

ADVANCE COPY

BASALT WASTE ISOLATION PROJECT

BASALT QUALITY ASSURANCE

REQUIREMENTS DOCUMENT

(BOARD)

REVISION 0

JANUARY 1986

PRINCIPAL AUTHOR:

John M. Clark 1/14/86

John M. Clark, QA Branch Date
Basalt Waste Isolation Division
U.S. Department of Energy - Richland, WA

REVIEWED:

R. P. Saget 1/17/86

R. P. Saget, QA Branch Chief (Acting) Date
Basalt Waste Isolation Division
U.S. Department of Energy - Richland, WA

APPROVED:

O. L. Olson 1/21/86

O. L. Olson, Director Date
Basalt Waste Isolation Division
U.S. Department of Energy - Richland, WA

8608180330 860717
PDR WASTE PDR
WM-10

BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT

("BQARD")

- FOREWORD -

"... Some of these projects have experienced problems in plant quality--parts of the plants were built incorrectly. Some of these projects experienced problems in the assurance of quality--the utility was unable to demonstrate whether its plant was built correctly..."

(Extracted from Chapter 1, NUREG 1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants" a.k.a., "The NRC Ford Amendment Study").

"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 to predetermined requirements."

(Extracted from Title 10, Chapter I, Code of Federal Regulations, Part 50, Appendix B, Introduction).

BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT ("BQARD")
For Site Characterization Activities
and/or
Design and Construction of a High Level Waste Repository

INTRODUCTION

1. **PURPOSE.** For items or activities "important to safety or waste isolation" (i.e., "Q-list" items or activities, and certain other items/activities assigned a "Level I" designation through use of the Graded Quality Assurance (QA) Methodology), the BQARD:
 - a. Identifies and consolidates all federally mandated QA programmatic requirements into a single document;
 - b. Provides guidance and consistency in interpretation of QA programmatic requirements;
 - c. Provides Basalt Waste Isolation Project (BWIP) specific QA requirements; and
 - d. Provides baseline control for BWIP participant Site Characterization and/or Design/Construction QA Programs.

2. **BQARD ORGANIZATION.** Each criteria within this document is comprised of two parts. The first part of the column entitled "BWIP Project Implementation" provides a discussion of the intent of the criteria requirements from the viewpoint of applying all of the elements to comprise a viable system. This portion of each criteria should not be construed as additional requirements but as guidance toward developing and implementing an acceptable system. It is recognized there may be other equally acceptable methods of meeting the requirements. The second part identifies the discrete QA requirements that shall apply during Site Characterization.

Within each Site Characterization section, the column on the left side contains the requirements from 10 CFR 50 Appendix B. Under each Appendix B requirement is additional guidance provided by the Nuclear Regulatory Commission (NRC) Review Plan on how to interpret the Appendix "B" requirement when applied to site characterization activities.

The column on the right side contains BWIP interpretations and implementing requirements. It frequently references NQA-1-1983 Supplements which are applicable to and not in conflict with Appendix "B" requirements and the NRC Review Plan guidance on the left side.

Discrete QA requirements that apply to potentially licensable construction are not included in the BQARD. However, Construction Participants are provided rather generalized guidance on QA Program Requirements. It is anticipated that participants performing construction work "Important to Safety or Waste Isolation" will have (or be required to comply with codes that require) NRC acceptable QA Programs (for example, NCA 4000 of the B&PV codes, section III). To amplify further, if a participant already has "N stamp" authority, the construction BQARD should cause minor, if any, changes to that QA Program.

3. BQARD SOURCE DOCUMENTS. The QA requirements included within the BQARD are from several requirements/guidance documents:
 - a. 10CFR 60;
 - b. 10 CFR 50, Appendix B;
 - c. NRC Review Plan: QA Programs for Site Characterization of High Level Nuclear Waste Repositories, dated June 1984;
 - d. Memorandum, Headquarters (Ralph Stein) to Lee Olson, BWIP, dated November 1984;
 - e. QA Management Policies and Requirements, OCRWM, October 1985;
 - f. QA Plan for Siting and Site Characterization, OGR, September 1984;
 - g. QA Manual for BWI Project Office, DOE-RL, Rev. 0, (not dated);
 - h. DOE Order 5700.6A, "Quality Assurance" and DOE-RL Order 5700.1A, "Quality Assurance";
 - i. DOE Order 6410.1, "Management of Construction Projects";
 - j. ANSI/ASME NQA-1 1983 and addenda 1a-1983;
 - k. Federal Acquisition Regulation (FAR) Part 46, "Quality Assurance";
 - l. NRC letter to WMPO, NV (Dr. Veith) dated June 25, 1985.
4. UTILIZATION of NQA-1 WITHIN THE BQARD. QA Programs which meet the requirements of 10 CFR 50, Appendix B will meet all of the 18 Basic Requirements of NQA-1. Therefore, the BQARD (for Level I site characterization activities) utilizes 10 CFR 50 Appendix B to define QA Program requirements - the 18 NQA-1 Basic Requirements are implicitly included therein. The NQA-1 supplements (or parts thereof) are explicitly utilized wherever they provide additional clear and relevant guidance and do not contradict Appendix B/Review Plan. Further, certain NQA-1 appendices identified as non-mandatory in the source document are included verbatim (except for title) as requirements in the BQARD, in order to preclude misunderstandings.

5. **QUALITY-RELATED INFORMATION NOT INCLUDED IN THE BOARD.** The following documents are not included within and will be distributed separately from the BQARD:

- a. "Q-list" Methodology
- b. "Graded QA" Methodology
- c. 10 CFR 60.73 and 10 CFR 21 "Deficiency Reporting Requirements".

6. **ADDITIONAL GUIDANCE PENDING.** Participants should note that the NRC is in the process of providing additional guidance in several areas directly affecting Site Characterization QA activities. The additional NRC guidance will be in the areas of:

- a. qualification of previously acquired data;
- b. configuration management for conceptual design;
- c. peer reviews;
- d. the Q-list;
- e. QA for exploratory testing (as opposed to confirmatory testing).

The attachment to this introduction provides further information on each of these subjects. Participants are advised that existing BQARD implementation direction in these five (5) areas is subject to change upon the receipt of the NRC Generic Technical Positions (GTP's). There are also a number of supplements to the Office of Geologic Repository (OGR) QA Plan, currently being reviewed by the NRC, that will be incorporated at a later date.

ATTACHMENT

The following is a brief summary of the issues and the development of the staff positions:

Qualification of Existing Data

It is expected that DOE will attempt to utilize at least some data not collected under the Appendix B QA program in its license application. These would be data collected early in the program (before the Site Characterization Plan was issued, for example). An important question is how to review that data to determine if it is adequate for licensing. The staff Generic Technical Position (GTP) as presently drafted acknowledges that qualification may be possible in certain limited circumstances. The staff believes that with proper documentation and consideration of the use and importance of the data in licensing and availability of independent corroborating information, some old data may be acceptable. The position will also describe generally the attributes of the data to examine and the process by which they should be examined. While it is not known how much (or little) old data may eventually be qualified, this position provides a starting point for this important issue.

Peer Reviews

The repository program, particularly the site characterization phase, will encounter technical issues characterized by a lack of unanimity among experts, a rapidly changing state of the art, and choices where no clearly superior technical approach is available. In such situations, peer reviews may be used to provide added assurance for the data used and decisions made. Guidance has been developed in the following areas: conditions under which a peer review should be performed, qualifications of a peer review group, content of the review and documentation of the review.

Configuration Management for Conceptual Designs

The concept behind this position is simple, but not addressed in the regulations or the QA Review Plan. Essentially it says that DOE should establish a baseline design with performance goals for the components of the natural and engineered systems, develop the site characterization program based on these goals and modify the goals based on test results obtained throughout the site characterization phase. The entire process of establishing the baseline, the test program and the changes to these should be controlled. The premise is that test programs based on conceptual designs will likely be utilized in licensing. Staff review of the tests, procedures and results and the premises upon which they are based will be too late at the time of licensing.

Q List

The term "Q list" used here to describe the scope of the Appendix B QA program for the repository items which are important to public health and safety or to waste isolation and the major program activities, such as major test programs during site characterization, which are also subject to the QA program. This GTP addresses the methodology for determining these items and activities, discusses graded QA and describes staff information needs so that the NRC will be able to thoroughly and systematically review the scope of the QA program. Our objective is to avert the kinds of problems experienced in the reactor program regarding the scope and applicability of the QA program.

QA For Research and Exploratory Testing

This GTP addresses assurance measures for research activities and testing where the results may not be predicted with any confidence beforehand, and the results of one test influence test parameters for a subsequent test. In this situation, the level of detail that can be put into the test procedure beforehand is limited. The key criterion regarding level of assurance associated with research and exploratory test results is the safety significance of the use of the results. This GTP addresses these issues and allows the preparation of a detailed test procedure after data are collected which describes the methods, test anomalies, etc. after the fact. The principal investigator for the test is assigned primary responsibility for the test results.

As noted earlier, these GTP's are but one important part in the NRC program for reviewing the DOE QA program for site characterization. They have been a major part of the staff's efforts to date. As these are completed, the staff will devote more attention to review of DOE documents and to the implementation of the program. The ASME's committee on Nuclear Quality Assurance (NOA) has recently established a subcommittee on waste management. The NRC staff actively supports and participated in the work of this subcommittee. Interaction with the subcommittee has been and will continue to be an important part of the GTP development process.

1/16/86

BQARD
CRITERION 1: ORGANIZATION
REVISION 0 (sheet 1 of 13)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish requirements for critical areas of each participant contractor's organization in order to assure that project activities are accomplished within a defined and controlled organizational structure. The criterion requires a defined organizational structure which delineates (a) overall responsibilities; (b) delegation of work; (c) evaluation of performance; (d) management controls and effective lines of communication; (e) interfaces; (f) management positions and responsibilities for each organizational element; (g) Quality Assurance personnel independence; (h) policies; (i) verification of performance; and (j) access to management.

Potentially Licenseable Construction

It is expected that potentially licenseable construction will be performed coincident with BWIP site characterization activities. Those participants who will perform both construction and site characterization work shall establish a project organization meeting site characterization Criterion I. Construction only participants performing level I construction work shall, to the extent practical, establish a project organization that conforms to the requirements of Site Characterization Criterion I. Deviations, and the alternate method of providing equivalent control, will be documented.

NOTE: "Contractor" as used in this BQARD refers to all contractors, subcontractors, vendors, consultants, agents or agencies, and institutions performing work covered by the quality assurance program.

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

The applicant shall be responsible for the establishment and execution of the quality assurance program.

For Site Characterization, additional guidance has been provided in Section 1.1 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 2.1 of NQA-1-1983 will be implemented.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

For Site Characterization, additional guidance has been provided in Section 1.2 through 1.6 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 1.2

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

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 2.2 of NQA-1-1983 will be implemented.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1983 will be implemented.

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

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 2 of NQA-1-1983 will be implemented.

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 13)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1983 will be implemented.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

For Site Characterization, additional guidance has been provided in Sections 1.7, 1.9, 1.10, and 1.15 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 1.9

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

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1983 will be implemented.

NRC REVIEW PLAN SECTION 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:

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

- a. Is at the same or higher organizational 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.

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 13)

Requirement

BWIP Project Implementation

- 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.

NRC REVIEW PLAN SECTION 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. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

These activities include both the performing functions of attaining quality objectives and the quality assurance functions.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 1.8 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 2 of NQA-1-1983 will be implemented.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 8 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 5: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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 11.5 are outlined in these sections.

For Site Characterization, additional guidance has been provided in Section 1.11 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 9 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 6: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 1.12, 1.13, and 1.14 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 10 of 13)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 1.14

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

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 1S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 11 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 7: 10 CFR 50 APPENDIX B

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.

For Site Characterization, additional guidance has been provided in Section 1.15 of the NRC Review Plan.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 12 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 8: 10 CFR 50 APPENDIX B

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 person and organizations assigned the quality assurance functions have this required authority and organizational freedom.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1983 will be implemented.

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 13 of 13)

Requirement

BWIP Project Implementation

REQUIREMENT 9: 10 CFR 50 APPENDIX B

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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1983 will be implemented.

1/16/86

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM
REVISION 0 (sheet 1 of 18)

BWIP Project Implementation

Site Characterization

The intent of this criterion during site characterization is to require DOE-RL (BWIP Division) to establish a comprehensive quality assurance program that controls both the design and construction of all items and activities important to safety or waste isolation, in order to assure the adequacy of the completed repository facility. Consequently, each BWIP participant shall establish a complimentary Quality Assurance program, consistent with its assigned scope of work. All quality assurance programs established shall meet the programmatic requirements identified within this criterion, along with the additional requirements included within the remaining seventeen (17) criteria of 10 CFR 50, Appendix B. Note that the NRC Review Plan, as incorporated herein, provides an acceptable means of meeting many of the Appendix B programmatic requirements.

In addition, NQA-1-1983 also provides an acceptable means of meeting Appendix B programmatic requirements, provided NQA-1 is applicable to the site characterization activity being considered and is not in conflict with NRC Review Plan guidance.

The NRC makes a distinction between (1) administrative QA procedures and (2) detailed technical or implementing procedures. 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

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM
REVISION 0 (sheet 2 of 18)

BWIP Project Implementation

plan development). The detailed technical (implementing) procedures are developed by technically 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.)

In order to meet the stated requirements, the QA and technical organizations shall define the QA controls to be applied to specific items and activities using a defined, graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR Part 60.2. Implementing procedures shall be prepared, controlled, and mandated through a policy statement signed by management. Management shall be required to assess the adequacy of the QA program through frequent contact with the program and a documented annual performance assessment.

Potentially Licenseable Construction

It is expected that potentially licenseable construction will be performed coincident with BWIP site characterization activities. Those participants who will perform both construction and site characterization work shall establish a project QA Program meeting site characterization Criterion 2. Construction only participants performing level I construction work shall, to the extent practical, establish a project QA Program that conforms to the requirements of Site Characterization Criterion 2. Deviations and the alternate method of providing equivalent control, will be documented.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 2.5 and 2.6 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 2.4

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

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

For Site Characterization, additional guidance has been provided in Section 2.3 and 2.4 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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 Part 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.

For Site Characterization, additional guidance has been provided in Section 2.1 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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."

For Site Characterization, additional guidance has been provided in Section 2.2 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 5: 10 CFR 50 APPENDIX B

Activities affecting quality shall be accomplished under suitably controlled conditions.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 8 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 6: 10 CFR 50 APPENDIX B

Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 9 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 7: 10 CFR 50 APPENDIX B

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 intent of this requirement is not specifically addressed in NQA-1-1983. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 10 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 8: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 2.8

Indoctrination, training, and qualification in 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.

For Site Characterization, additional guidance has been provided in Section 2.8 of the NRC Review Plan.

1. For personnel performing quality-related activities, NQA-1-1983 does not specifically provide supplemental guidance for this requirement. Therefore, the intent of this requirement will be met if requirements 2.8a, c, and d are implemented as stated.
2. For personnel verifying quality-related activities, a, b, c, d, and e are to be implemented. NQA-1-1983 provides supplemental guidance as follows:

Design Reviewers - Supplement 3S-1, Section 4
Inspectors - Supplements 2S-1 and/or 2S-2
Auditors - Supplement 2S-3.

Note that the Review Plan Criterion 3.8 provides qualification standards for Peer Reviewers.

In addition, the prospective Lead Auditor should have verifiable evidence that a minimum of ten (10) credits under the following score system have been accumulated. (DOE-RL)

1. Education (4 Credits Maximum)

Associate degree from an accredited institution: score one (1) credit, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) credits; or

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 11 of 18)

Requirement

BWIP Project Implementation

A bachelor's degree from an accredited institution: score two (2) credits, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) credits; in addition, score one (1) credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

2. Experience (9 Credits Maximum)

Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) credit for each full year with a maximum of five (5) credits for this aspect of experience.

If two (2) years of this experience have been in the nuclear field, score one (1) additional credit; or

If two (2) years of this experience have been in quality assurance, score two (2) additional credits; or

If two (2) years of this experience have been in auditing, score three (3) additional credits; or

If two (2) years of this experience have been in nuclear quality assurance, score three (3) additional credits; or

If two (2) years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 12 of 18)

Requirement

BWIP Project Implementation

3. Other Credentials of Professional Competence
(2 Credits Maximum)

For certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency or National Professional or Technical Society: score two (2) credits.

4. Rights of Management (2 Credits Maximum)

The Lead Auditor's employer may grant up to two (2) credits for other performance factors applicable to auditing which may not be explicitly called out in this Appendix. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.

The sample form shown in NQA-1 may be utilized as a record of Lead Auditor qualification.

In addition, the following requirements on the qualifications of inspection and test (verification) personnel are made mandatory: (DOE-RL)

NOTE: NQA-1 uses "Test and Inspection personnel" in the context of verifiers of previously completed work. For site characterization, Test personnel actually perform the site characterization tests (refer to Criterion XI), not verify it, and thus are not required to meet these specific qualifications. However, personnel assigned to the testing organization and designated by the testing supervisor to be an "in-process Inspector," shall have the qualifications identified herein (as well as other required qualifications, see Review Plan 2.8(b) that are consistent with the In-process Inspection tasks assigned.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 13 of 18)

Requirement

BWIP Project Implementation

1. FUNCTIONAL QUALIFICATIONS

Three levels of qualification shall be utilized depending on the complexity of the functions involved. The recommendations for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional activities.

1.1 Level I Personnel Capabilities

A Level I person shall be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in user's written procedures.

1.2 Level II Personnel Capabilities

A Level II person shall have all of the capabilities of a Level I person for the inspection or test category or class in question. Additionally, a Level II person shall have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in supervising or maintaining surveillance over the inspections and tests; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 14 of 18)

Requirement

BWIP Project Implementation

1.3 Level III Personnel Capabilities

A Level III person shall have all of the capabilities of a Level II person for the inspection or test category or class in question. In addition, the individual shall also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered in this requirement. In addition a Level III person shall review and approve inspection and test procedures, evaluating the adequacy of such procedures to accomplish test and inspection objectives.

2. EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience recommendations shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the activity may provide reasonable assurance that a person can competently perform a particular task. Other factors which may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency shall be documented.

2.1 Level I

2.1.1 Two years of related experience in equivalent inspection or testing activities; or

2.1.2 High school graduation and six months of related experience in equivalent inspection or testing activities; or

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 15 of 18)

Requirement

BWIP Project Implementation

2.1.3 Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.

2.2 Level II

2.2.1 One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or

2.2.2 High school graduation plus three years of related experience in equivalent inspection or testing activities; or

2.2.3 Completion of college level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities; or

2.2.4 Graduation from a four-year college plus six months of related experience in equivalent inspection or testing activities.

2.3 Level III

2.3.1 Six years of satisfactory performance as a Level II in the corresponding inspection or test category or class; or

2.3.2 High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection or testing activities with at least two years as Level II and with at least two years

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 16 of 18)

Requirement

BWIP Project Implementation

associated with nuclear facilities-or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

2.3.3 Completion of college level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

2.3.4 Graduation from a four-year college plus five years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities-or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 17 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 9: 10 CFR 50 APPENDIX B

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

The intent of this requirement will be met by implementing all the requirements of NRC Review Plan Section 1.4 as addressed in Criterion 1, Requirement 2 of the BQARD and Requirement 10 of this criterion of the BQARD.

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 18 of 18)

Requirement

BWIP Project Implementation

REQUIREMENT 10: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 2.7

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

- a. Frequent contact with program status through reports, meetings, and/or audits.
- b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.

For Site Characterization, additional guidance has been provided in Section 2.7 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

Also refer to Criterion 15, Requirement 2 and Criterion 16, Requirement 1.

In addition, participants shall submit audit schedules, schedule revisions, and audit reports to the integrating contractor (HQ-OGR).

BOARD
CRITERION 3: DESIGN CONTROL
REVISION 0 (sheet 1 of 12)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the requirements for controls over the repository design activities in order to assure that (a) design products to be used during site characterization data collection/testing/analysis (such as detailed procedures, or data analysis computer programs) are correct and consistent with repository conceptual design, and (b) resultant repository design products are correct and consistent with the analyzed data obtained through site characterization activities. Refer to Review Plan Section 3.1 of this Criterion (sheet 2) for additional information.

Potentially Licenseable Construction

The intent of this criterion during construction is to establish the requirements for controls over the repository definitive design processes, in order to assure that applicable regulatory requirements and design bases (in part derived from site characterization activities) are correctly translated into construction specifications, drawings, procedures, and instructions (definitive design products), and that any subsequent change to a verified definitive design product is consistent with the original correct translation.

It is expected that definitive design for potentially licenseable construction will be performed coincident with BWIP site characterization design work. Those participants who will perform both construction and site characterization design work shall establish Design Controls meeting site characterization Criterion 3. Those participants performing only definitive design for Level I construction work shall establish those Design Controls required by the specific Code or Standard to be met, and, to the extent practical, shall conform to the requirements of Site Characterization Criterion 3. Deviations, and the alternate method of providing equivalent control, will be documented.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in Sub-section 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.

NRC REVIEW PLAN SECTION 3.1

The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data 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 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.

For Site Characterization, the NRC has reworded this requirement to read as shown in Sections 3.1 and 3.2 of the NRC Review Plan.

Additional guidance has been provided in Sections 3.1 and 3.2 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 3S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, data acquisition, verification, and analysis requires that data and information that is received from literature searches be validated from the technical adequacy perspective and correct application (HQ-OGR).

BOARD

CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 12)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 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 (of the NRC Review Plan). 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 3S-1, Sections 2, 3, and 7 of NQA-1-1983 will be implemented.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

The intent of this requirement will be met by implementing Requirement 1 of this criterion of the BQARD.

Additional guidance has been provided in Section 3.6 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 3.6

Procedures require that design drawings, specifications, criteria, and analysis 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 3S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

The intent of this requirement will be met by implementing Requirement 1 of this criterion of the BQARD.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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

NRC REVIEW PLAN SECTION 3.5

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

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 3.5 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 3S-1, Section 6 of NQA-1-1983 will be implemented.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 5: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 3.3

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

The intent of this requirement will be met by implementing Supplement 3S-1, Section 6 of NQA-1-1983.

Additional guidance has been provided in Section 3.3 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 3S-1. Therefore, the intent of this requirement will be met if implemented as stated. In addition, design/engineering "holds" shall be included. (DOE-RL)

Note the use of the word "Validating." It pertains only to the design of computer codes, as discussed in NuReg 0856 in the definitions of "Validating" and "Verifying" when used in the context of computer codes.

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 8 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 6: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementing the requirements of NQA-1-1983, Supplement 3S-1, Section 4.

Additional guidance has been provided in Sections 3.4 and 3.8 of the NRC Review Plan.

The intent of this requirement will be met by implementing the Criterion 15 controls.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 3S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 9 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 7: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, the NRC has reworded this requirement to read as shown in Sections 3.7 and 3.9 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 3S-1, Section 4 of NQA-1-1983 will be implemented.

Note that design verifiers shall be qualified. Refer to Criterion 2, sheet 10 of 18.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 3S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 10 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 8: 10 CFR 50 APPENDIX B

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.

The intent of this requirement will be met by implementing Supplement 3S-1, Subsection 4.2.3 of NQA-1-1983.

Refer to Criterion 11 for additional information.

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 11 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 9: 10 CFR 50 APPENDIX B

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 in-service inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 3S-1. Therefore, the intent of this requirement will be met if implemented to the level of detail apparent in the requirement.

In addition, the word "reactor" is deleted and the words "high level waste disposal" added in its stead. (DOE-RL)

In addition, the delineation of acceptance limits for inspections and tests (site characterization testing) shall be directly relatable to the design assumption that must be confirmed via performance of the test. (DOE-RL)

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 12 of 12)

Requirement

BWIP Project Implementation

REQUIREMENT 10: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 3.10 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 3S-1, Section 5 of NQA-1-1983 will be implemented.

1/16/86

BQARD
CRITERION 4: PROCUREMENT DOCUMENT CONTROL
REVISION 0 (sheet 1 of 4)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the requirements for the control of Procurement Documents including content, in order to assure that only correct and complete procurement documents are utilized by BWIP. Also, at the option of the participant, this Criterion or Criterion 7 shall establish the requirements for the control of procurement activities, from procurement planning through supplier QA program approval, in order to assure that qualified suppliers furnish BWIP materials, equipment, and services. (Refer to BQARD interpretation of NRC Review Plan Section 4.2 for additional information.)

Note the NQA-1 definitions of "Procurement Documents," "Final Design (Documents)," and "Design Output (Documents)." As used herein, Procurement Documents means all documents included within the "bid package" (or equivalent) transmitted to suppliers, and other directly related documents, such as RFP's, contract modifications, etc. Procurement documents include "Final Design" documents which, during site characterization are often approved "Statements of Work." Final Design documents shall include those technical QA requirements applicable to the procurement, and the organization preparing the Final Design documents shall recommend to the purchaser those programmatic QA requirements applicable to the procurement. It is preferable that the supplier documentation to be submitted for both the QA technical and QA programmatic requirements be identified in a consolidated "Deliverable List" (or "submittal list") that is an integral part of the Final Design documents. In any case, agreement between the design organization and the purchaser with respect to both QA technical and

BQARD
CRITERION 4: PROCUREMENT DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)

Requirement

BWIP Project Implementation

recommended programmatic requirements shall be reached prior to Design review of the Design Output documents. The purchaser shall assure that any QA requirements not included in the Final Design documents are included within the Procurement documents.

Note that Criterion 6-Document Control, NRC Review Plan 6.5 identifies Procurement documents for inclusion within a document control system.

Note that Procurement document changes (i.e., contract modifications) that result from unsatisfactory supplier performance shall, in general, be considered "Significant Conditions adverse to quality" and shall be supported by the Corrective Action Reports required by Criterion 16, NRC Review Plan Section 16.4.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize the Site Characterization Criterion 4 or alternatively, NQA-1-1983 Basic Requirements 4 and Supplement 4S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BOARD
CRITERION 4: PROCUREMENT DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 4.2 of the NRC Review Plan.

Note that implementation guidance for activities (1), (3), (4), and (5) is included in Supplement 7S-1 of NQA-1-1983. Therefore, the intent of this requirement will be met by implementation as stated, in either Criterion 4 or Criterion 7.

In addition, Sections 2, 3, and 4 of Supplement 4S-1, NQA-1-1983, will be implemented for activity (2).

BOARD
CRITERION 4: PROCUREMENT DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 4.1

Procedures are established for the review of procurement documents by QA personnel to determine the 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.

For Site Characterization, additional guidance has been provided in Section 4.1 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 4S-1, Sections 2 and 3 of NQA-1-1983 will be implemented.

Note that Federal Acquisition Regulations (FARs) may require Acceptance Inspections if the procurement includes turnover of tangible, capital equipment to the purchaser.

It is anticipated that BWIP Site Characterization activities will require a limited number of Acceptance Inspections. These will be planned and conducted on a case-by-case basis in response to project procurement regulations and procedures.

1/16/86

BQARD
CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS
REVISION 0 (sheet 1 of 3)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the requirements for the control of project quality-related activities through the use of written procedures, instructions, and drawings (that have been subjected to a documented review/verification and approval process), in order to assure that activities are performed correctly, and if required, can be reproduced at a later date.

NOTE: NQA-1 Supplement S-1 makes a distinction between "Procedure" and "Qualified Procedure," which is "an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose." Qualified procedures are normally required in advance of performance of a special process (Criterion 9). Those technical procedures required by Criterion 5 may be converted to "Qualified Procedures," if desired, upon determination by the Design Organization (Criteria 3) that the procedure produced valid results. Also refer to Criterion 2 for additional procedural information.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 5 or alternatively, NQA-1-1983 Basic Requirements 5, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 3)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

Additional guidance has been provided in Section 5.1 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 5.1

Organizational responsibilities are described for assuring that quality-related activities are: (1) specified in instruction, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described in Section 3 (of the NRC Review Plan).

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 3)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 5.2 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

1/16/86

BQARD
CRITERION 6: DOCUMENT CONTROL
REVISION 0 (sheet 1 of 4)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the requirements for the control of Project quality-affecting documents, in order to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.

NOTE: NQA-1 Supplement S-1 provides an acceptable definition of "Document" and "QA Record," as well as the distinction between the two. Further, NQA-1 permits a "Deviation" from the specified requirements of a controlled document provided an approved "waiver" is obtained on a case-by-case basis. Project participants shall establish a Deviation/Waiver procedure that assures adequate control over case-by-case changes to controlled documents, if deviations/waivers are to be used.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 6 or alternatively, NQA-1-1983 Basic Requirements 6 and Supplement 6S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 6: DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 6.1

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

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 6.6

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

The intent of this requirement will be met if implemented as stated.

Additional guidance has been provided in Sections 6.1, 6.2, 6.5, and 6.6 of the NRC Review Plan.

The intent of this requirement will be met by implementing all requirements in NQA-1-1983, Supplement 6S-1, Section 2, provided the requirement to describe the scope of the document control program is addressed.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 6S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 6S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 6S-1. Therefore, the intent of this requirement will be met if implemented as stated, and in addition, any project data resulting from application of the unverified document is clearly identified. (DOE-RL)

BQARD
CRITERION 6: DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met if implemented as stated.

Additional guidance has been provided in Sections 6.3 and 6.4 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 6S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 6S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 6: DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

The intent of this requirement will be met by implementing Supplement 6S-1, Section 3 of NQA-1-1983.

BOARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES
REVISION 0 (sheet 1 of 6)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the minimum requirements for control of purchased material, equipment and services, to assure they conform to the procurement documents. Documentary evidence that items (not limited to materials and equipment) conform to procurement requirements shall be provided by the supplier and reviewed and accepted by the purchaser prior to installation or use of the items.

Procedures shall be written to provide for: (a) source evaluation and selection; (b) inspection of items at the source and upon delivery; and (c) periodic assessment of the suppliers quality program. Documentary evidence that items conform to procurement requirements shall be provided by the supplier and retained at the nuclear facility.

Note that this criterion provides greater definition of "QA Records" as it applies to external suppliers. Refer also to NQA-1 Supplement S-1 for definition of the terms used herein.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 7 or alternatively, NQA-1-1983 Basic Requirements 7 and Supplement 7S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 6)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 7.1

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

For Site Characterization, additional guidance has been provided in Section 7.1 of the NRC Review Plan.

The intent of this requirement will be met by implementing Supplement 7S-1, Section 2 of NQA-1-1983.

In addition, receiving inspection requirements may be minimized for items packaged for preservation at the suppliers activity, provided inspection is performed at the supplier's activity and Criterion 13, "Handling, Storage, and Shipping," is appropriately implemented for the procurement. (DOE-RL)

BQARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 6)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 7.2 of the NRC Review Plan.

The intent of this requirement will be met by implementing Supplement 7S-1 Section(s) 3, 4, 5, 8, and 10 of NQA-1-1983.

BOARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 6)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 7.3

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

- a. Documentation that identifies the 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.

For Site Characterization, additional guidance has been provided in Section 7.3 of the NRC Review Plan.

The words "repository site" will be substituted where appropriate.

The intent of this requirement will be met by implementing Supplement 7S-1, Section 8 of NQA-1-1983.

The intent of this requirement will be met by implementing Supplement 7S-1, Section 8 of NQA-1-1983.

The intent of this requirement will be met by implementing Supplement 7S-1, Section 9, Subsection (b) of NQA-1-1983.

The intent of this requirement will be met by implementing Supplement 7S-1, Sections 5, 6, and 7 of NQA-1-1983.

BOARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 6)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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 intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 7S-1. Therefore, the intent of this requirement will be met if implemented as stated, provided the words "repository site" are substituted where appropriate.

Refer to Criteria 17 for additional records retention requirements.

BQARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 6)

Requirement

BWIP Project Implementation

REQUIREMENT 5: 10 CFR 50 APPENDIX B

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.

For Site Characterization, additional guidance has been provided in Sections 7.4 and 7.5 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 7.4

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

The intent of this requirement will be met by implementation as stated. In addition, Supplement 7S-1, Section 8.2.1 of NQA-1-1983 will be implemented.

NRC REVIEW PLAN SECTION 7.5 (This guidance on hold by DOE-RL until receipt of NRC clarification.)

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). When 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.

1/16/86

BOARD

**CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS
REVISION 0 (sheet 1 of 4)**

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the requirements for identification and control of samples in order to assure that the identity of a discrete sample is known with certainty at all times during its useful life on the BWIP. This criterion may also have applicability to other critical site characterization items. Note Test Procedure Requirements.

Potentially Licenseable Construction

The intent of this criterion during Construction is to establish the requirements for identification and control (including traceability) of Materials, Parts, and Components used in Level I repository construction, in order to assure that only correct materials, parts, and components are utilized.

Implementation of the requirements within Supplement 8S-1 of NQA-1-1983 will meet the intent of this Criterion for construction, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BOARD

**CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)**

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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

For Site Characterization, additional guidance has been provided in Section 8.1 and 8.3 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 8.1

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

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 8S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, the method used to determine identification markings for each sample shall preclude the assignment of a discreet identifier to more than one discrete sample.
(DOE-RL)

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 8S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD

**CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)**

Requirement

• BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 8.2

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

For Site Characterization, additional guidance has been provided in Section 8.2 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 8S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD

**CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)**

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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

NRC REVIEW PLAN SECTION 8.4

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

For Site Characterization, additional guidance has been provided in Section 8.4 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 8S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, for a sample discretely identified only by its container, verification and documentation shall be extended to include sample return to the discrete container, if permitted by lab practice. Any transfer of material shall contain the sample identification number.
(DOE-RL)

BQARD
CRITERION 9: CONTROL OF SPECIAL PROCESSES
REVISION 0 (sheet 1 of 3)

BWIP Project Implementation

Site Characterization

The intent of the criterion during Site Characterization is to establish the minimum requirements for the Control of Special Processes, in order to assure that Site Characterization processes where direct inspection is impossible or disadvantageous produce results which are demonstrably valid through the use of other accepted assurance techniques.

The distinction between requirements for a test (conducted per Criterion 11) and a test conducted as a special process (conducted per Criterion 9) is that special process testing requires "Qualified Procedures" (refer to Criterion 5), utilizing "Qualified Equipment," and "Qualified Personnel" (refer to Criterion 2, Section 2.8.e), in conjunction with monitoring process variables.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 9 or alternatively, NQA-1-1983 Basic Requirements 9 and Supplement 9S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 9: CONTROL OF SPECIAL PROCESSES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 3)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

For Site Characterization, the NRC has reworded this requirement to read as shown in Sections 9.1 through 9.5 of the NRC Review Plan.

Additional guidance has been provided in Sections 9.1 through 9.5 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 9S-1. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 9.2

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

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 9S-1. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 9S-1 of NQA-1-1983 will be implemented.

BOARD
CRITERION 9: CONTROL OF SPECIAL PROCESSES - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 3)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 9.4

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

The intent of this requirement may be met by implementation of Criterion 14.

NRC REVIEW PLAN SECTION 9.5

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

The intent of this requirement will be met by implementation as stated. In addition, Supplement 9S-1, Section 3.3 of NQA-1-1983 will be implemented.

BQARD
CRITERION 10: INSPECTION
REVISION 0 (sheet 1 of 10)

BWIP Project Implementation

Site Characterization

Inspection as used herein means the independent verification of a physical characteristic being determined during a Site Characterization activity. The wording utilized by Participants to implement this activity is not critical, provided implementation meets the functional intent of this criterion.

The intent of this criterion during Site Characterization is to establish the requirements for an Inspection Program that directly complements the Site Characterization Test Program, and to establish controls on inspections being performed within the program, in order to assure that any resultant physical data is demonstrably valid. In addition to independent verification of the physical data being obtained, Inspection shall also verify conformance to the instructions, procedures, and drawings being utilized.

The Inspection program provides for three types of inspections: In-process ("Detailed"), Final ("General"), and Acceptance ("Functional") ("Final Inspection for Acceptance"). In-process Inspections may be performed by the same organization performing the site characterization activity, except that the inspection shall be performed by qualified individuals other than those who performed the activity being inspected, and may be the supervisor of the activity. The supervisor of the performing organization is directly responsible for the quality of the work performed, and may use in-process inspections to determine quality attainment. The supervisor shall not request final inspection until fully satisfied that the site characterization data was properly obtained.

BOARD
CRITERION 10: INSPECTION
REVISION 0 (sheet 2 of 10)

BWIP Project Implementation

Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusions. Final Inspections may be performed by qualified personnel reporting organizationally to the QA Manager. Final Inspections should be performed just prior to "tear down" or "cover up" of a site characterization activity; they are normally indicated by "Hold Points" on the Inspection Plan; although they incorporate the In-process Inspection procedure, they are of a more general scope (including, for example, a review of all In-process Inspection Reports and all activity NCR's).

It is preferable that Final Inspections utilize calibrated M&TE that was not utilized during performance of the site characterization activity. If not practical, certified standards that permit verification of the accuracy of the operating M&TE assembly at the test location shall be provided at the time of final Inspection. In general, if neither standards or separate M&TE are practical, and it is therefore, impossible or disadvantageous for the final Inspector to verify the accuracy of the operating M&TE assembly at the location where it was used, the site characterization activity being inspected may be considered a "Special Process" and its adequacy verified by other means (for example, Criterion 9).

Acceptance Inspections are discussed within Criterion 4, Procurement Document Control.

BQARD
CRITERION 10: INSPECTION
REVISION 0 (sheet 3 of 10)

BWIP Project Implementation

All project personnel, and particularly project Inspection personnel, shall be advised that the phrase "Acceptance Inspection" has a specific contractual meanings and must be used with discretion. In addition, Inspection Planners and those producing Inspection Procedures shall assure they are aware of and responsive to Federal Acquisition Regulations pertaining to Inspections.

Potentially Licenseable Construction

The intent of this criterion during Construction is similar to its intent during Site Characterization, with the possible exception of Inspection Report distribution, and greater utilization of the guidance in DOE Order 6410.1. Therefore, participants may utilize Site Characterization Criterion 10 (modified) or alternatively, NQA-1-1983 Basic Requirements 10 and Supplement 10S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 10)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

For Site Characterization, additional guidance has been provided in Section 10.1 of the NRC Review Plan.

In addition, the program shall be operative and provide input to the design documents and procurement documents used during site characterization (DOE-RL).

In addition, the procedures shall require that adequate interfacing occurs between the performing organization and the inspecting organization to permit cost effective use of personnel on a daily basis from both organizations (DOE-RL).

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 10S-1, Sections 4, 5.1, and 6 of NQA-1-1983 will be implemented.

BQARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 10)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 10.3

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

For Site Characterization, additional guidance has been provided in Sections 10.2, 10.3, and 10.6 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 10S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, when one contractor is to inspect the work of another, written instructions should be furnished to the inspecting contractor defining his responsibilities and stating that he is not authorized to modify the terms and conditions of the contract, nor to direct additional work, nor to waive any requirements of the contract, nor to settle any claim or dispute. Copies of these instructions should be furnished to the contractor whose work is to be inspected, with a request that he acknowledge receipt on a copy to be returned to the contracting officer. In this manner, both contractors are on express notice of the authority, an limitations on the authority, of the inspecting contractor. (Reference DOE Order 6410.1).

The intent of this requirement will be met by implementation as stated. In addition, Supplement 10S-1, Section 2.2 of NQA-1-1983 will be implemented.

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 10)

Requirement

BWIP Project Implementation

In addition, Inspection requirements and testing required to be performed by the contractor or vendor shall be clearly established in the contract documents. Specific instructions shall be issued to define the scope of authority delegated to inspectors and the specific duties and responsibilities assigned to them, and concerned contractors and vendors shall be furnished copies of such instructions to avoid disputes concerning inspection or acceptance of services or supplies (DOE Order 6410.1)

NRC REVIEW PLAN SECTION 10.6

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

The intent of this requirement will be met by implementing Supplement 10S-1, Section 8 of NQA-1-1983.

In addition, each Inspection shall be documented in an Inspection Report, and all reports pertaining to an activity shall be furnished to the reviewer of the resultant data (Criterion 3) (DOE-RL).

BQARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 10)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 10.4 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 10S-1, Section 8 of NQA-1-1983 will be implemented.

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 8 of 10)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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

The intent of this requirement will generally be met by implementation of Criterion 9. In addition, Supplement 10S-1, Section 5 of NQA-1-1983 provides additional guidance.

BQARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 9 of 10)

Requirement

BWIP Project Implementation

REQUIREMENT 5: 10 CFR 50 APPENDIX B

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

The intent of this requirement will be met by implementation as stated. In addition, Supplement 10S-1, Section 5 of NQA-1-1983 may be implemented.

BQARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 10 of 10)

Requirement

BWIP Project Implementation

REQUIREMENT 6: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 10.5

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

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 10.5 of the NRC Review Plan.

The intent of this requirement will be met by implementing Supplement 10S-1, Section 3 of NQA-1-1983.

For the BWIP project, refer to the PMP/SEMP for identification of the BWIP designated inspectors.

BQARD
CRITERION 11: TEST CONTROL
REVISION 0 (sheet 1 of 8)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the minimum requirements that shall be met by the implemented Site Characterization Test Program. These controls are necessary in order to assure that information resulting from the Test Program is both complete and of demonstrably adequate quality. Note that Test Program as used by the NRC during Site Characterization refers to testing performed in advance of, or concurrent with, and in support of, the design of the repository system components (both engineered and natural). Therefore, this criterion requires significant interfacing with the repository design organization to assure that an adequate basis exists to support repository design development and verification. The criterion extends the design organization interfacing down to a level of detail that includes review of specific test procedures, as well as evaluation and acceptance of Test Results.

It is not intended that this criterion apply to testing performed incidental to the development of a test process that will later be used for site characterization testing, unless the purpose of the testing is to verify the adequacy of the test process design. Also excluded are preliminary borings and geophysical testing needed to decide whether site characterization should be undertaken, unless it is intended that the test results have an additional use within the site characterization phase.

NOTE: The requirements of this criterion may be selectively applied to "Exploratory" testing, upon issuance of an NRC Generic Technical Position.

BOARD
CRITERION 11: TEST CONTROL
REVISION 0 (sheet 2 of 8)

Requirement

BWIP Project Implementation

Potentially Licenseable Construction

The intent of this criterion during Construction is similar to its intent during Site Characterization, except that interfacing with the design organization is not required unless testing is for design prototype qualification. Therefore participants may utilize Site Characterization Criterion 11 or alternatively, NQA-1-1983 Basic Requirements 11 and Supplement 11S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 8)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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 intent of this requirement may be met by implementing the requirements of NQA-1-1983, Supplement 11S-1 as further defined herein.

Additional guidance has been provided in Sections 11.1, 11.2, and 11.3 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 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.

A. The intent of the first sentence of this requirement is not specifically addressed in NQA-1-1983, Supplement 11S-1. Therefore, the intent of this requirement will be met by implementing the guidance provided in figure 3 of the NRC Review Plan, as summarized below.

1. A Test Control Program Plan shall be developed which defines program requirements based on:
 - a. Site Issues
 - b. Information Needs
 - c. Program Objectives.

This plan shall include:

- a. Purpose
- b. Scope
- c. Description of work

BQARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 8)

Requirement

BWIP Project Implementation

- d. Specific Requirements
- e. Interfaces
- f. Equipment and facilities
- g. Milestones.

From this Test Control Program Plan, individual test plans shall be developed which define how needed information will be gathered. These plans will include:

- a. Test Objectives
- b. Scope of Tests
- c. Justification
- d. Test Descriptions
- e. Expected Results
- f. Listing of Required Technical Implementing Procedures
- g. Responsibilities/Personnel
- h. Schedule
- i. Format of Reports
- j. References
- k. List of Applicable QA Administrative Procedures
- l. List of Required QA Technical Procedures.

- B. The intent of the second sentence of this requirement is not specifically addressed in NQA-1-1983, Supplement 11S-1. Therefore, requirement "(a)" of this sentence will be met if implemented as stated and requirement "(b)" of this sentence will be met as implemented in Criterion 2 of the BQARD.
- C. The intent of sentence three is that the Quality Assurance organization shall, as a minimum, audit the implementation of the programmatic requirements of this Criterion in accordance with the requirements of Criterion 18, "Audits."

BQARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 8)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 11.2

Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9 (of the NRC Review Plan).

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 11S-1. Therefore the intent of this requirement will be met if implemented as stated. See Criterion 3 of the BQARD for the detailed interpretation of NRC Review Plan, Sections 3.7, 3.8, and 3.9

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 11S-1. Therefore the intent of this requirement will be met if implemented as stated.

Note that NRC Review Plan, Section 11.3 provides identification of some of the inspectable characteristics that are to be verified in accordance with Criterion 10, NRC Review Plan, Section 10.4.

BQARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 8)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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 operations, of structures, systems, and components.

The intent of this requirement will be met by implementing all the requirements of NQA-1-1983, Supplement 11S-1 Section 2, sentence 2, providing the following modification is made:

- A. The words "prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperations tests, and operational tests" shall be deleted and the words "site characterization activities" substituted in their stead. Involved are performance of 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 performed, including development of performance requirements for repository system components.
(DOE-RL)

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 8)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

Test procedures shall include provisions for assuring that 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.

NRC REVIEW PLAN SECTION 11.4

Test procedures or instructions provide for the following:

- A. The requirements and acceptance limits are 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.

For Site Characterization, the NRC has reworded this requirement to read as shown in the NRC Review Plan Section 11.4.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 11S-1. Therefore the intent of this requirement is met if implemented as stated.

In addition, the test procedures shall be complete to the extent that another qualified individual may at a later date, reproduce the test results, if deemed necessary. Test results that are outside of the identified acceptance limits, or other nonconformances with respect to a test procedure, shall be dispositioned utilizing Criterion 15, nonconformances. (DOE-RL)

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 8 of 8)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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

For Site Characterization, the NRC has reworded this requirement to read as shown in the NRC Review Plan Checklist, Section 11.5.

NRC REVIEW PLAN SECTION 11.5

Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.0 (of the NRC Review Plan).

The intent of this requirement will be met by implementing NQA-1-1983, Supplement 11S-1, paragraph 4, provided: the words "as described in Criterion 3" are added after the "responsible party."

The requirement for test records will be met by implementing the requirements of the NRC Review Plan Section 17.3, in lieu of the requirements of NQA-1-1983, Supplement 11S-1, paragraph 5.

BOARD
CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT
REVISION 0 (sheet 1 of 4)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the minimum controls necessary over Measuring and Test Equipment, in order to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are demonstrably accurate. Measures shall be established to define the scope of the program, describe the types of equipment to be controlled, the organizations responsible for implementing the program, and the records to be maintained to show evidence that the program is functioning.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore participants may utilize Site Characterization Criterion 12 or alternatively, NQA-1-1983 Basic Requirements 12 and Supplement 12S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 12.2

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

For Site Characterization, the NRC has reworded this requirement to read as shown in Sections 12.1 through 12.7. Additional guidance has been provided in Sections 12.1 through 12.7 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 12S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 12S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 12S-1. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 12S-1, Section 5 of NQA-1-1983 will be implemented.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 12S-1, Section 2.0, Sections 3.2 and 3.3 and Section 4.0 of NQA-1-1983 will be implemented.

BQARD

**CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)**

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 12S-1, Section 3.1 of NQA-1-1983 will be implemented.

In sentence 2 of the supplement section the words "the basis for calibration shall be documented" are deleted and the words "provisions are established to document acceptability of the calibration standard used" are added in their place.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 12S-1, Section 3.2 of NQA-1-1983 will be implemented.

In addition, refer to Criterion 15 for documentation requirements. (DOE-RL)

BOARD

**CRITERION 13: HANDLING, SHIPPING AND STORAGE
REVISION 0 (sheet 1 of 3)****BWIP Project Implementation****Site Characterization**

The intent of this criterion during Site Characterization is to establish the minimum requirements for the control of samples during Handling, Shipping and Storage to assure that samples are appropriately and adequately handled, preserved, stored, packaged, and shipped. Significant interfacing is required with the Site Testing Organizations to establish correct methods for the preservation and shipping of sensitive items such as Environmental and Geological samples taken during Site Characterization. This criterion may also have applicability to other critical site characterization items. Note Test Procedure Requirements.

Potentially Licenseable Construction

The intent of this criterion during Construction is to establish requirements for controlling the handling, storage, shipping, cleaning and preservation of materials and equipment used in level I repository construction, in order to prevent damage or deterioration.

Implementation of the requirements within Basic Requirements 13 and Supplement 13S-1 of NQA-1-1983 will meet the intent of this criterion, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 13: HANDLING, SHIPPING AND STORAGE - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 3)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, Additional guidance has been provided in Section 13.1 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 13S-1, Sections 2 and 4, and Sections 3.3 and 3.4 of NQA-1-1983 will be implemented.

BOARD
CRITERION 13: HANDLING, SHIPPING AND STORAGE - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 3)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 13.2 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 13S-1, Sections 3.1 and 3.2 of NQA-1-1983 will be implemented.

1/16/86

BOARD
CRITERION 14: INSPECTION, TEST AND OPERATING STATUS
REVISION 0 (sheet 1 of 4)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the minimum requirements for controlling the status of Site Characterization Inspection, Test, and Testing equipment to assure the status of inspection and test activities for a specific sample or material are known with certainty, and the operating/operational status of test equipment is also known.

In addition, it is preferred that project participants implement an "integrated lab traveler" system where both test procedural steps and inspection steps are sequentially listed, completion signatures are recorded, and any NCR's are identified. Alternate status methods may also be acceptable.

Potentially Licenseable Construction

The intent of this criterion during Construction is similar to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 14 or alternatively, NQA-1-1983 Basic Requirements 14, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BOARD

**CRITERION 14: INSPECTION, TEST AND OPERATING STATUS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)**

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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 powerplant or fuel reprocessing plant.

NRC REVIEW PLAN SECTION 14.1

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

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 14.1 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, the authority for the application and removal of markings shall be specified. (DOE-RL)

In addition, procedures shall be established to control the issuance and use of unique marking devices such as stamps, tags, labels, etc., to assure traceability to the individual or to the specific activity utilizing the marking device. (DOE-RL)

BQARD
CRITERION 14: INSPECTION, TEST AND OPERATING STATUS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 14: INSPECTION, TEST AND OPERATING STATUS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated, provided the following modification is made:

- a. The reworded requirement is: Measures shall also be established for indicating the operating status of structures, systems, and components of the high-level waste repository and site characterization testing equipment, such as by tagging valves and switches to prevent inadvertent operation.

In addition, the authority for application and removal of tags shall be specified. (DOE-RL)

BQARD

CRITERION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS
REVISION 0 (sheet 1 of 4)

BWIP Project Implementation

The intent of this criterion during Site Characterization is to establish the minimum requirements for controlling Project Nonconformances, to assure that all nonconformances affecting site characterization activities are identified, documented, segregated, reviewed, tracked, dispositioned, affected organization notified, corrected, and trended, and the implementation of the corrective action is verified.

Refer to NQA-1-1983 Supplement S-1 for Nonconformance definition. Note that procedural deficiencies are included. Because the design organization originates site characterization technical procedures, all NCR's related to site characterization technical activities shall, in general, be dispositioned by the responsible design organization.

An additional NCR disposition "RETEST" may be used during site characterization. "REJECT" shall not be used to disposition test data unless the root cause clearly establishes a basis for rejection of the data. "ACCEPT" or "USE-AS-IS" dispositions generally implies a design change will be made to the technical procedure.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore participants may utilize Site Characterization Criterion 15 or alternatively, NQA-1-1983 Basic Requirements 15 and Supplement 15S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Section 15.1 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 15S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD
CRITERION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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

NRC REVIEW PLAN SECTION 15.2

QA responsibilities related to nonconformance control are described.

NRC REVIEW PLAN SECTION 15.3

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

NRC REVIEW PLAN SECTION 15.4

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

For Site Characterization, additional guidance has been provided in Sections 15.1, 15.2, 15.3, and 15.4 of the NRC Review Plan. In addition, Supplement 15S-1, Sections 2, 3, and 4 of NQA-1 will be implemented.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 15S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 15S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 15S-1. Therefore, the intent of this requirement will be met if implemented consistent with Criterion 16.

BOARD
CRITERION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

The intent of this requirement will be met by implementing as stated. In addition, Supplement 15S-1, Sections 4.4 and 4.5 of NQA-1-1983 will be implemented.

1/16/86

BOARD
CRITERION 16: CORRECTIVE ACTION
REVISION 0 (sheet 1 of 4)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the minimum requirements for controlling project corrective actions, to assure that conditions adverse to quality are identified and corrected in a timely manner. Each Project Participant shall identify the need for corrective action, assure that corrective action is initiated (which may involve actions to preclude recurrence), and verify that corrective action is implemented in a timely manner. Participants shall define a method to classify significant conditions adverse to quality and shall provide for documenting and reporting these conditions, including actions taken to preclude repetition, as well as evaluation of the impact on completed work, and report these actions to higher management for review and assessment.

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore participants may utilize Site Characterization Criterion 16 or alternatively, NQA-1-1983 Basic Requirements 16, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 16: CORRECTIVE ACTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

For Site Characterization, additional guidance has been provided in Sections 16.1, 16.2, and 16.3 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 16.1

Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 16: CORRECTIVE ACTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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 intent of this requirement is not specifically addressed in NQA-1-1983 Supplements. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 16: CORRECTIVE ACTION - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 4)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 16.4 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, trend analysis of NCR's and audit findings shall be used to help identify significant conditions adverse to quality, and the cause of the conditions. (DOE-RL)

In addition, significant conditions adverse to quality may require an Unusual Occurrence Report. (HQ-OCRWM)

Unusual Occurrence Reporting - Contractors are required to report any significant event which results in any deviation from the planned or expected behavior of an activity or operation of course of events which has or could have significant programmatic, (reliability, cost, or schedule) safety, health, or environmental impacts. Significant events are to be reported in accordance with DOE Order 5000.3 (HQ-OGR).

In addition, significant conditions adverse to quality shall be reported to both the Integrating Contractor and DOE-RL, BWIP QA as soon as possible but not later than 5 calendar days from the date of occurrence. (DOE-RL)

1/16/86

BQARD
CRITERION 17: QUALITY ASSURANCE RECORDS
REVISION 0 (sheet 1 of 7)

BWIP Project Implementation

Site Characterization

The intent of this criterion during Site Characterization is to establish the requirements for control of Project Records, to assure that documents and samples which furnish evidence of activities affecting quality remain valid and retrievable.

In general, a QA record is preceded by a controlled document. Upon completion of the controlled document, it is incorporated into the QA Records System. Subsequent changes to the controlled document also become QA Record, identifiable to but distinct from the initial QA Records. It is essential that QA Records be correct and complete, and allow accurate determination of the "final" or "as-built" conditions.

In addition, records submitted to the Commission must be of demonstrable validity. Therefore, access to the "QA Record" copy of BWIP documents and samples will be limited and controlled. Corrections to a QA Record may be accomplished under limited and controlled conditions, provided the original, incorrect area of the QA Record remains legible. Samples, if removed from the Controlled Storage Facility, shall be handled in such a manner as to preclude adulteration. (DOE-RL)

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 17 or alternatively, NQA-1-1983 Basic Requirements 17 and Supplement 17S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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

The intent of this requirement will be met by implementation as stated.

NRC REVIEW PLAN SECTION 17.2

QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 17S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BQARD

**CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 7)**

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 17.1

The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspections; test, 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.

For Site Characterization, additional guidance has been provided in Section 17.1 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 17S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, each participant shall establish a definitive list of documents which are to become Quality Assurance Records. (DOE-RL)

In addition, each participant's records program shall be consistent with the project Records Management Plan. (HQ-OGR)

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

The records shall also include closely related data such as qualifications of personnel, procedures, and equipment.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 17S-1. Therefore, the intent of this requirement will be met if implemented as stated.

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 17S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, the inspection record shall be identifiable to the test activity inspected, and the person evaluating test or inspection results shall be identified. (DOE-RL)

BQARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 5: 10 CFR 50 APPENDIX B

Records shall be identifiable and retrievable.

The intent of this requirement will be met by implementing Supplement 17S-1, Sections 2 and 5 of NQA-1-1983, provided any Participants Record Storage Facility is consistent with Requirement 17.4.

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 6: 10 CFR 50 APPENDIX B

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

The intent of this requirement will be met by implementing Supplement 17S-1, Sections 2 and 4 of NQA-1-1983.

Additional guidance has been provided in Section 17.4 of the NRC Review Plan.

NRC REVIEW PLAN SECTION 17.4

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

The intent of this requirement will be met by implementing Supplement 17S-1, Sections 4.1 and 4.4 of NQA-1-1983.

1/16/86

**BQARD
CRITERION 18: AUDITS
REVISION 0 (sheet 1 of 7)**

BWIP Project Implementation

The intent of this criterion during Site Characterization is to establish requirements for a comprehensive system of planned and periodic audits, as well as establish controls over the audit process, in order to assure that the management feedback information contained in BWIP audit reports is timely, impartial, and correct.

Project participants are advised that audit planning must include consideration of surveillance results, inspection results, previous audit results, NCR's, and project deliverables, as well as the need to provide coverage over a defined period of time.

After confirmation of QA program implementation, audits performed within BWIP shall place emphasis upon verification of the achievement of quality in project end products. (Reference: NRC Memorandum dated 8/5/85, from G. Ted Ankrum to Leland C. Rouse, subj., IE comments on DOE's audit of R.M. Parsons Company.)

Potentially Licenseable Construction

The intent of this criterion during Construction is identical to its intent during Site Characterization. Therefore, participants may utilize Site Characterization Criterion 18 or alternatively, NQA-1-1983 Basic Requirements 18 and Supplement 18S-1, provided NQA-1 implementation is to a level of detail consistent with NRC requirements for adequate project control.

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 2 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 1: 10 CFR 50 APPENDIX B

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.

NRC REVIEW PLAN SECTION 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.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, additional guidance has been provided in Sections 18.1, 18.2, 18.3, 18.6, 18.7, and 18.8 of the NRC Review Plan.

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 18S-1. Therefore, the intent of this requirement will be met if implemented as stated.

The intent of this requirement will be met by implementing Supplement 18S-1, Section 2 and each audit of the audit plan shall receive the detailed planning required by Section 3.1 of NQA-1-1983.

In addition, frequency of regularly scheduled internal and external audits should be based upon evaluation of all applicable and active elements of the quality assurance programs. These evaluation should include an assessment of the effectiveness of the applicable and active elements of the program based upon such information as the following: (DOE-RL)

- (a) Previous audits and corrective actions;
- (b) Nonconformance reports;
- (c) Independent information (e.g., from other sources such as generic experience of the nuclear industry, ASME, peer organizations, regulating bodies, etc.).

BOARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 3 of 7)

Requirement

BWIP Project Implementation

Regularly scheduled audits should be supplemented by additional audits for one of the reasons given in (a) through (f) below:

- (a) To determine the capability of a Supplier's quality assurance program prior to awarding a contract or purchase order;
- (b) When after award of a contract sufficient time has elapsed for implementing the quality assurance program and it is appropriate to determine that the organization is adequately performing the functions as defined in the quality assurance program description, codes, standards, and other contract documents;
- (c) When significant changes are made in functional areas of the quality assurance program such as significant reorganization or procedure revisions;
- (d) When it is suspected that the quality of an item is in jeopardy due to deficiencies in the quality assurance program;
- (d) When a systematic, independent assessment of program effectiveness is considered desirable;
- (f) When it is necessary to verify implementation of required corrective action.

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementing Supplement 18S-1, Section 4 of NQA-1-1983.

In addition, the external audit shall include an evaluation of the extent to which top management is aware of and acts on critical project information related to quality. (DOE-RL)

In addition, participants shall submit audit schedules, audit schedule revisions, and audit reports to the integrating contractor. (HQ-OGR)

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 4 of 7)

Requirement

BWIP Project Implementation

NRC REVIEW PLAN SECTION 18.6

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

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 18S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, each audit report shall include an "Executive Summary" of the audit findings. (HQ-OCRWM)

NRC REVIEW PLAN SECTION 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.

The intent of this requirement will be met by implementing Supplement 18S-1, Section 6 of NQA-1-1983.

NRC REVIEW PLAN SECTION 18.8

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

The intent of this requirement is not specifically addressed in NQA-1-1983, Supplement 18S-1. Therefore, the intent of this requirement will be met if implemented as stated.

In addition, the impact of the findings upon completed work will be evaluated (DOE-RL).

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 5 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 2: 10 CFR 50 APPENDIX B

The audits shall be performed in accordance with the written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.

NRC REVIEW PLAN SECTION 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.

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 18.5 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. In addition, Supplement 18S-1, Sections 3.1, 3.2, and 3.3 of NQA-1-1983 will be implemented.

In addition, auditor orientation should be specific to the audit to be performed, so that the auditors are prepared for their specific roles during the audit, and are familiar with the audited organization, key individuals, and policies and procedures, as well as how to select systems for reviews. (DOE-RL)

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 6 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 3: 10 CFR 50 APPENDIX B

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

NRC REVIEW PLAN SECTION 18.4

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

For Site Characterization, the NRC has reworded this requirement to read as shown in Section 18.4 of the NRC Review Plan.

The intent of this requirement will be met by implementation as stated. The auditee's and auditor's organizations (for external audits) respond to this Requirement and to Requirement 18.6.

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 7 of 7)

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

Follow-up action, including reaudit of deficient areas, shall be taken where indicated.

The intent of this requirement will be met by implementing Supplement 18S-1 Sections 6 and 7 of NQA-1-1983.

memorandum

DATE: MAY 20 1986

REPLY TO
ATTN OF: RW-24

SUBJECT: Approval of SRPO Quality Assurance Plan?

TO: Jeff Neff, SRPO-CH

We have reviewed the SRPO Quality Assurance Plan and approve it for use and implementation. We were disappointed that the plan did not specify how the SRPO will meet the various QA requirements imposed. We feel the plan does a fine job of specifying the QA requirements for the Salt Repository program, but fails to specify how the SRPO will meet them.

In our review of the four SRPO Quality Assurance Administrative Procedures (QAAP's) submitted to us for approval, we are finding the answers to how SRPO will meet the QA requirements. We look forward to receiving the remaining QAAP's and feel that the SRPO QA plan together with the QAAP's will provide a satisfactory "plan" for SRPO.

We have also reviewed the following QAAP's and approve all for issuance and implementation:

QAAP No.	Title	Revision	Issue Date
2.1	Preparation of the QA Plan	0	01/06/86
5.1	Preparation of QAAP's	0	01/06/86
18.1	Auditor and Lead Auditor Qualification and Certification	0	01/06/86
18.2	Planning, Scheduling, and Performance of Audits	0	01/06/86

I would like to ask you to prepare a matrix showing which elements of the SRPO QA plan are delegated to contractors and which are to be carried out by SRPO. I also want to remind you that plans and procedure are not to be issued as "final" until approved by OGR; it is permissible to issue them for interim use pending OGR approval, provided that those to whom they are issued are so advised.

- 2 -

Please contact Carl Newton if any questions arise about our approval of your plan or the four QAAP's.



William J. Purcell
Associate Director for
Office of Geologic Repositories

APPENDIX A

Quality Assurance Manual Evaluation

Check List

Project Name Salt Repository Project

Revision No. 0

Manual Title QA Plan

Revision Date 12/4/85

Review Date 1/29/86

To be acceptable, the program must meet the applicable portions of 10 CFR 50, Appendix B; and HQ-OGR QA Plan, OGR/B-3.

Organization (Section 1.0)

1. Is the responsibility for the overall program 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, does the QA organization verify the proper performance of work through implementation of appropriate QA controls?
2. Does DOE describe major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations?
3. Has the DOE described how responsibility is exercised for the overall QA program? Is the extent of management responsibility and authority from DOE headquarters and from the field office addressed?
4. Does DOE evaluate the performance of work delegated to other organizations? Does this include audits of the prime contractor's QA program and audits of representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE? Is the frequency and method of evaluation specified?
5. Are qualified individual(s) or organizational element(s) identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities?
6. Have clear management controls and effective lines of communication been established for QA activities between DOE and its contractor, to assure direction of the QA program?

Yes	No	N/A	Para.
X			1.3
			1.3.3
X			1.3
X			1.3 & 1.3.4
X			1.3.4
X			1.3.5.3
X			1.4.2
X			1.3.4 1.4.1.1
X			1.3.5.3 1.4.1.1

Organization (Continued)

7. Do organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines or responsibility? Are the repositories of each major organizational element specified?

8. Is the QA organization involved in the aspects of the high level waste repository program that affect safety and waste isolation? Are the extent of QA controls determined by 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?

9. Has DOE described the QA responsibilities of each of the organizational elements noted on the organization charts?

10. Does the DOE identify a management position within its 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 it 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 been established?

c) Has responsibility for approval of QA Manual(s), changes thereto, and interpretations there of been established?

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

11. Is verification of conformance to established requirements 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

12. Do persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a) Identify quality problems?

Yes	No	N/A
X		
X		
X		
X		
X		
X		
X		
X		
X		
X		
X		
X		
X		

Attachment
A & B
1.4.1.1

1.3

1.3.4

1.4.1.6

Attachment
A & B
1.4.1.4

1.4.1.3
1.4.1.6

1.4.1.6.C

1.4.1.6.c

1.4.1.4

1.3.3

Organization (Continued)

- b) Initiate, recommend, or provide solutions through designated channels?
- c) Verify implementation of solutions?
- d) Stop unsatisfactory work?
- 13. Have the persons and organizations with the above authority been identified and is a description of how those actions are carried out provided?
- 14. Have provisions been established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel?
- 15. Are policies regarding the implementation of the QA program documented and made mandatory?
- 16. Are the persons responsible for supporting the overall QA program identified and do they have appropriate organizational position and responsibilities to exercise proper control over the QA program? Are these individuals free from non-QA duties and thus give full attention to assuring that the QA program is being effectively implemented?
- 17. Does the Plan establish line and staff organizational responsibilities for QA program implementation within the project office organizational structure and identify interfaces with HQ and contractors?

Yes	No	N/A
X		
X		
X		
X		
X		
X		
X		
X		

1.3.3
 1.3.3
 1.3.3
 1.3.3.1
 1.3.1
 1.4.1.3
 1.3.1
 1.4.1.6
 1.3.5

QA Program (Section 2.0)

1. Does the QA program include all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2? Are the items and activities covered by the QA program 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? Are these terms defined as numerical performance objectives and standards? Does the rationale include systems analyses that are used to determine what specific items and activities are covered?
2. Does the QA program include a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program? Is guidance for the content of documentation of computer codes provided by NUREG-0856, "Final Technical Position on Documentation of Computer codes for High-Level Waste Management?"
3. Have provisions been 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?
4. Does the QA organization review and document concurrence with the quality-related procedures relative to QA requirements?
5. Does the QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls that are to be applied to specified items and activities? Does this effort involve 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?
6. Are existing or proposed QA procedures and detailed technical procedures identified and documented, reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met?

Yes	No	N/A	Para.
X			2.2
X			2.4.1
X			2.4.2
X			2.4.3
X			2.4.4
X			2.4.5

QA Program (Continued)

7. Is a description 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?
- Do these measures include:
- a) Frequent contact with program status through reports, meetings, and/or audits?
- b) Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked?
8. Have indoctrination, training and qualification programs been 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? Does a system of annual appraisal and evaluation satisfy this criterion?
- e) Are qualified personnel certified in accordance with applicable codes and standards?
9. Does the Plan describe the project office QA program and identify applicable lower tier documents, such as QA Administrative Procedures which, with the QA plan, comprise the project office overall QA program?
10. Does the Plan describe the process for the project office review and approval of the QA programs of their contractors?

Yes	No	N/A
X		2.3.8 2.4.11
X		2.4.11.a
X		2.4.11.b
X		2.4.12
X		2.4.12.a
X		2.4.12.b
X		2.4.12.c
X		2.4.12.d
X		2.4.12.e
X		Attachment A 2.3.2
X		2.3.10

QA Program (Continued)

11. Does the Plan identify those elements of the overall field project office QA program that have been delegated to the contractors and describe the controls that are implemented by the project office to monitor the performance of the contractor in these delegated elements?

12. Does the Plan describe the program being implemented for the indoctrination and training of the project office personnel who perform activities affecting quality? Does the Plan identify the areas of inspection and testing that will require training, qualification and certification, and describe the method for accomplishing this?

Yes	No	N/A
X		2.3, 10 2.4
X		2.4, 13

Design Control (Section 3.0)

1. Are the definitions of design, design information, and design activities used in the design control program defined in this section? (The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system).
2. Does it include designs at each stage of design development (i.e., from conceptual design to final design)?
3. Is the design control program implemented at the time of submission of the Site Characterization Plan and include design and design activities as described in 1? Does it provide for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents?
4. Are performance requirements specified for repository system components to support:
 - a) identification of which items are important to waste isolation?
 - b) establishment of a graded QA approach;?
 - c) establishment of data gathering and analysis needs?
5. Are organizational responsibilities described for preparing, reviewing, approving, verifying and validating design and design information documents?
6. Are errors and deficiencies in approved design information documents documented, and action taken to assure that all errors and deficiencies are corrected?
7. Are interface controls among organizations or groups involved in design development and other design activities described?
8. Do 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?
9. Have procedures been established that describe for verification of designs and design activities, the verifier who 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:

Yes	No	N/A	Para.
X			Glossary: 3.4.1
X			3.2
X			3.2.3 3.4
X			3.4
X			Sec. 2.0 Para. 2.3.3
X			Sec. 2.0 Para. 2.3.3
X			Sec. 3.0 3.4 & 3.4.1
X			3.4.1.
X			3.4.5.6
X			3.4.10
X			3.3.2.4. a
X			3.4.5.3

Design Control (Continued)

- 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?
- 10. 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, is a peer review conducted? Do the procedures define the selection process for a peer group, and the process by which the peer group conducts its review? Is a peer review a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work? Have outside consultants been retained for needed expertise, where required?
- 11. Have the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation been identified in the procedures?
- 12. Are design changes, including field changes, subjected to the same design controls that were applicable to the original design? Is a configuration control system in place at the earliest practicable time? Are these changes analyzed to assure that change is required? Have associated changes to procedures and training been considered, and are changes communicated to all affected groups or individuals?
- 13. Does the plan describe the project office process for monitoring contractors' design controls and the extent of participation of the project office in design reviews?

Yes	No	N/A
X		3.4.5.3
X		3.4.5.3
X		3.4.6.3
X		3.4.6.3
X		3.4.6.3
X		3.4.5
X		3.4.9
X		3.4.9
X		3.4.9
X		3.3.3

Procurement Document Control (Section 4.0)

1. Have procedures been 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? Are adequate acceptance and rejection criteria, stated where appropriate? Have procurement documents been prepared, reviewed, and approved in accordance with QA program requirements? Do procurement documents require contractors, subcontractors and consultants to provide an acceptable quality assurance program?
2. Are the organizational responsibilities described for:
 - a) Procurement planning?
 - b) The preparation, review, approval, and control of procurement documents?
 - c) Supplier selection?
 - d) Bid evaluations?
 - e) Review and concurrence of supplier QA programs prior to initiation of activities affected by the program?
 - f) Is the involvement of the QA organization described in the procedure?
3. Does the plan describe the process for the project office review of procurement documents to assure that appropriate quality provisions have been specified?
4. Does the plan describe the controls applied by the project office over the contractors procurement activities?

Yes	No	N/A	Para.
X			4.3.2.3
X			4.4.1
X			
X			
X			4.4
X			4.4
X			4.3.1
X			4.3.1
X			4.3.2.3
X			4.3.2.3
X			4.3.2 3.4 205 1/10/06
X			4.4.1

Instructions, Procedures and Drawings (Section 5.0)

1. Are organizational responsibilities described for assuring that quality-related activities are:
 - a) Specified in instructions, procedures, and drawings?
 - b) Accomplished through implementation of these documents?
2. Have procedures been established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality-related activities have been satisfactorily accomplished?
3. Have these documents been verified and approved as described in Section 3, Design Control?
4. Does the plan describe the project office's program for developing, reviewing, approving, and controlling the distribution of internal procedures, instructions, and drawings that affect quality?
5. Does the plan identify the types of documents to be submitted by the contractors for project office review and approval and describe this review and approval process?

Yes	No	N/A	Para.
X			5.3
X			5.3
X			5.4
X			5.3.1.2. ^c d
X			5.3.1.2 a, b, c, d
X			5.3.1.1.a & 5.3.2

Document Control (Section 6.0)

1. Is the scope of the document control program described, and the types of controlled documents identified?
2. Have procedures for the review, approval, issuance, and revision of documents been established? Do these procedures assure technical adequacy and inclusion of appropriate quality requirements? Does the QA organization review and concur with these documents with respect to quality-related aspects?
3. Have procedures been established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work?
4. Are procedures established that describe how obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.?
5. Has a master list or equivalent document control system been established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents?
6. When documents which require verification are released prior to verification, are they so identified and controlled?
7. Does the plan describe how the project office controls documents being transmitted to and from contractors and other project participants to assure controlled transmittal, receipt, internal distribution, and recall?

Yes	No	N/A	Para.
X			6.1 & 6.4.1.a
X			6.4.1.b
X			6.4.1.b
X			6.3.1.2
X			6.4.1.e
X			6.4.1.f
X			6.4.1.g
X			6.4.2.3
X			6.4.1.h & 6.4.1.i

Identification and Control of Items (Section 8.0)

1. Have controls been established that describe the methods to identify and control samples? Does the description include organizational responsibilities?
2. Have procedures been established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto?
3. Can identification of samples be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports?
4. Is correct identification of samples verified and documented prior to release for use or analysis, described?
5. Does the plan describe the methods used by the project office to monitor contractors' inspection, testing, calibration, and sample identification activities?

Yes	No	N/A	Para.
X			8.1 & 8.3
X			8.4.2.1
X			8.4.1
X			8.4.6
X			8.3.1

Control of Special Processes (Section 9.0)

1. Is the criteria for determining what special processes are to be controlled described? Is a complete listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, provided?
2. Are organizational responsibilities, including those for the QA organization, described for qualification of special processes, equipment, and personnel?
3. Are procedures, equipment, and personnel associated with special processes qualified and are they in conformance with applicable codes, standards, QA procedures, and specifications? Is the QA organization involved in the qualification activities to help assure they are satisfactorily performed?
4. Have procedures been established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel?
5. Have qualifications records of procedures, equipment, and personnel associated with special processes been established and maintained?

Yes	No	N/A	Para
X			9.1 & 9.2
X			9.3
X			9.4.3
X			9.4.3.4
X			9.4.4.2
X			9.4.4.1

Inspection (Section 10.0)

1. Does the scope of the inspection program describe an effective inspection program and has it been implemented? Do program procedures provide criteria for determining when inspections are required or define how and when inspections are performed? Does the QA organization participate in these functions?
2. Are the organizational responsibilities for inspection described? Are individuals performing inspections part of the QA organization? For inspections requiring special expertise are other individuals used providing the independence of the inspection function is maintained?
3. Has a qualification program for inspectors been established and documented, and the qualifications and certifications of inspectors kept current?
4. Do 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?
5. Do procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector?
6. Are inspection results documented and evaluated, and their acceptability determined by a responsible individual?

Yes	No	N/A	Para.
X			10.1 & 10.2
X			10.3
X			10.3.1.2
X			10.4.5.C
X			10.4.5.a
X			10.4.1
X			e
X			b
X			c
X			d
X			e
X			f
X			g
X			10.4.1-h
X			10.4.4

Test Control (Section 11.0)

1. Does the description of the scope of the test control program indicate an effective test program has been established?

Does the program's procedures provide criteria for:

 - a) Determining when a test is required or how and when testing activities are performed?
 - b) Requiring that the test program is conducted by trained or appropriately qualified personnel?
 - c) The QA organization to audit these functions?
2. Are test plans and procedures reviewed in accordance with the verification requirements in Design Control?
3. Are 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, identified?
4. Do test procedures or instructions provide for the following:
 - a) That the requirements and acceptance limits are 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?
5. Are test results documented, evaluated, and their acceptability determined by a responsible individual or group as described in Design Control?

Yes	No	N/A	Para.
X			11.1
X			a & b
X			c
X			Section 18.18.4.1..
X			11.4.1.4
X			11.4.2.1.2
			11.4.2.1
X			b
X			c
X			h
X			d
X			e
X			f
X			g
X			h
X			11.4.5

Control of Measuring and Test Equipment (Section 12.0)

1. Has the scope of the program for the control of measuring and test equipment been described and are the types of equipment to be controlled established?
2. Are QA and other organizations' responsibilities described for establishing, implementing, and assuring effectiveness of the calibration program?
3. Have procedures been established and do they describe 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? Is the review and documented concurrence of these functions identified?
4. Is measuring and test equipment labeled, tagged or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data?
5. Is measuring and test equipment calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability, characteristics, and other conditions which could affect measurement?
6. Are calibration standards traceable to nationally recognized standards? Where national standards do not exist, have provisions been established to document acceptability of the calibration standard used?
7. When measuring and test equipment is found to be out of calibration, are evaluations made and documented to determine the validity and acceptability of measurements performed since the last calibration? Are inspections or tests repeated on items determined to be suspect?

Yes	No	N/A	Para.
X			12.1 & 12.2
X			12.3
X			12.4 & 12.4.1
X			12.4.7
X			12.4.7.3
X			12.4.4.1
X			12.4.3.1
X			12.4.3.2
X			12.4.4.2
X			12.4.4.3

Handling Storage and Shipping (Section 13.0)

1. Are sampling, handling, preservation, storage packaging, and shipping requirements established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions?
2. Have procedures been established that describe 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?

Yes	No	N/A	Para.
X			13.4
X			13.4.1.4

Inspection, Test and Operating Status (Section 14.0)

1. Have procedures been established which describe the use of label, tags or other markings to indicate the status of inspections or tests on an item?
2. When this function is delegated to others, does the program describe the controls imposed on the contractors to determine that the work is accomplished to the requirements of NQA-1 and/or Appendix B?

Yes	No	N/A	Para.
X			14.4.1
X			14.3.2

Nonconformances (Section 15.0)

1. Have procedures been established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities? Do the procedures identify individuals authorized to dispose of and close out nonconformances?
2. Is the QA responsibilities related to nonconformance control described in the procedure?
3. Does documentation identify and describe the nonconformance, disposition the nonconformance, and include signature approval of the disposition?
4. Do the procedures require that nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances?
5. Does it also require that significant results be reported to upper management for review and assessment?
6. Does the plan describe the field project offices' procedures for identifying and reporting unusual occurrences which are encountered during their own surveillance and review activities?
7. Does the plan include provisions for analyzing both the project office and contractor-identified non-conformances to permit early detection of quality trends?
8. Does the plan develop the criteria and describe the method for reporting, evaluating, and follow-up of unusual occurrences?

Yes	No	N/A	Para.
X			15.4.1.1 & 15.4.1.
X			15.4.4.1
X			15.3.2.2
X			15.4.7
X			TBD QAAP16.
X			15.4.7
X			15.4.7

Corrective Action (Section 16.0)

1. Have procedures been written, establishing an effective corrective action program? Has the QA organization reviewed and documented concurrence with the procedures?
2. Is corrective action documented and initiated following a nonconformance to preclude recurrence? Is the QA organization involved in the documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied?
3. Is follow-up action taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner?
4. Are significant conditions adverse to quality, the cause of the condition, and the corrective action taken to preclude repetition documented and reported to immediate management and upper levels of management for review and assessment?

Yes	No	N/A	Para.
X			16.1
X			16.3.2.2
X			16.4.3
X			16.4.15
X			16.4.5
X			16.4.4

Quality Assurance Records (Continued)

- 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 records are the designated ones?
- e) The rules governing access to and control of the files?
- f) A method of maintaining control of and accountability for records removed from the storage facility?
- g) A method for filing supplemental information and disposal of superseded records?
- 8. Does the record storage facility meet the requirements of a:
 - a) Single Facility
 - 1. Reinforced concrete, concrete block, masonry or equal construction?
 - 2. Forced air circulation with filter system?
 - 3. Fire protection system?
 - 4. Sealant applied to walls as a moisture or condensate barrier?
 - b) Dual Facility
 - 1. Sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard?
 - 2. Meet the other requirements of limited access, record index, etc.?
- 9. If this function is delegated, does the plan describe how the requirements are transmitted to the contractor?

Yes	No	N/A
X		c
X		d
X		e
X		f
X		g
X		17.4.14
X		17.4.12.1
X		a
X		g
X		h
X		d
X		17.4.14.3
X		17.4.14.3
X		17.4.14.3
X		17.3.3

Quality Assurance Records (Section 17.0)

1. Is the scope of the records program described in a written procedure? Do 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?
2. Are QA and other organizations identified and their responsibilities described for the definition and implementation of activities related to QA records?
3. Do 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?
4. Are records classified as Lifetime or Nonpermanent in accordance with written instructions?
5. Does the record and/or record indexing system provide sufficient information to permit identification between the record and the item or activity to which it applies?
6. Does the record indexing system include as a minimum:
 - a) Record retention time?
 - b) Location of the record in the system?
7. Does the record procedure include, as a minimum, the following:
 - a) A description of the storage facility?
 - b) The filing system to be used?

Yes	No	N/A	Para.
X			17.3
X			17.4.2
X			17.3
X			Section 10.0
X			10.4.7
			a
X			b
X			c
X			d
X			e
X			f
X			17.4.16
X			17.4.6
X			17.4.4
X			17.4.4
X			17.4.10
X			a
X			b

Audits (Section 18.0)

1. Does the plan describe internal and external audits to assure that procedures and activities comply with the overall QA program to be performed by DOE and its contractors? Does it describe DOE performed audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program?
2. Is an audit plan prepared identifying audits to be performed, their frequencies, and schedules? Are audits regularly scheduled based upon the status and safety importance of the activities being performed and are they initiated early enough to assure effective QA?
3. Do 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?
4. Is audit data analyzed by the QA organization and the results reported to responsible management for review, assessment, and appropriate action?
5. Are audits performed in accordance with pre-established written procedures or check lists?
6. Is a tracking system for audit findings established to help assure that all findings are appropriately addressed and to trend audit findings?
7. Does the audited organization describe in a formal report the corrective action to be taken to address findings? Is this report submitted to the auditing organization and/or responsible management?
8. In the resolution of findings, is the root cause of each finding identified and corrective action for it described?
9. Are audits conducted by properly trained and certified personnel having no direct responsibilities in the areas being audited?
10. Are auditors trained and certified to a written procedure?
11. Are records maintained of auditors training, qualification and certifications?

Yes	No	N/A	Para.
X			18.4
X			18.4
X			18.4.2
X			18.4.1.e
X			18.4.9
X			18.4.8
X			18.4.1.f
X			18.4.10
X			18.4.13.
X			18.4.13.2
X			18.4.13.3 18.3.2.2.c