Basic Requirement and Supplement 13S-1, Definition p. XIII-2. (The definition of material has been modified in the revision to include samples.), XVII.5.1, NQA-1 Supplement 17S-1 4.2 Preservation.

14.1 Criterion XIV Appendix B Requirement 1, XIV.1.1.

15.1 Criterion XV Appendix B Requirement 2, NQA-1 15.0 Basic Requirement and Supplement 15S-1, XV.2.1.

15.2 II.2.2(b) and (c).

15.3 XV.2.2.

15.4 XV.1.2, XV.1.3.

16.1 Criterion XVI Appendix B Requirement 1, VI.2.1, II.2.2(b) and (c).

16.2 Criterion XVI Appendix B Requirement 1 and 3, XVI.1.2, VI.2.1, II.2.2(b) and (c).

16.3 NQA-1 16.0 Basic Requirement, XV.1.2, II.2.2(b) and (c).

16.4 Criterion XVI Appendix B Requirement 2 and 3, NQA-1 16.0 Basic Requirement, XVI.3.1.

17.1 Criterion XVII Appendix B Requirement 1, NQA-1 17.0 Basic Requirement and Supplement 17S-1, XVII.2.1. (In the revision, design review reports and peer review reports are considered "results of reviews.")

17.2 Criterion I Appendix B Requirement 3, II.2.2(b) and (c).

17.3 NQA-1 Supplement 10S-1 8.0 Records, X.1.3, NQA-1 Supplement 11S-1. (The position of the staff is that the contents of inspection and test records, particularly the results of the inspection or test and the determination of acceptability, provide "information related to conditions adverse to quality".)

17.4 Criterion XVII Appendix B Requirement 5, NQA-1 Supplement 17S-1, 4.0 Storage, Preservation, and Safekeeping, XVII.5.1.

18.1 Criterion XVIII Appendix B Requirement 1, NQA-1 18.0 Basic Requirement and Supplement 18S-1, XVIII.1.5, XVIII.1.6.

18.2 NQA-1 Supplement 18S-1 2.0 Scheduling and 3.0 Preparation, XVIII.1.1. (The position that audits be scheduled based on the "safety importance" of the activities is covered by NQA Supplement 18S-1 which states that audits should be scheduled based on the "importance" of the activities. In the repository program "importance" includes both importance to safety and importance to waste isolation.)

18.3 Criterion XVIII Appendix B Requirement 1, NQA-1 18.0 Basic Requirement XVIII.1.1.

18.4 Criterion XVIII Appendix B Requirement 3, NQA-1 18.0 Basic Requirement and Supplement 18S-1. (Assessment should be considered part of the review process.)

18.5 Criterion XVIII Appendix B Requirement 2, NQA-1 18.0 Basic Requirement and Supplement 18S-1.

18.6 XVIII.3.2.

18.7 XVIII.4.1.

18.8 XVIII.4.2.

U. S. NUCLEAR REGULATORY COMMISSION

NRC REVIEW PLAN:

QUALITY ASSURANCE PROGRAMS

FOR SITE CHARACTERIZATION

OF HIGH LEVEL NUCLEAR WASTE REPOSITORIES

Compiled by
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety and Safeguards

Quality Assurance Branch
Division of Quality Assurance, Safeguards, and Inspection Programs
Office of Inspection and Enforcement

June 1984

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.

TABLE OF CONTENTS

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 safety-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.

The design control measures shall provide for verifying or checking the adequacy 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 powerplant 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 affec ality. These measures shall assure tha. ..ments, 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 ··quirements.

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 Ass ; Records

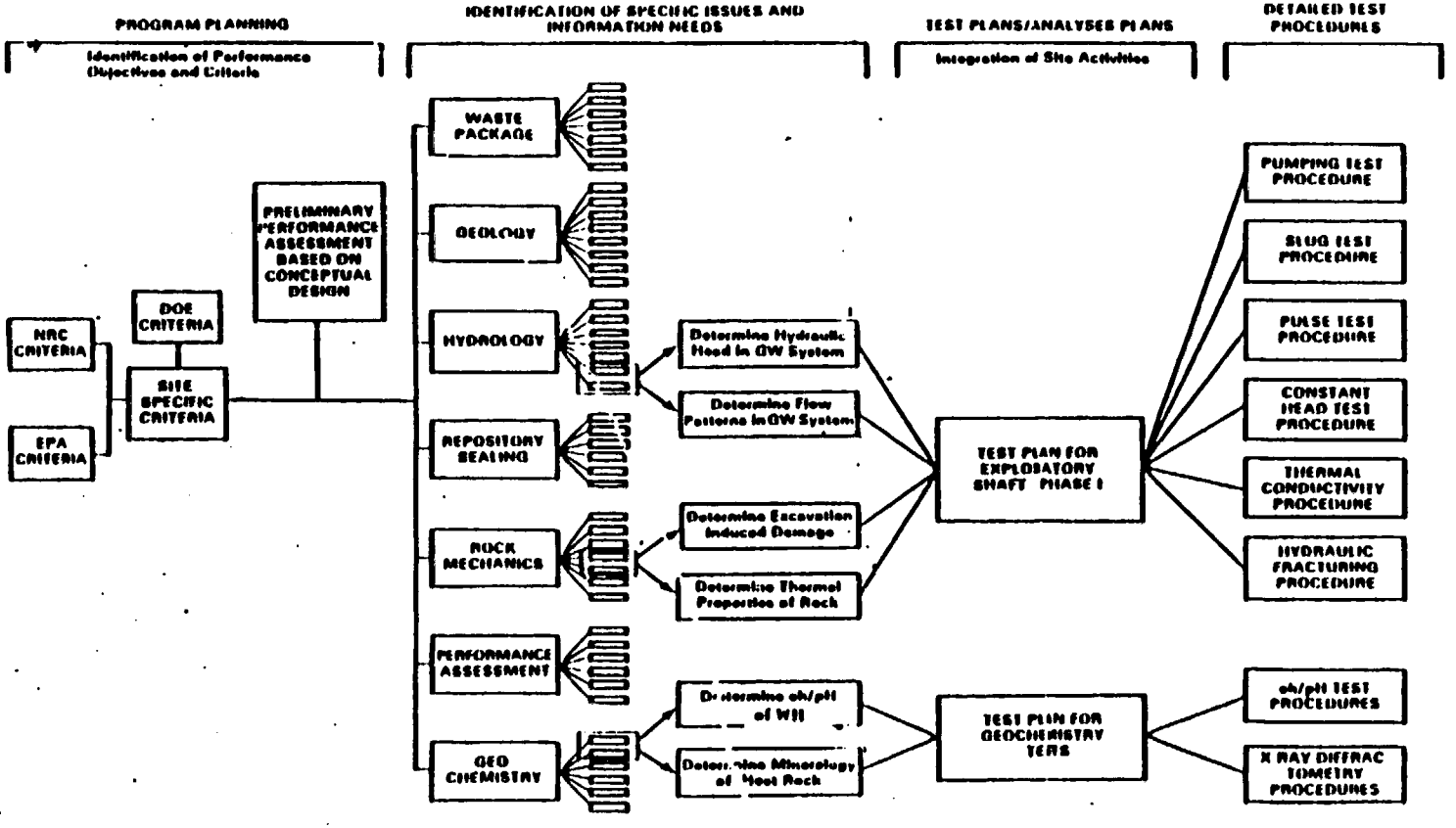
Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related 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]

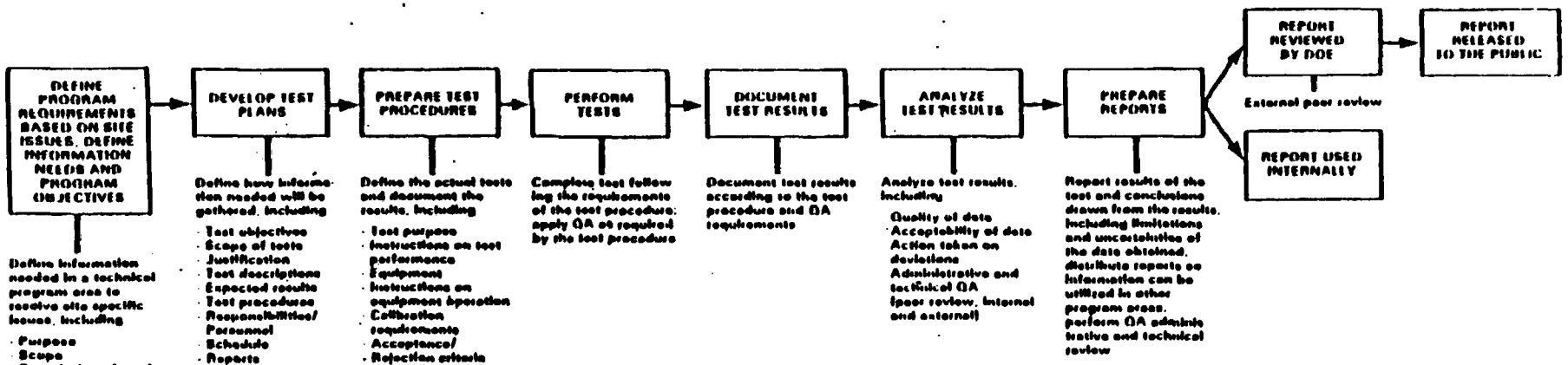
FIGURE 1, page 2



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



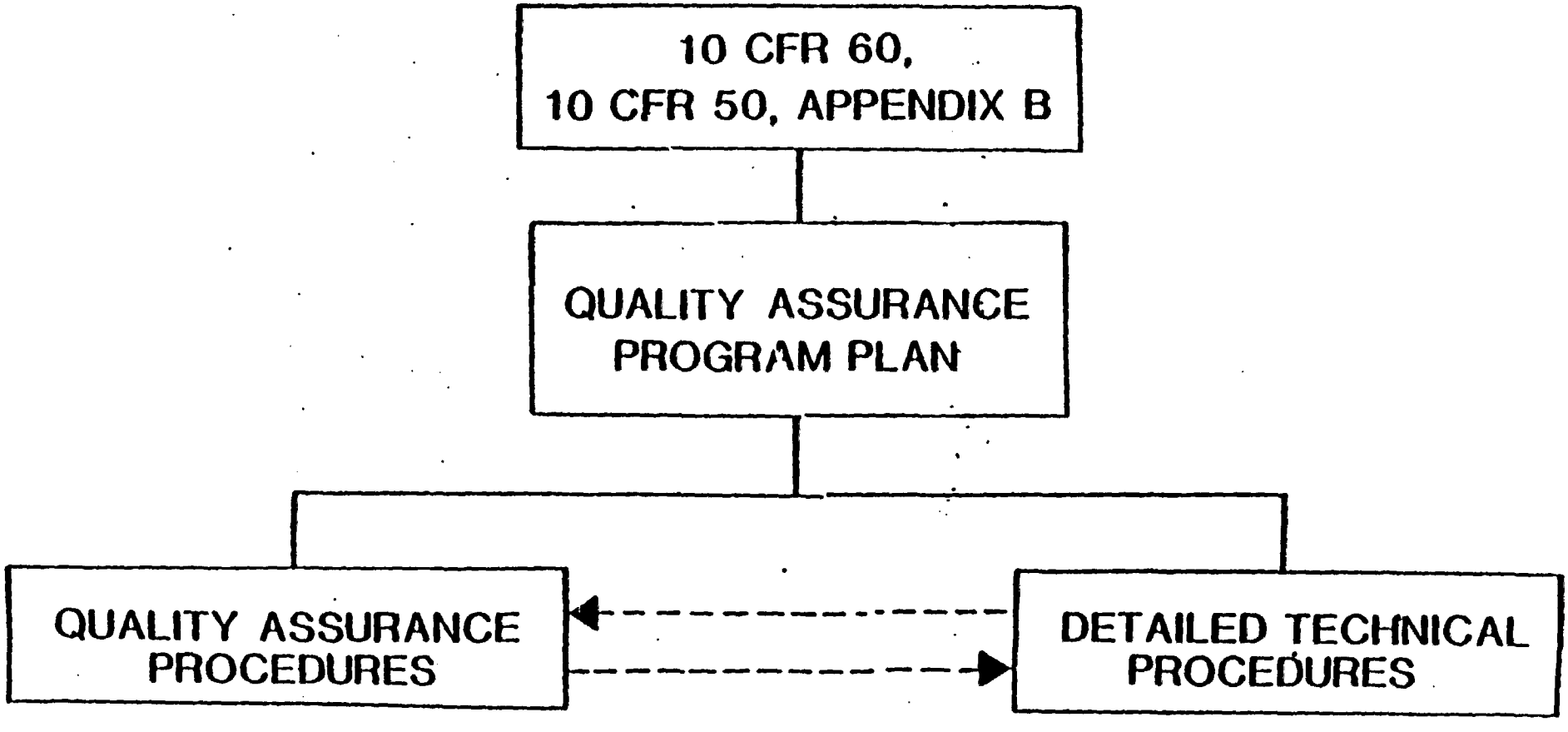
*QA administrative procedures include procedures for: (1) document control; (2) documented instructions, procedures, and drawings; (3) control of materials, equipment, and services, (4) use of qualified personnel; (5) inspections, (6) documented test plans, (7) control of test equipment; (8) control 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,

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* "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:

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*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 <u>design</u>, <u>design information</u>, and <u>design activities</u> used in the design control program are as defined in this section. The term <u>design</u> 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). <u>Design information</u> and <u>design activities</u> 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.

11.3 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 documentation such as drawings, specifications, procurement documents, calibration procedures and reports; design review reports; peer review reports; nonconformance reports; and corrective action reports.

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of 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.

Resolution of DOE Comments on the 1984 NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories

1. DOE comment 1(a) is a general comment:

The title, scope and purpose of "Site Characterization" are inconsistent with the content, in that the review plan contains considerable criteria which are not applicable to site characterization, but are applicable to the engineered design and the components of the geologic repositories.

DOE Proposed Change/Clarification:

Revise title, scope and purpose to include the engineered design and components of the geologic repositories.

Response:

The staff agrees and has replaced "site characterization" with "site characterization phase" in the revision. The site characterization phase of the repository program includes data collection and analysis activities that will be used to characterize the components of the geologic repository and includes engineered designs such as design of waste packages and conceptual designs of the repository. By the addition of the word "phase", engineered design and components of the geologic repository are covered.

2. DOE comment 1(b) is a general comment:

The HLW repository program is comprised of activities involving engineered design as well as scientific investigations. The Review Plan should reflect this in its format and content.

DOE Proposed Change/Clarification

The content should identify which criteria/requirements are applicable to both scientific investigations and engineered design, and which would be applicable to one or the other. Enclosed for your consideration is a strawman outline for such a review plan. It is based on the criteria and format of Appendix B (18 Criteria) for the engineered design, but identifies where there should be major differences for scientific investigation.

ATTACHMENT TO COMMENT 1.b.

PROPOSED CONTENT OF A QA STANDARD REVIEW PLAN
APPLIED TO ITEMS IMPORTANT TO
SAFETY, WASTE ISOLATION, AND SITE CHARACTERIZATION

Section 1
- Organization
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both scientific investigation and engineered design

Section 2
- QA Program
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both scientific investigation and engineered design

Section 3
- Engineered design and scientific investigation control
- Separate into three major sections: Engineered Design, Scientific Investigation, and Computer Software Development
- For engineered design, utilize typical existing requirements (Appendix B and NQA-1)
- For scientific investigation, identify specific requirements
    - o Need for scientific investigation planning document
    - o Highlights of the steps of the scientific investigation process, e.g., plan, procedures, implement, analyze, interpret, and report with an independent technical review following every step
    - o Highlight the need for scientific investigation surveillances by QA and technical personnel
- Identify a section for software QA that is applicable to both engineered design and scientific investigation
    - o Acknowledge the difference between scientific and engineering software versus auxiliary software.

Section 4
- Procurement Document Control
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both engineered design and scientific investigation

Section 5
- Instruction, Procedures, Drawings
- Typical to existing requirements (Appendix B and NQA-1) for engineered design
- Expand to include requirements for the control of procedural documents when the activity being performed requires significant professional judgement, e.g., constant changes have to be made as the process evolves

Section 6
- Document Control
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both engineered design and scientific investigation

Section 7 - Control of Purchased Items and Services
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both engineered design and scientific investigation

Section 8 - Identification and Control of Items
- The typical existing requirement (Appendix B and NQA-1) shall be applied to those engineered design items (hardware) that will become part of the permanent repository
- Will not apply to scientific investigation

Section 9 - Control of Processes
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to engineered design only

Section 10 - Inspection
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to engineered design only

Section 11 - Test Control
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to engineered design only

Section 12 - Control of M&TE
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both engineered design and scientific investigation

Section 13 - Handling, Shipping and Storage
- The typical existing requirements (Appendix B and NQA-1) shall be applied to engineered design items (hardware) that will become part of the permanent repository
- For scientific investigation this section will be supplemented with specific requirements for samples (gas, liquid, solid)

Section 14 - Inspection, Test and Operating Status
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to engineered design only

Section 15 - Control of NCR
- Typical to existing requirements (Appendix B and NQA-1) for engineered design item that will be part of the repository
- Develop specific requirements for a deficiency report system for programmatic problems and data

Section 16 - Corrective Action
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both engineered design and scientific investigation

Section 17 - QA records
- Typical to existing requirements (Appendix B and NQA-1)
- Applies to both engineered design and scientific investigation
- Excludes samples (covered in Section 13)

Section 18 -
- Audits and surveillances
- Typical to existing requirements for audits (Appendix B and NQA-1)
- Develop specific requirements for the implementation of a surveillance program
- Applies to both engineered design and scientific investigation

Response:

The staff agrees that the content of the review plan should contain requirements and guidance for both the engineered design and scientific investigations. The staff considers most of the requirements and guidance in Appendix B and NQA-1, with some clarification of terms, to be applicable to both engineered design and scientific investigations. In addition, the staff has added guidance specifically for scientific investigations such as the control of plans for data collection and analysis and the control of data and technical reports. In the revision, staff positions are tied directly to 10 CFR Part 50 Appendix B requirements. The GTP also incorporates NQA-1 requirements and supplements. The following addresses specific content proposed by DOE in the attachment to DOE Comment 1b.

Section 1: The staff agrees.

Section 2: The staff agrees.

Section 3: The revision does not separate the design control section into three parts. Instead, each of these areas, engineered design scientific investigation, and computer software development is addressed below each applicable 10 CFR 50 Appendix B requirement.

The revision addresses the need for a scientific investigation planning document in Criterion III and indicates that design control measures should be applied to plans for scientific investigations and discusses the level of detail which should be incorporated in the plans.

The revision does not specifically address the steps of the scientific investigation process in a staff position. The steps

are covered by the entire document in the same manner that the steps required for design, procurement, and other activities are addressed by the entire document. The revision, however, provides a definition for scientific investigations which indicates that a scientific investigation may include a test, data analysis, interpretation, and conclusion.

The criterion for inspection highlights the need for in-process inspections and suggests that surveillances and readiness reviews be utilized to supplement the inspections of scientific investigations. NQA-1 Supplement 10S-1 specifies that personnel who perform inspections be qualified to perform the assigned task. In addition, the discussion following Criterion X Requirement 2 notes that the NRC staff considers that it would be desirable to have inspections, surveillances and readiness reviews performed periodically by personnel knowledgeable or formally trained in the area inspected, surveilled, or readiness reviewed.

Software QA is addressed by NQA-1 and NRC Supplementary Staff Positions. This guidance is generic to software for both engineered design and to scientific investigations. Supplementary NRC Staff Position in Criterion III acknowledges that software such as word processing and accounting packages should not require verification and validation unless they are supplemented with user-designed programs.

Section 4: The staff agrees.

Section 5: The staff agrees. Supplementary NRC Staff Position in Criterion V permits the procedures for scientific investigations to be general in nature when the step-by-step process is not known in advance. The guidance also suggests that procedures state how changes should be controlled.

Section 6: The staff agrees. The staff also added supplemental guidance for the peer review of technical documents when they meet the criteria for peer review.

Section 7: The staff agrees. The staff added supplemental guidance for the control of procuring data and software.

Section 8: The staff disagrees. In scientific investigations, chemicals and other materials will be used. In addition data will be generated. These items need to be identified and controlled. As a result, the staff added supplementary guidance specifically for the identification and control of samples, data, software and consumables.

Section 9: The staff disagrees. The staff considers that special processes include numerous activities that will be conducted as part of scientific investigations. The staff has modified the methods by which procedures should be qualified to better address scientific investigations. (See discussion in GTP Criterion IX)

Section 10: The staff disagrees. The Supplementary NRC Staff Positions in Criterion IX indicate that inspections should be conducted to verify that items, data, activities related to safety or waste isolation, reports, quality assurance records and services conform to documented instructions, procedures, drawings, specifications, or other documents. The supplementary staff positions also indicate that in-process inspections should be performed of data collection activities.

Section 11: The staff disagrees. The requirements for test control apply to scientific investigations when the investigations include a test. The revision established a broader definition of the word test to include data collection activities, such as experiments.

Section 12: The staff agrees.

Section 13: The staff agrees. The revision added supplemental guidance for handling, shipping, storage of samples as well as data.

Section 14: The staff disagrees. This criterion applies to any item that is inspected, tested, or operated. The items include engineered components, data or samples.

Section 15: The staff added supplementary guidance which includes procedures, plans, instructions, work, services, programs, equipment, and data in the program for nonconformances. The DOE should establish a system for identifying, reporting and correcting nonconformances in these areas.

Section 16: The staff agrees.

Section 17: The staff added supplemental guidance in this criterion which includes samples and data.

Section 18: The staff did not developed specific requirements for surveillances but has suggested that the DOE use surveillances to supplement the audit and inspection program. Specific requirements for surveillances if used should be developed by the DOE.

3. DOE Comment 2(a) addresses the 1984 NRC Review Plan paragraph 1.0 and 1.10(d) which state respectively:

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:

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

DOE Comment 2(a):

It is the position of DOE that the management position that retains overall authority and responsibility for the "QA Function" has no other

duties or responsibilities unrelated to QA. However, the management position that retains overall authority and responsibility for the QA program, also has responsibility for line functions.

DOE Proposed Change/Clarification

Revise Section 1 of the review plan to recognize the verification of proper performance and conformance of the work as a line management responsibility, not the QA organization. The "QA Function" is responsible for overall assurance of QA program adequacy and implementation. The review plan should differentiate between responsibility for quality verification and the over-all assurance of quality.

Responses:

The staff agrees with DOE comment 2(a) and the Supplemental NRC Staff Positions in Criterion I clarify the NRC staff positions in 1.10 and 1.10(d) of the 1984 NRC Plan.

With regard to the DOE Proposed Change/Clarification for Comment 2(a), this revision endorses NQA-1, Supplement 1S-1, which recognizes that the performance of quality work is a line function and the verification of this performance is performed by persons not directly responsible for performing the work. The Supplementary NRC Staff Positions elaborate on this by indicating that QA functions may be performed by the line organization but should be overseen by the QA organization.

4. DOE Comment 2(b) addresses the NRC Review plan paragraph 1.11 as underlined below:

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.

DOE Comment 2(b):

It is the position of DOE that the verification of conformance to established requirements can be performed by the line organization, provided the individuals are independent of the activity being verified. The QA organization provides an independent assessment of the status and adequacy of the QA program.

DOE Proposed Change/Clarification:

Same as Proposed Change/Clarification for DOE Comment 2(a).

Response:

The staff agrees, and paragraph 1.11 has not been retained in the revision. See also the response to DOE Comment 2(a).

5. DOE Comment 2(c) which is the same as DOE Comment 2(a) addresses the 1984 NRC Review Plan paragraph 1.15 which states:

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. These individuals are free from non-QA duties and can thus give full attention to assuring the QA program is being effectively implemented.

DOE Comment 2(c):

Same as DOE Comment 2(a).

DOE Proposed Change/Clarification:

Same as DOE Proposed Change/Clarification for comment 2(a).

Response:

See response to DOE Comment 2(a).

6. DOE Comment 3 addresses the 1984 NRC Review Plan Paragraph 2.2 which states:

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."

DOE Comment 3:

This requirement would be more appropriate under criteria 3, "Design control."

DOE Proposed Change/Clarification:

Relocate this requirements to Section 3 of the Review Plan.

Response:

The staff agrees. QA guidance for computer programs is addressed in Criterion III. Paragraph 2.2 is covered in the revision by NQA-1, Supplement 3S-1, 3.1 Design Analysis and by Supplementary NRC Staff Position in Criterion III.

7. DOE Comment 4 addresses the 1984 NRC Review Plan Paragraph 3.10 which states:

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.

DOE Comment 4:

Design control applied to design changes while commensurate with those applied to the original design, may not always be the same.

DOE Proposed Change/Clarification:

Revise 1st sentence to state

"Design changes . . . . subject to design controls commensurate with those applied to the original design."

Response:

The staff agrees. The revision endorses NQA-1, Basic Requirement 3.0 Design Control which indicates that "Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design."

In the revision, paragraph 3.10 is covered by NQA-1 as discussed above, by NQA-1, Supplement 3S-1, 5.0 Change Control, and by requirements and guidance for interface control in Criterion III.

8. DOE Comment 5 addresses the 1984 NRC Review Plan Paragraph 5.1 which states:

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

DOE Comment 5:

Review of procedures and instructions other than those related to data acquisition may be more appropriate under paragraph 6.2 than Section 3, which is primarily related to design activities.

DOE Proposed Change/Clarification:

Either (1) add a reference to paragraph 6.2, or (2) change reference from "Section 3" to "Paragraph 6.2".

Response:

The reviews of documents, including instructions, procedures, and drawings, are addressed in Criterion VI by Appendix B, NQA-1 and Supplementary NRC Staff Positions. The review criteria for specific types of documents are contained elsewhere in the document. For example, specific criteria for the review of procurement documents are contained in Criterion IV. In addition, general requirements for instructions, procedures, and drawings are contained in Criterion V. The Criteria are not meant to be independent; thus, each Criterion should be examined for its applicability to a given document or situation. In the QA Plans or the implementing procedures, DOE should specify the reviews and criteria for the reviews of various documents. References to requirements and guidance in this GTP, or the QA Plan under which a procedure was developed, could be used to cross-reference the requirements and/or guidance when they are derived from more than one place.

9. DOE Comment 6 addresses the 1984 NRC Review Plan Paragraph 7.5 which states:

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.

DOE Comment 6:

It is not clear what has to be done to satisfy the second sentence.

DOE Proposed Change/Clarification:

Rewrite this paragraph to clarify the intent.

Response:

This position has been rewritten in Criterion XI.

10. DOE Comments 7 addresses the 1984 NRC Review Plan Paragraph 10.2 as underlined below:

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.

DOE Comment 7:

It is not necessary that individuals performing inspections are part of the QA organization as long as they are independent of the items/activities being inspected.

DOE Proposed Change/Clarification:

Revise the Review Plan to require that inspections be performed by individuals other than those who performed the activity being inspected.

Response:

The staff agrees and the underlined portion of this position has not been retained in the revision. Criterion X, Appendix B, Requirement 2 states that inspections shall be performed by individuals other than those who performed the activity being inspected.

11. DOE Comment 8 addresses the 1984 NRC Review Plan Paragraph 14.1 which states:

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

DOE Comment 8:

Marking of individual items is not always practical.

DOE Proposed Change/Clarification:

Revise to state that the status of inspections and tests shall be identified either on the items or in documents traceable to the items.

Response:

The staff agrees. Supplementary NRC Staff Position in Criterion XIV has been added to the revision to incorporate this clarification.

12. DOE Comment 9 addresses the NRC Review Plan Paragraph 18.7 which states:

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.

DOE Comment 9:

Audit responses should be issued to the auditing organization by the responsible management of the audited organization.

DOE Proposed Change/Clarification:

Delete "and/or Responsible Management" to clarify the intent.

Response:

The staff agrees. Paragraph 18.7 was reworded in Criterion XVIII to incorporate this change.