

Department of Energy
Washington, DC 20585

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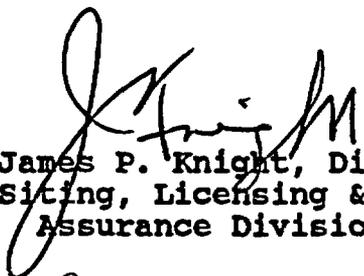
Mr. B.J. Youngblood, Chief
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards.

Dear Mr. Youngblood:

Attached for your review are the responses to the NRC's Request for Additional Information (RAI) on the BWIP QA Plan Revision "1" and the Basalt Quality Assurance Requirements Document (BQARD), Revision "0" (Refer to attached RAI dated March 9, 1987).

Also attached for your information are the BWIP QA Plan (DOE/RL 86-6), Revision 3, note that this is undated and not yet approved by BWIP, and the BQARD (DOE/RL 86-1), Revision 3, March 1987 (Draft). These revisions compromise the Incorporation/Resolution of the NRC's comments.

HQ-OGR has performed a review of the responses to the RAI, the BWIP QA Plan, Revision 3 and the BQARD, Revision 3 and concludes that the necessary incorporations have been made to resolve the NRC comments.


James P. Knight, Director
Siting, Licensing & Quality
Assurance Division

Attachments

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8712100149 870828 PDR WASTE WM-10	PDR	88132270 WM Projects WM-10 PDR w/encl (Return to WM, 623-55)	WM Record Files: 101.7 LPDR w/encl
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WM Record File

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WM Project

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Docket No.

PDR

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Distribution:

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SUBJECT: Transmittal of DOE/OGR Response to the NRC's RAI on
the BWIP QA Plan (Rev.1) and the "BQARD" (Rev. 0)
FROM: J.P. Knight
TO: B.J. Youngblood, NRC
PC CODE: KS 104 (MARIE ADAMS' IBM)
ORIGINATOR: KARL SOMMER

QA FILE # E3
OCRWM CCRU, RW-13 (5)
OCRWM ARCHIVES (2)
ORIGINATOR'S CHRON: SOMMER
OGR READING FILE
S,L,& QA DIV CHRON

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAR 9 1987

Mr. James Knight, Director
Siting, Licensing, and Quality Assurance Division
Office of Geologic Repositories
Office of Civilian Radioactive Waste Management
U.S. Department of Energy RW-20
Washington, DC 20545

Dear Mr. Knight:

Your letter of July 17, 1986 to the NRC provided a number of DOE QA plans for NRC staff review. Several of these reviews have been furnished to you in letters dated August 25 and November 21, 1986 (NNWSI QA Plan NVO-196-17), and January 28, 1987 (OGR QA Plan OGR-B-3). The purpose of this letter is to transmit staff review comments on the remaining plans, which are in the following attachments:

- Attachment 1 Basalt Waste Isolation Division
QA Plan, Revision 1, April 15, 1986
- Attachment 2 Basalt Quality Assurance
Requirements Document (BQARD),
Revision 0, January 1986
- Attachment 3 Salt Repository Project Office
QA Plan, Revision 0, November 26, 1985

As part of our overall review of the QA program prior to site characterization, we have commented or will be commenting on the QA plans for OGR, the project offices, Rockwell, Battelle, and several NNWSI participants. Novel or unique-QA procedures will also be reviewed in detail. In order for the DOE to achieve a fully qualified program prior to the start of site characterization, it will be necessary that these staff reviews be completed and comments resolved. We believe it would be helpful if a planning meeting could be held in the near future to discuss the status of the DOE QA Plans and NRC reviews of them.

As we have noted in the past, it is important to recognize the limits of the review of the QA program plans. The extent that the program is actually used throughout the high-level waste repository program as a management tool as opposed to being put in place merely to satisfy the NRC requirement cannot be measured through a QA program plan review. In the several cases where serious construction quality problems occurred at nuclear power plants, QA program plans had been reviewed and found acceptable by the NRC as meeting the requirements of Appendix B of 10 CFR Part 50. However, these programs were not properly implemented. The QA program plan review provides only a portion of what is necessary to develop confidence that work will be done adequately--that is, to assure that adequate information on the quality of work implementation is being developed for management and being met in a demonstrable fashion. A most important indicator of the successful implementation of these plans will

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be the detailed, results-oriented technical reviews that will be performed by the NRC staff as work progresses.

Questions on the enclosed comments or arrangements for a meeting between our staffs should be referred to James Kennedy of my staff on 427-4786.

Sincerely,

~~John J. Linehan, Jr.~~
John J. Linehan, Acting Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:
As stated

cc: C. Newton, OGR
L. Olson, BWIP
J. Neff, SRPO
D. Vieth, NNWSI

REQUEST FOR ADDITIONAL INFORMATION
BASALT WASTE ISOLATION PROJECT QUALITY ASSURANCE PLAN
REVISION 1, APRIL 15, 1986

1. The BWI Project Quality Assurance Plan was written prior to the following NRC June 1986 draft generic technical positions (GTPs):
 - a. Peer review.
 - b. Qualification of existing data.
 - c. Items and activities subject to QA requirements.

An evaluation should be made against the draft guidance of these GTPs, and differences between the plan and the draft GTPs should be addressed.

2. Expressions such as "are expected to" or "is expected that" are found throughout the plan. Change these expressions to "shall" or justify not doing so.
3. Section 1.3 and Appendix A of the plan describe QA responsibilities within the BWI Division. Identify who (by position title) in the Richland Operations Office is responsible for the overall BWI program. Clarify the meaning of the dashed lines, arrowheads, and ellipses on Figure 1.3 of the plan. Also indicate what ESH stands for on Figure 1.3 and in Section 1.5 of the plan. (1.1)*
4. Discuss how the Integrating Contractor avoids conflict of interest in its roles of project management and project participant. Clarify whether the Integrating Contractor, the Architect/Engineer, the Construction Manager, and other participants under direct contract to DOE for BWI Project work report to DOE-HQ, DOE-RL, or DOE-BWI Division. (1.3)
5. Section 1.2.2 of the plan indicates the BWI Division verifies effective implementation of the QA program. Clarify that this includes at least an annual audit of the Integrating Contractor. (1.4)
6. Sections 1.4 and 1.5 of the plan discuss QA interface with DOE-HQ and interdivision interface within DOE-RL respectively. Similarly, discuss the DOE-RL interface with Project participants. (1.6)

* The number in parenthesis after an RAI refers to the specific guidance in the NRC review plan.

7. Clarify whether the Director, BWI Division, reports through the Office of Commercial Nuclear Waste (Section 1.3.1) or the Office of Civilian Nuclear Waste (Figure 1-2). Identify the onsite and offsite organizational elements which function under QA program controls or justify not doing so. Show the ES&H Division, the Procurement Division, and the Personnel Division on an organization chart. (1.7)
8. Describe measures which ensure that DOE-RL's BWI Division Quality Systems Branch Chief is involved in the aspects of the BWI Project that affect safety and/or waste isolation and how the extent of DOE-RL QA controls is determined. (1.8)
9. Identify a management position within DOE-RL, the Integrating Contractor, Architect/Engineer, and Construction Manager organizations that retains overall authority and responsibility for the applicable QA program. Describe the management, CA, and technical experience and knowledge requirements for these positions. Verify that each of these positions has the following characteristics:
 - a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
 - b. Has effective communication channels with other senior management positions.
 - c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.
 - d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10)
10. Describe measures which ensure that 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.Describe how these actions are accomplished. (1.12)

11. Section 1.2.6 of the plan addresses stop work. Clarify the retention time of records of stop work requests. (1.12)
12. Identify items and activities covered by the QA program. Section 2.0 of the plan indicates that analytical processes are used to determine importance to safety and/or waste isolation. Clarify whether importance to safety and importance to waste isolation are defined as numerical performance objectives and standards. Justify why not if not. (2.1)
13. Section 3.2 of the plan indicates that Supplement 6 of the OGR QA plan addresses computer software control. Update Section 3.2 to reflect the fact that Supplement 6 of the OGR plan no longer addresses computer software. (2.2)
14. Section 2.4 of the plan indicates a management team assesses effectiveness of the overall Project QA program. Clarify that the management team is composed of personnel above or outside the DOE-FL organization. (2.7)
15. Section 3.1 of the plan indicates that design controls include those used to ensure the correct translation of design inputs into designs. Describe the controls which ensure that applicable regulatory requirements and design bases are reflected in design, procurement, and procedural documents. Also, describe measures which ensure that performance goals are specified for repository subsystems and components to support the establishment of data gathering and analysis needs. Discuss the timeliness of specifying these requirements. At the latest, planned performance allocation should be addressed in the SCP consistent with agreements reached in NRC/DOE meetings of April 17, 1981 and September 26 and 27, 1985 on this matter. (3.2)
16. Describe measures which ensure that (1) errors and deficiencies in approved design and design information documents are documented and (2) action is taken to ensure that all errors and deficiencies are corrected. (3.4)
17. Section 3.4 of the plan addresses design verification, and it includes in Section 3.4.4, "Design Verification by Similarity," an addition to the 3 methods of 10 CFR 50 Appendix B. This method would be acceptable if a fourth condition was added: (4) the design characteristics (attributes, features) that are not identical are identified and verified in a manner other than by similarity. Add such a condition or justify not doing so. Also, describe measures which ensure that design checking, which includes such things as confirmation of the numerical accuracy and computations and the accuracy of data input to computer codes, will be performed. (Confirmation that the correct computer code has been used is part of design verification.) Design verification should be performed by persons other than those performing design checking. Clarify whether personnel performing design verification can be associated with the responsible design organization. (3.7)

18. Clarify whether procedures prescribe the extent of documentation required for design verification. (3.9)
19. Section 3.6 of the plan addresses design changes. Clarify whether a configuration control system is in place such that design changes, including field changes, are analyzed to ensure they are required, are subject to the same design controls as the original design, are communicated to all affected groups and individuals, and are considered for changes to procedures and training. (3.10)
20. Section 5.0 of the plan refers to personnel "who meet the independence criteria specified in Section 3.4 of this QAP." Clarify what these criteria are.
21. Section 5.2 of the plan requires review of technical procedures by QA personnel. Clarify whether DOL-PL requires such review of administrative procedures (Categories 1 and 2 per Section 5.1 of the plan), instructions, and drawings. Also clarify whether "each participating entity in the Project" as specified in Section 5.0 of the plan is the same as "each Project participant" which is used elsewhere in the plan. (5.1)
22. Describe the scope of the DOE-RL document control program and identify the types of documents controlled by this program. Section 6.1 of the plan describes what the BWI Division requires of all Project participants in the area of document control. Clarify that the BWI Division requires the same of DOE-RL. This clarification should be made, as appropriate, throughout the plan since page v of the plan indicates that "all project participants" does not include the BWI Division of DOE-RL. (Section 4.1 and 7.0 are examples where clarification is required.) (6.1)
23. Describe measures which ensure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner. (6.4)
24. Section 7.3.1 and 10.4 of the plan address mandatory hold points for inspection or witnessing and use the term "where appropriate." Identify the organization(s) that determine when these (and similar) activities are appropriate. (7.1 and 10.5)
25. Describe the BWI Division Quality Systems Branch and other DOE-RL organizational responsibilities for qualification of special processes, equipment, and personnel. Provide examples of processes during site characterization that will be classified as special processes and those that will not. (9.2)
26. Clarify that special processes (standard or not standard) are required to be in conformance with applicable codes, standards, QA procedures, and specifications. The last sentence of Section 9.2 of the plan requires that participant's QA Plan describes QA's role in special processes. Clarify whether the BWI Division requires involvement of QA organizations. (9.3)

28. Section 7.5 of the plan indicates that DOE-RL's BWI Division is responsible for ensuring that delivered items and materials comply with applicable QA requirements, but Section 10 assigns inspection to Project participants. Describe how the BWI division meets the responsibility noted from Section 7.5 without performing inspections. Indicate how the BWI Division participates in determining when inspections are required and in defining how and when inspections are performed. (10.1)
29. Section 10.2 of the plan addresses inspector qualification and permits inspections by personnel outside QA organizations. Clarify that inspections are accomplished by individuals or groups who do not have direct responsibility for performing the work being inspected. The inspection function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity. (10.2)
30. Section 10.2 also refers to personnel with "particular" or "special" expertise. Describe QA's involvement in determining the expertise required commensurate with the technical complexity of the inspector function and the acceptability of the qualifications of the inspector. Also clarify that the qualifications and certifications of inspectors (both in and outside QA) are documented and kept current. Section 10.2 uses the term, "participant's QA inspection function." Clarify whether this is the same as the participant's QA organization. (10.2)
31. Describe measures which ensure that, when practicable, tests of structures, systems, and components shall be at conditions which simulate both normal and anticipated off-normal operations. (11.5)
32. Describe the scope of the QA program for the control of M&TE and identify the types of equipment to be controlled. (12.1)
33. Sections 12, 13, and 14 of the plan appear somewhat inconsistent. Sections 12 and 13 make the Integrating Contractor responsible for the controls, but 14 doesn't. Sections 13 and 14 address each Project participant, but 12 doesn't. Section 12 addresses cognizant QA organizational responsibilities, but 13 and 14 don't. Sections 12 and 13 specify surveillance and audit by DOE BWI Division QS, but 14 doesn't. Clarify these sections to eliminate these apparent inconsistencies, and describe how the involved organizations will meet their assigned responsibilities.
34. Describe measures which ensure that nonconforming items and samples are segregated from those which are acceptable. (15.1)
35. Section 15.2 of the plan requires that "use-as-is" and "repair" dispositions receive technical review and approval at the next higher level of project participation. Describe QA responsibilities regarding this review and approval. (15.2)

36. Section 15.1 of the plan requires that each nonconformance be documented. Clarify that nonconformance documentation identifies the item, describes the nonconformance, shows the disposition of the nonconformance, and includes signature approval of the disposition. (15.3)
37. Section 15.4 of the plan states that "The Project" will monitor and analyze nonconformance trends on a Project-wide basis. Identify what organization is responsible for these activities. Clarify that the trend analyses are used to help identify root causes of nonconformances. Identify the management level of DOE responsible to review and assess significant results of the nonconformance trend information. (15.4)
38. Describe measures which ensure that the significance of each nonconformance is assessed to determine whether corrective action is required to prevent recurrence. Identify the organization responsible for this assessment. (16.2)
39. Describe the scope of the record program. That is, identify by type of data what records will be maintained within the records management system. (17.1)
40. Describe the responsibilities of the project participants' QA organizations in the records management system. (17.2)
41. Section 17.3 of the plan addresses an archival facility for long-term storage of project records. Describe record storage facilities to be used prior to the availability of such a facility. (17.4)
42. Section 18.3 of the plan addresses audit scheduling. Clarify that audit scheduling considers the safety importance of the activities being performed. (18.2)
43. Section 18.13.2 of the plan addresses follow-on activities by auditing organizations. Clarify that these include analysis of audit data by the QA organization with the results being reported to responsible management for review, assessment, and appropriate action. (18.4)
44. Describe measures which ensure that audited organizations describe in a formal report the corrective action to be taken to address adverse audit findings and that this report is submitted to responsible management and the auditing organization. (18.7)
45. Clarify that technical audits which provide a comprehensive independent verification and evaluation of procedures and activities affecting quality are included in the audit program, that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited, and that audit team leaders are from the QA organization. (18.9)

46. Appendix A of the plan gives exceptions/clarifications to the NRC review plan. The following comments result from the staff review of Appendix A:
- a. The last sentence of clarification item 1 states that QA program controls are exercised by line functions. Clarify whether "line functions" refer to BWI Division personnel. If so, identify these line functions with the organization shown in Figure 1-2 of the plan. If not, identify what is meant by "line functions." Also clarify whether the "QA program controls" are the surveillances performed by BWI Division technical personnel as described in Section 18 of the plan. If not, clarify what is meant by QA program controls.
 - b. Clarification item 2 states that qualified individual(s) or organizational element(s) will be identified within DOE's organization, prior to initiation of activities, as responsible for assuring that delegated work meets established quality standards. Identify such individual(s) or organizational element(s) with this responsibility for ongoing delegated work. (1.5)
 - c. Clarification item 3 indicates that DOE will identify a DOE management position that retains overall authority and responsibility for: (1) performing QA functions relative to direct quality affecting activities within DOE, (2) verifying effectiveness of quality-related controls applicable to quality affecting work performed by DOE personnel, and (3) verifying proper performance of QA functions within contractor QA programs. Clarify who (by position title) has these responsibilities within DOE-RL for the BWI Project.
 - d. Clarification item 4 indicates that both DOE and contractor verification of conformance to established requirements may be performed by people outside the QA organization. When this is the case, clarify that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
 - e. The last sentence of clarification item 7 states: "Geological data acquisition "testing" is not considered to belong to the "special process" category for purposes of process demonstration. Explain the QA significance of this statement.
 - f. Clarification item 9 is acceptable if only "samples" will require handling, preservation, storage, etc; i.e., if no structures, systems, components, or other materials are involved. If this is not the case, delete this clarification or justify not doing so.

- g. Section 16.0 of the plan defines significant problems, and Appendix A of the plan describes significant conditions adverse to quality. Rectify these terms and their definitions or justify not doing so. (16.4)

REQUEST FOR ADDITIONAL INFORMATION
BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT (BQARD)
REVISION 0, January 1986

1. A statement used throughout BQARD is: "Therefore, the intent of this requirement will be met if implemented as stated." As a requirements document, BQARD should address meeting a requirement rather than meeting "the intent" of a requirement. Also, requirements document should use "shall" instead of "will" or "may". Further, the term "if implemented" should be clarified as was done on Sheet 3 under Criterion 3. Therefore the quoted statement should read: "Therefore, this requirement shall be implemented as stated," or words to that effect.
2. Sheet 10 under Criterion 2 addresses requirements for personnel performing quality-related activities. For these personnel (the "doers"), reference is made to NRC's Review Plan items 2.8a, c, and d. Item 2.8e, "Qualified personnel are certified in accordance with applicable codes and standards," should also be referenced as some of these personnel (welders, for example) require certification. The second sentence under item 1 should read: "Therefore, this requirement shall be met by implementing the requirements of 2.8a, c, d, and e as stated."
3. The note on Sheet 12 under Criterion 2 indicates that test inspectors (i.e., inspectors of testing activities) can be "... assigned to the testing organization and designated by the testing supervisor to be an in-process Inspector...." Clarify that "in-process Inspectors" do not have direct responsibility for performing the work being verified. The quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
4. The note on Sheet 7 under Criterion 3 limits the use of the word "validating" to the context of computer codes. The definition of validation from NUREG-0856 should be expanded to: "Assurance that a model is a correct representation of the process or system for which it is intended." Note that the definition of verification in ANSI N45.2.11 expands the definition in NUREG-0856 in a similar fashion.
5. The first paragraph on Sheet 1 under Criterion 4 states that site characterization participants have the option of controlling procurement activities per the requirements of either Criterion 4 or Criterion 7. While there may be some duplication in these criteria, there are also differing requirements, and the requirements of both criteria should be met.
6. The last paragraph on Sheet 2 under Criterion 4 states that construction participants have the option of using either the Site Characterization Criterion 4 or NQA-1 Basic Requirement 4 and Supplement 4S-1. Here again there are differing requirements, all of which should be met. The

proviso at the end of this paragraph does not appear to address this. A comparable comment applies to Criteria 5 through 18.

7. Supplements 4S-1 and 7S-1 of NQA-1 do not address the involvement of the QA organization in the various activities. The NRC Review Plan Sections 4.2 and 7.2 do. BQARD should require that these sections of the review plan be met. (See Sheet 3 under Criterion 4 and Sheet 3 under Criterion 7.)
8. The second paragraph on Sheet 1 under Criterion 9 implies that tests conducted per Criterion 11 do not require qualified procedures, qualified equipment, qualified personnel, and monitoring of process variables. This implication should be eliminated.
9. The first sentence under BWIP Project Implementation on Sheet 2 under Criterion 9 indicates that the NRC has "reworded" Criterion 9. The NRC has not reworded Criterion 9, and this sentence should be deleted or revised. A similar problem exists on Sheet 10 under Criterion 10, Sheets 7 and 9 under Criterion 11, Sheet 2 under Criterion 12, Sheet 2 of Criterion 14, Sheet 4 of Criterion 16, and on Sheets 5 and 6 under Criterion 18.
10. The discussion of inspection on Sheets 1 and 2 under Criterion 10 needs clarification. The first sentence indicates inspection is an "independent verification," but the third paragraph indicates that in-process inspections may be performed by the supervisor of the activity. We agree that the doer's supervisor is directly responsible for the work, and we believe that supervisors can and should make (or have made) in-process checks (i.e., nonindependent verification) and final checks before having work inspected. We do not agree that a doer's supervisor has the independence required to perform inspections, and the discussion should be revised to reflect this. Note that some work may require inspection during processing, some may require checking, and some may require neither.

The first sentence on Sheet 2 under Criterion 10 states: "Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusion," indicating a personal inspector vs. line supervisor relationship which is not desirable. The inspector's responsibility is neither to confirm nor deny "the adequacy of the supervisor's conclusion," and the sentence should be deleted or revised. Finally, clarify the significance of the parenthetical words in the third and fourth paragraphs under Criterion 10.

11. Sheet 6 under Criterion 10 indicates that Section 8 of 10S-1 of NQA-1 will be implemented to ensure that inspection results are documented and evaluated and that their acceptability is determined by a responsible individual. Beyond documentation, Section 8 does not appear to address this guidance. Clarify.
12. Explain the last sentence on Sheet 10 under Criterion 10 which states: "For the BWIP project, refer to the PMP/SEMP for identification of the BWIP designated inspectors."

13. Item C on Sheet 4 under Criterion 11 addresses the fact that QA should, as a minimum, audit the test program. Item C should specify that this will be done.
14. Under Criterion 11, BOARD should address whether testing will test the item under conditions which will be present during normal and anticipated off-normal operation when practicable.
15. The last paragraph on Sheet 8 under Criterion 11 states, "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." Test records should meet both Section 17.3 of the NRC Review Plan and paragraph 5 of supplement 11S-1 of NQA-1, and the paragraph should be so clarified.
16. Under criterion 12, clarify that both technical and QA programmatic audits are performed and that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN

REVISION 3

EFFECTIVE DATE: _____

**U. S. Department of Energy
Richland Operations Office
Office of Assistant Manager for
Commercial Nuclear Waste**

RECOMMENDED FOR APPROVAL

**R. P. Saget, Director
Quality Systems Division**

APPROVED

**J. H. Anttonen, Assistant Manager
for Commercial Nuclear Waste**

APPROVED

**Associate Director
Office of Geologic Repositories**

**BASALT WASTE ISOLATION PROJECT
QUALITY ASSURANCE PLAN, REV. 3**

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POLICY STATEMENT

This Quality Assurance Plan (QAP) is the top Basalt Waste Isolation Project QA planning document. It establishes Project QA responsibilities and authorities and describes the overall QA program for the Project. It constitutes the implementation plan specified by DOE Order 5700.6B and OGR/B-3 and establishes controls necessary to satisfy the QA requirements identified and interpreted in the Basalt Quality Assurance Requirements Document (BQARD). Compliance with applicable provisions of this QA Plan is mandatory for DOE-RL AMC BWI and QS Divisions and all Project participants.

This QAP shall be reviewed annually and revised as necessary. Issuance of revisions shall be on or near the beginning of each fiscal year.

NOTE: The term "participant", when used in this document, refers to organizations performing work under contract to the Basalt Waste Isolation Project.

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN, REV. 3

1.0 ORGANIZATION

1.1 OVERALL ORGANIZATION

The Basalt Waste Isolation Project is one of the projects established by the DOE Office of Civilian Radioactive Waste Management (OCRWM) under the geologic repositories options in response to the Nuclear Waste Policy Act of 1982 (PL 97-425). The Director, OCRWM, has established the Office of Geologic Repositories (OGR) under an Associate Director. Responsibility for basalt waste isolation studies has been assigned to the DOE field office at Richland, Washington (DOE-RL), where the Office of Assistant Manager for Commercial Nuclear Waste serving as the Project Manager has established the Basalt Waste Isolation and the Quality Systems Divisions for managing the Basalt Waste Isolation Project. Figure 1-1 shows overall organization of geologic repository projects. Figure 1-2 shows DOE-RL AMC BWIP organization.

1.2 BASALT WASTE ISOLATION PROJECT ORGANIZATION RESPONSIBILITIES

1.2.1 DOE-RL Office of Assistant Manager for Commercial Nuclear Waste (AMC)

The Manager, DOE-Richland Operations, has established the Office of Assistant Manager for Commercial Nuclear Waste (AMC) as the DOE-RL project office for the BWI Project. The BWI and QS Divisions establish Project policy within the constraints of requirements and guidelines set forth in licensing regulations and overall DOE policy (see Section 2.1, QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES).

1.2.2 Project

The BWI Project is organized for quality assurance as shown in Figure 1-3. The AMC QS Division establishes QA policy, defines the overall Project QA program, approves the QA program descriptions and QA administrative procedures prepared by the Integrating Contractor, the Construction Management Contractor and the Architect Engineer, and verifies effective program implementation through surveillances and annual audits.

Personnel within the project QA organizations shall have direct access to management levels which assures their ability a) identify quality problems; b) initiate, recommend or provide solutions through designated channels; and c) verify implementation of solutions. (Within DOE-RL, AMC Procedures BP 3.1 and BP 2.7 provides formal methods for assuring that this avenue is available for quality, technical, and administrative personnel within AMC. The QA plans and administrative procedures of the Integrating Contractor, the Architect/Engineer and the Construction Management Contractor provides similar freedom for QA personnel).

1.2.3 Integrating Contractor

The Integrating Contractor has two roles in the Project: (a) Project Management under DOE-RL direction, and (b) direct performance of specified technical work. In his Project Management role, the Integrating Contractor ensures that the activities of all Project participants are planned and carried out in such a manner as to provide coherent site characterization and design. In the direct performance role, the Integrating Contractor's technical resources are applied to designated conceptual design and development tasks and to site characterization.

The Integrating Contractor's Project Management role includes responsibility for ensuring that AMC BWI and QS Divisions policy and direction are implemented effectively and consistently among all contractor project participants.

Specifically, the Integrating Contractor's QA organization provides the following Project services:

- a. Reviews and recommends DOE approval of QA program descriptions and QA administrative procedures prepared by the Construction Management Contractor and the Architect/Engineer,
- b. Approves the QA program descriptions and QA administrative procedures prepared by (1) Project participants under direct contract to DOE for their Project work, other than the Architect/Engineer and the Construction Manager, and (2) all Project participants under direct contract to the Integrating Contractor for their Project work,
- c. Establishes Project-wide systems and/or methods for implementing QA program elements for which such uniformity produces important cost and/or control benefits by issuing controlled documents such as project directives,

- d. Verifies effective implementation of the QA program by means of audit, surveillance, trending and management assessment of QA activities of (1) the Architect/Engineer, (2) the Construction Manager, (3) the other Project participants under direct contract to DOE for their Project work, and (4) all Project participants under direct contract to the Integrating Contractor for their Project work, and
- e. Ensures that applicable elements of his (the Integrating Contractor's) QA program are effectively implemented for direct work performed in-house.

1.2.4 Architect/Engineer, Construction Manager and Other Participants Under Direct Contract to DOE-RL for Project Work.

Each of the organizations identified in the heading of this section is responsible for the following:

- a. Developing and implementing a QA program that (1) meets all applicable requirements identified in the Basalt Quality Assurance Requirements Document (BQARD), (2) is consistent with the Project QA program described in this QAP, and (3) reflects any Project-wide QA systems or methods specified by the Integrating Contractor, or by the DOE Project Office,
- b. Submitting to the Integrating Contractor for review QA program descriptions and QA administrative procedures and revisions where DOE approval is required.
- c. Approving the QA Plans and QA administrative procedures of participants doing Project work under contract to him (as shown in Figure 1-3), and
- d. Verifying effective implementation of his own QA program and of the QA programs of participants doing Project work under direct contract to him, as shown in Figure 1-3. The architect/engineer and his QA organization are not located onsite. The Construction Manager's Home Office provides functional management responsibilities in project management, QA management and corporate safety.

1.2.5 Project Participants on Subcontract

Organizations or individuals either onsite or offsite who do Project work under contract to Project participants other than DOE are required by the purchaser to implement applicable QA measures consistent with requirements of the Project QA program. QA requirements for such procurements are determined and specified by the purchasing organization on a case-by-case basis, as indicated in Section 4.0 and 7.0 of this QAP.

1.2.6 Stop Work Authority

STOP WORK authority is implicitly vested in line management throughout the Project for situations in which imminent danger to personnel is identified, or where it is determined that continued work will produce results that cannot be used in support of Project objectives.

In addition, STOP WORK authority is explicitly vested in members of Project QA organizations if, in the judgment of the individual, the work is performed contrary to or in the absence of prescribed controls or approved methods, and further work would make it difficult or impossible to establish acceptability of the results.

Work may also be stopped by any Project participant's senior management upon QA recommendation if:

- a. Corrective action for substantive quality problems has not been accomplished, and the responsible organization(s) has/have not established an acceptable plan of corrective action or the approved corrective action plan is not being implemented in a timely manner, or
- b. One or more elements of the established QA program is determined to be out of control, so that the usability of work performed under existing conditions is in serious question.

The integrating contractor coordinates stop work for other DOE funded project participants with the AMC Project Manager to provide contract direction to the participant(s), if required.

The Assistant Manager, AMC, the Project Manager for BWIP is to be notified immediately of any STOP WORK on the Project. Notification is expected to include the intended criteria for resumption of work. The Project Manager reserves the authority to require that work be resumed only upon his approval.

Similarly, the next higher authority in the Project management hierarchy is to be notified of any STOP WORK issued by, or upon, a lower tier Project participant, and has the authority to require that work be resumed only with his approval. STOP WORK and resulting corrective action documents become project records which are forwarded to the BRMC for retention.

1.2.7 Resolution of Disputes Involving Quality

Disputes involving differences of opinion regarding quality assurance matters between QA personnel and other department personnel anywhere in the Project shall be elevated to a level where agreement can be reached, up to and including DOE-HQ.

1.3 DOE-RL INTERNAL ORGANIZATION FOR AMC PROJECT QUALITY ASSURANCE

1.3.1 AMC BWIP Organization

The Manager, DOE-RL, has the line management responsibility and accountability for overall project implementation. The Manager has delegated appropriate authority to the Assistant Manager for Commercial Nuclear Waste (AMC) to manage and direct the Basalt Waste Isolation Project.

The Assistant Manager for Commercial Nuclear Waste serves as the Project Manager and has direct primary responsibility and accountability for the execution and implementation of the project in accordance with the BWIP Quality Assurance Plan through all phases of the BWIP, including siting, site characterization, design, construction, operation, decommissioning, closure and institutional interfacing. The Assistant Manager for Commercial Nuclear Waste has established two divisions to provide day-to-day management of the BWIP.

DOE-RL has engaged a Support Services Contractor (SSC) to strengthen administrative, technical and quality assurance resources and depth within the AMC Project Organization in carrying out its management responsibilities. Figure 1-4 shows the organization and reporting relationships within AMC.

In quality-assurance-related matters, the Assistant Manager is responsible for the following:

- a. Approving the BWIP Quality Assurance Plan and the procedures necessary for its implementation.
- b. Approving project plans, as necessary, to permit the AMC Divisions to fulfill their technical and quality assurance program requirements.
- c. Assuring adequate funding for technical and quality assurance activities.
- d. Appointing the AMC Training Coordinator and approves the QA Training Plan for AMC personnel.

- e. Effectively implementing the quality assurance program.
- f. Approving formal quality and technical program direction issued by the BWI Division and Quality Systems Division to BWI project participants.
- g. Ensuring and evaluating the effectiveness of implementation of the quality assurance program.
- h. Evaluating the quality of delegated work as reported by the BWI and Quality Systems Divisions.
- i. Evaluating management assessment reports of quality assurance program implementation.
- j. Fulfilling other management responsibilities, as assigned by the DOE-RL Manager.

1.3.2 AMC BWI Division

The Director, BWI Division, reports to the Assistant Manager for Commercial Nuclear Waste, and is responsible for the following:

- a. Effectively implementing the quality assurance plan in the engineering, geoscience, and licensing areas.
- b. Evaluating technical effectiveness of quality assurance program control by participants prior to and during ongoing work.
- c. Serving on and providing support for the DOE-RL Readiness Review Board.
- d. Preparing and issuing management plans and instructions as required.

1.3.3 AMC Quality Systems Division

The Director, Quality Systems Division, reports to the Assistant Manager for Commercial Nuclear Waste, and exercises the highest direct-line authority in the BWIP for QA functions. The Director, Quality Systems Division, has no other responsibilities that prevent the devotion of full attention to quality activities. The Director's responsibilities include the following:

- a. Preparing and maintaining the BWIP Quality Assurance Plan and procedures necessary for its implementation.

- b. Preparing and maintaining the QA Training Plan for AMC personnel.
- c. Establishing requirements for BWI Division participants' QA programs.
- d. Review and approval of the quality assurance plan and implementing quality assurance administrative procedures prepared by the integrating contractor.
- e. Evaluating the integrating contractor's recommendations for approval of the quality assurance program descriptions and quality assurance administrative procedures prepared by the construction management contractor and architect-engineer.
- f. Approval of the quality assurance program and administrative procedures of the construction management contractor and the architect-engineer for use on the BWIP.
- g. Exercising BWIP oversight of overall quality assurance program implementation.
- h. Verifying effective implementation of the BWIP Quality Assurance Plan and procedures by the BWI Division.
- i. Reviewing and (or) specifying quality assurance requirements in procurement documents.
- j. Approving contractor and subcontractor quality assurance programs when their work is not subject to cognizance by the integrating contractor.
- k. Approving government agency quality programs when the scope of work is covered by a Memorandum of Understanding.
- l. Providing direct quality assurance support to the BWI Division.
- m. Serving on and providing support for the DOE-RL Readiness Review Board and Readiness Review Teams.
- n. Verifying the effectiveness of the Integrating Contractor QA organization in providing management and QA program guidance to project participants.

1.4 QA INTERFACE WITH DOE HEADQUARTERS

Quality assurance direction and policy guidance from DOE-HQ reaches DOE-RL through the Office of Geologic Repositories (OGR) in the form

of the OGR QA Plan, the requirements documents cited therein, and through directives issued from that office.

The Project QA Plan and Basalt QA administrative procedures are submitted to OGR for review and approval. OGR personnel verify effective implementation of the project QA program and project compliance with applicable regulations, codes and standards.

A free, informal flow of information between DOE-RL personnel engaged in Project QA-related activities and cognizant personnel in OGR is encouraged to supplement formal reporting.

1.5 INTERDIVISION INTERFACES WITHIN DOE-RL

The primary interfaces between AMC Divisions and other DOE-RL organizations in establishment and implementation of the Project QA program involve the Procurement Division and the Personnel Division, who report to the Office of Assistant Manager for Administration, and the Environment, Safety, Health and Quality Assurance Division who reports to the Office of Assistant Manager for Safety, Environment and Security, as follows:

a. Procurement Division (PRO)

All direct procurement for the DOE AMC Division is accomplished by PRO. The PRO interfaces with the AMC Division/Branch that initiated the procurement regarding technical matters, and with the QS Division on quality assurance matters. (Refer to Sections 4.0 and 7.0 of this QAP for details.) The AMC Divisions and PRO interface at the following points in the procurement process:

- (1) When requirements for the item or service(s) are delivered to PRO in the procurement initiation stage,
- (2) When PRO is determining which bids are responsive to the specified requirements,
- (3) When PRO is determining which responsive bidders are qualified to provide the required items or services,
- (4) During contract performance, as determined by verification planning, and
- (5) At the time of shipment (or delivery) of the purchased item or service during the acceptance action (PRO contracts with project participants to perform inspections of items and materials).

b. Personnel Division

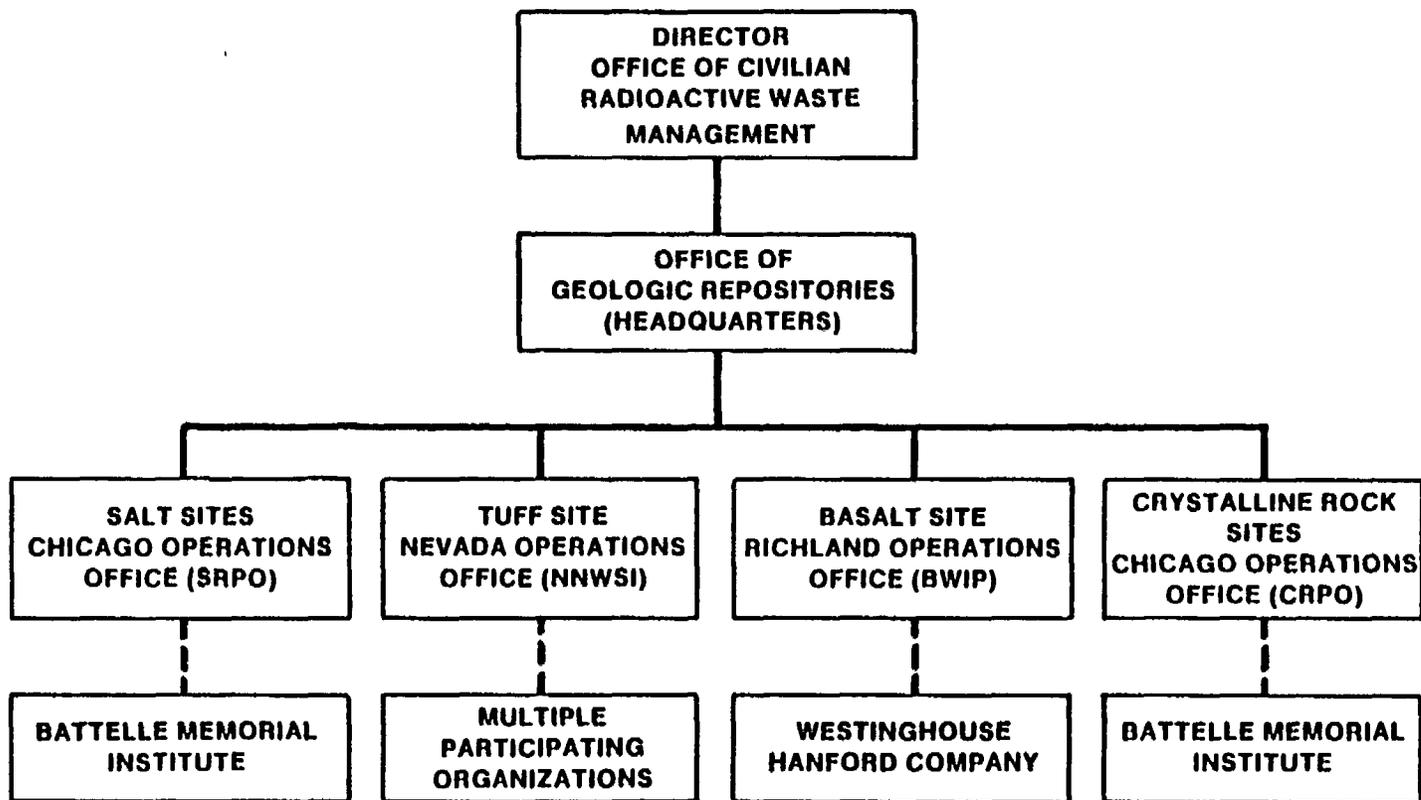
AMC relies on the Director, Personnel Division, to provide personnel for AMC positions and to verify that such personnel meet applicable position qualification requirements defined by the AMC Divisions.

c. ES&H Division

The Quality Assurance Branch of the Environmental, Safety, Quality Assurance and Health Division conducts or has third parties under their auspices audit the QA Program implementation of the AMC Quality Systems Division.

FIGURE 1-1

GEOLOGIC REPOSITORY PROGRAM



LEGEND:

———— PROGRAM/PROJECT MANAGEMENT RESPONSIBILITY

- - - - MAJOR CONTRACTOR SUPPORT

FIGURE 1-2

BWI PROJECT ORGANIZATION

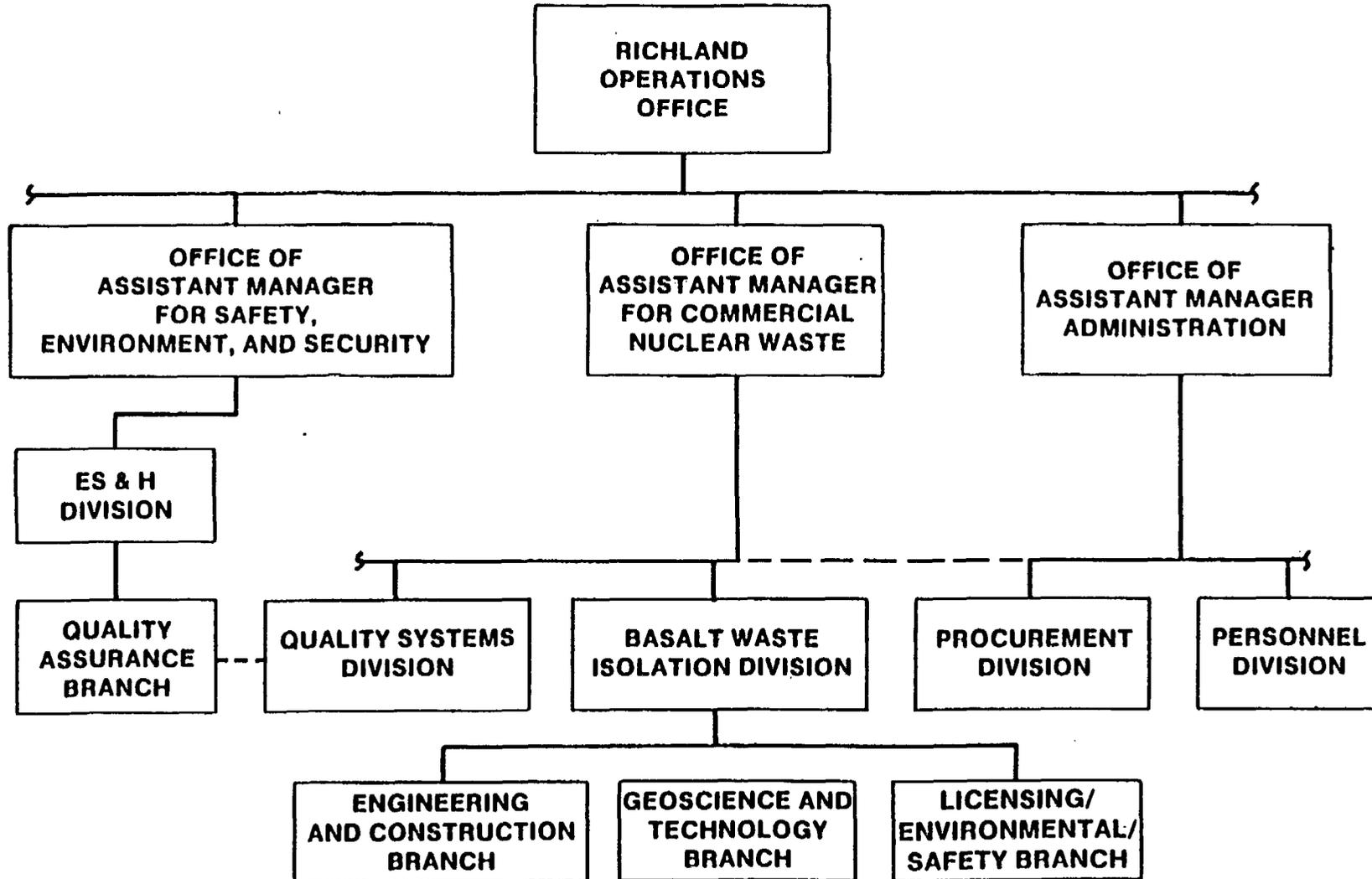
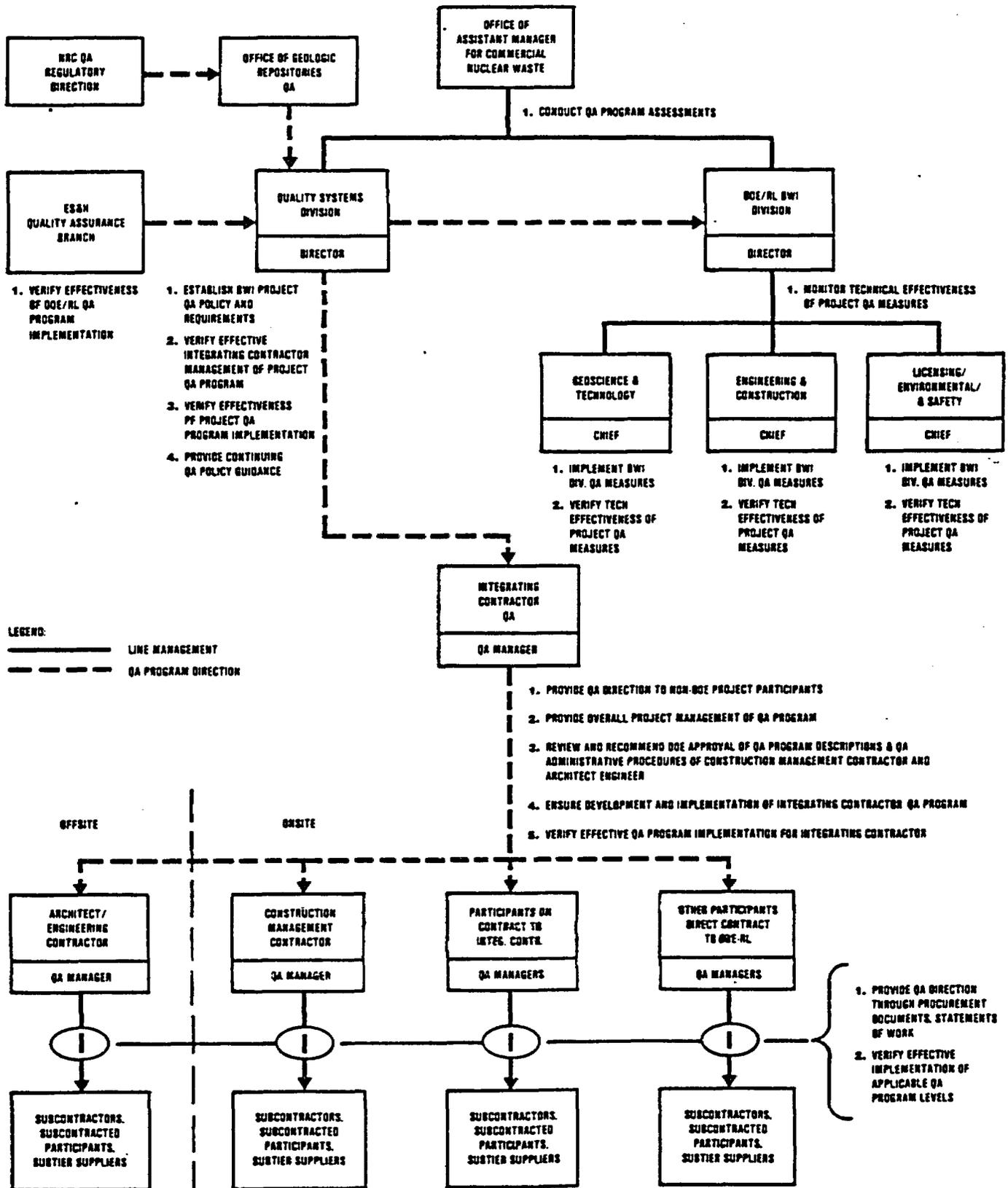
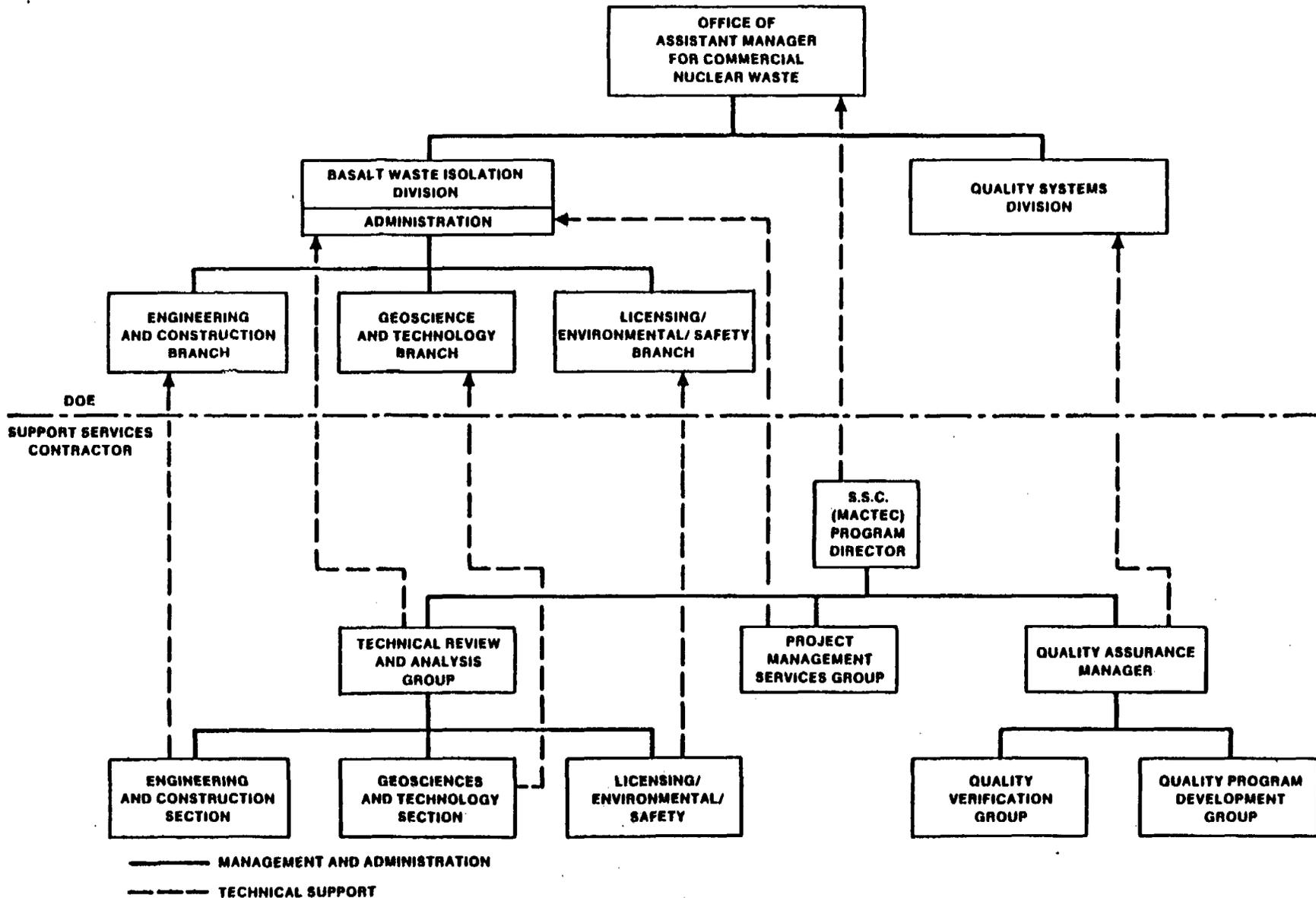


FIGURE 1-3 BWI PROJECT QA PROGRAM MANAGEMENT RESPONSIBILITIES



**FIGURE 1-4
BWI PROJECT ORGANIZATION WITH SUPPORT SERVICES CONTRACTOR**



2.0 QUALITY ASSURANCE PROGRAM

The Project QA program described in this implementation plan applies to systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to collection, reduction and analysis of data in support of site characterization. In addition, appropriate controls described in this QAP are applied to other items and activities in accordance with the approved Graded QA approach (see Section 2.2.3).

Importance to safety and waste isolation is determined by analytical processes involving failure modes and effects analysis, fault tree analysis, which develop numerical performance objectives and standards, and incorporation of scientific and engineering judgment. The process is described in the Project's Performance Assessment Plan. Project QA organizations are involved in the process at all appropriate points. These iterative processes provide the basis for the Project Q-list, and provide important inputs to assignment of items and activities to quality levels within the Graded QA program.

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES

- a. DOE Order 5700.6B, Quality Assurance
- b. DOE/RL Order 5700.1A, Quality Assurance
- c. DOE/RW-0032, Quality Assurance Management Policies and Requirements
- d. 10CFR60, Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures
- e. 10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- f. NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories, June 1984
- g. OGR/B-3, Quality Assurance Plan for High-Level Radioactive Waste Repositories, and Supplements
- h. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities, Supplements and Appendices
- i. Basalt Quality Assurance Requirements Document, (DOE/RL 86-1)
- j. DOE Order 4700.1, Project Management System.

The Project QA Program described in this QA Plan is intended to comply with applicable provisions of these documents with the clarifications noted in Appendix A to this QAP. Where conflicts exist the AMC QS Division will provide policy guidance.

Table 2-2 is a requirements matrix reflecting the criteria in ANSI/ASME NQA-1, 1986, the NRC review plan sections and the sections of the BWIP QA Plan which describes the QA program controls.

Table 2-3 shows the QA programmatic responsibilities and duties of BWIP participants using the 18 criteria of 10CFR50, Appendix B.

2.2 BWI PROJECT QA PROGRAM STRUCTURE AND EXECUTION

2.2.1 QA Program Controls

The QA program consists primarily of controls over technical and support activities. These controls are exercised by participants' line organizations that perform the activities. The extent of these controls is established by joint effort of cognizant technical and QA organizations, with successive iterations of the various performance assessment analyses providing the foundation. DOE project management responsibility involves establishment of Project objectives, oversight of participants' management, and verification that participants implement planned controls effectively. DOE AMC BWI Division technical personnel, in the course of evaluating contractor technical progress, satisfy themselves that applicable controls have been and are being exercised effectively - i.e., not only that the technical approach is valid, but that it is based on properly controlled supporting data and analyses.

DOE's Project oversight of contractor performance, therefore, includes (a) AMC QS Division verification that contractors are effectively implementing the control systems that constitute the required Project QA program, and (b) AMC BWI Division technical staff evaluation of the technical effectiveness of those controls.

Certain activities performed by DOE-RL personnel directly affect technical outcome of the project (e.g., decisions selecting from among technical alternatives, approval of contractor technical recommendations, direction with respect to approaches, etc.). QA controls affecting these activities are specified in DOE AMC Basalt Procedures. AMC QS Division verifies effective implementation of specified controls by QA audit and surveillance and participation in technical evaluations performed by AMC personnel.

2.2.2 Project QA Program Documentation

This Project Quality Assurance Plan is the top Project QA planning document. It establishes Project QA responsibilities and authorities and describes the overall quality assurance program for the project.

The DOE AMC issues Project Management Directives (PMDs) as Annexes to the Project Management Plan (DOE-RL-87-3). PMDs establish detailed requirements for Project Participants. Quality provisions are included in the PMDs when they specify requirements for activities within the scope of the Project QA Program. The DOE AMC issues procedures and instructions to implement PMD requirements in-house.

The DOE AMC issues Basalt Procedures (BPs) providing direction and guidance for in-house management of the BWIP. Certain of these BPs are QA administrative procedures which prescribe how the QA Program is implemented within DOE. Table 2-1 lists the AMC QA administrative procedures.

Each participant on the Project is required to prepare a top-level description of his internal QA program, including a listing of QA administrative procedures necessary to implement his Project-related activities. Each participant on the Project is also required to prepare and maintain a master list of quality affecting technical procedures. Approval of QA program descriptions and QA administrative procedures prepared by the Integrating Contractor, Construction Manager and Architect/Engineer is addressed in Sections 1.2.4 and 1.3. The Integrating Contractor, Construction Manager and Architect/Engineer are responsible for review and approval of QA program descriptions and QA administrative procedures prepared by their subcontractors. The Integrating Contractor is also responsible for review and approval of the QA program descriptions and QA administrative procedures prepared by direct-DOE-funded participants other than the Construction Management Contractor and the Architect/Engineer.

Each Project participant's QA program description shall include a policy statement or equivalent document, signed by a responsible official, that mandates compliance with his QA program description and implementing procedures on work within the scope of the BWIP QA program.

2.2.3 Graded Quality Assurance

Quality assurance measures for Project activities are applied on the basis of the Graded QA Approach adopted for DOE's geologic repository program. The graded approach establishes three quality levels, as follows:

Quality Level 1 (QL-1), the highest quality level available for assignment on a geologic repository project will be based on the 18 basic requirements of NQA-1, all NQA-1 supplements (where NQA-1 does not conflict with applicable regulatory requirements), nonmandatory Appendix 2A-1, OGR/B-3 Supplements, the 18 criteria of Appendix B to 10CFR50, and the NRC Review Plan.

Quality Level 2 (QL-2), the intermediate quality level, will be based on the 18 basic requirements of NQA-1 and NQA-1 supplements S-1, 2S-3, 2S-4, 3S-1, 4S-1, 7S-1, 10S-1, 15S-1, 17S-1, 18S-1, and OGR/B-3 Supplements. The other supplements to NQA-1 were judged to be unnecessary for Quality Level 2 because they contain additional detail requirements that were not considered mandatory for the level of quality desired. (However, see individual sections of this QAP for portions of other NQA-1 supplements that may be applied to QL-2 for the BWI Project, in order to avoid hazards inherent in operating under two different systems.)

Quality Level 3 (QL-3) will require the use of good work practice and will meet appropriate quality program requirements as determined by the project on a case-by-case basis or as prescribed in DOE Order 4700. This would include non-permanent facilities and services used during site characterization and construction.

Deviations from requirements specified are permitted where written justification is provided and approved by the individual or organization that makes the initial determination of quality level. Deviations include deletion of a requirement, addition of a requirement, or any modification to a requirement.

2.2.3.1 QL-1

The following Items/Activities will be assigned to QL-1:

All Q-List Items/Activities.

This will include items/activities important to public safety, waste isolation and activities

important to waste placement or retrieval and items/activities designated by OGR-HQ.

2.2.3.2 QL-2

Items/activities falling into the following categories will be assigned QL-2:

Worker safety features whose failure or malfunction could result in whole body exposure to radiation in excess of the limits prescribed in 10 CFR 20.

Cost or schedular impacts of more than \$10,000K.

Regulatory requirements other than the NRC's 10 CFR 60, and the EPA Standard, 40 CFR 191 (such as OSHA, MSHA, etc., excluding lost time accidents and incidents).

2.2.3.3 QL-3

All items/activities not falling into Quality Levels 1 and 2 will be assigned QL-3.

The Integrating Contractor will develop, issue, maintain and control a document for the Project Q-list and graded QA to reflect assigned levels and rationale or reference to its location for items and activities for the BWIP.

Participants whose responsibilities include establishment of Q-list items and activities and application of graded QA shall provide the necessary information including justifications and deviations to the integrating contractor to produce the project listing for inclusion in the SCP and the SCP progress reports.

2.2.4 AMC Evaluation Role

AMC technical personnel will be involved in the graded quality assurance process in two ways. The cognizant AMC individual will participate in or observe selected graded QA activities conducted by project participants, and AMC technical individuals may initiate a reevaluation of graded QA for appropriate quality level if they have reason to believe project grading in their area of expertise has been incorrectly performed or justified in the criteria of Section 2.2.3 of this QAP. (ref. AMC Procedure BP 3.4, Graded Quality Assurance).

2.3 INDOCTRINATION, TRAINING AND QUALIFICATION

2.3.1 Indoctrination

New personnel on the Project, and personnel newly assigned Project duties, shall receive indoctrination in Project objectives, the Project QA program and controls that apply to their activity area.

2.3.2 Training

Within DOE's AMC, cognizant Division Directors/Branch Chiefs are responsible for determining training needs of their personnel. The AMC Training Coordinator prepares and maintains a BWI Project Training Plan to meet these needs in a timely manner. The AMC QS Division Director identifies QA-oriented training needed by non-QA personnel for performance of evaluations of contractor control effectiveness. AMC training and qualification are addressed by AMC Procedure BP 2.5, Personnel Training.

To ensure that all BWIP participant personnel performing activities affecting quality achieve and maintain suitable proficiency, a BWIP-wide program to provide appropriate training and indoctrination is required. The AMC Project Manager has delegated to the Integrating Contractor the responsibility for determining appropriate scope and content of the training program commensurate with the current project phase and for forecasting and planning training needs for future work. The IC is to ensure training requirements are implemented by project participant organizations and to perform verifications of the effectiveness of each training program.

Project participant organizations are required to maintain documented training programs which are regularly audited by the cognizant QA organization. Participant management shall monitor personnel performance and determine the need for retraining and/or replacement.

2.3.3 Qualification

Personnel qualification in the Project falls into two general categories. The first concerns competence in designated skills (i.e., inspection, nondestructive examination, auditing and performance of special processes). The other involves the more general and universal requirement that individuals be competent to perform adequately in their jobs. Personnel who verify activities affecting quality shall become to be fully knowledgeable in the principles, techniques, equipment and requirements of the activity being performed.

Qualification in the "designated skills" indicated above is established by education and/or training, evaluation of credentials, and demonstration of the specific capabilities in question. Such special skills qualification is certified by specifically authorized individuals, and certifications become part of the record that substantiates work performed by those personnel. For NDE inspection acceptance, the inspection personnel shall be certified as Level II or higher in accord with SNT-TC-1A.

Qualification of individuals in job assignments is assured by use of valid position descriptions, verification of qualification evidence submitted or referenced by the position applicant or incumbent, and continuing management evaluation of performance. Individual task assignments require supervisory matching of personnel qualifications to the needs of the specific task.

2.3.4 Documentation and Records

Each Project participant conducting formal training and/or qualification programs is expected to document such training and/or qualification for the formal Project record. Documentation of formal training sessions shall include the training objective(s), training content, attendees and date(s) of attendance.

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

At intervals determined by the AMC, but not exceeding one year, a management team above or outside the QS Division assesses effectiveness of the overall Project QA program. The structure of the assessment team and mechanics of the assessment process are addressed by an approved procedure. (AMC Procedure BP 2.1, Quality Assurance Program Assessment, describes how DOE-RL performs management assessments.)

Each Project participant shall accomplish similar assessments of the effectiveness of his QA program. Such assessment shall include frequent contact with program status through reports, meetings, and/or audits, as well as performance of a preplanned, documented assessment, with corrective action identified and tracked.

2.5 PROJECT QUALITY ASSURANCE STATUS REPORTING

The Integrating Contractor shall compile and submit a monthly Quality Assurance Status Report to the Office of Assistant Manager for Commercial Nuclear Waste. The report style is optional; however, the reports are to be based upon direct work performed by the Integrating Contractor along with input by participating major contractors.

2.5.1 Report Content

The report content should consider and typically address, but not be limited to the following:

- o Results of verifications, surveillances, and audits (including positive results)
- o Significant quality accomplishments, issues, problems and nonconformances
- o The status of open corrective actions
- o A listing of corrective action items closed since the previous status reports
- o Staffing levels
- o Status of action items for QA program implementation
- o Training program status
- o Results and/or issues raised based upon interactions with major contractors, the regulatory agencies, etc.
- o Results of any management assessment activity.

2.5.2 Submittal Requirements

The Integrating Contractor shall establish input cut-off dates from the participating major contractors to allow compilation and submittal to the AMC within 15 working days after the end of each calendar month. The reports are used in the Management Assessment of QA program effectiveness as addressed in Section 2.4.

TABLE 2-1

DOE-RL AMC BWI PROJECT QA ADMINISTRATIVE PROCEDURES

BP	1.1	ORGANIZATION
BP	1.7	COMMITMENT/ACTION ITEM TRACKING
BP	1.8	CORRESPONDENCE CONTROL
BP	1.11	STOP WORK
BP	2.1	QA PROGRAM ASSESSMENT
BP	2.2	WORK PROGRESS AND DESIGN REVIEWS
BP	2.5	PERSONNEL TRAINING
BP	2.7	APPEALS ON QUALITY CONCERNS
BP	2.8	CONTROL OF AND RELEASE OF LICENSING DOCUMENTS
BP	2.10	REPORTING OF SIGNIFICANT DEFICIENCIES
BP	2.11	REVIEW OF QUALITY AFFECTING SOURCE DOCUMENTS
BP	3.1	PROJECT REVIEWS
BP	3.2	DISPOSITION OF CHANGE REQUESTS
BP	3.3	PEER REVIEW
BP	3.4	GRADED QUALITY ASSURANCE
BP	3.5	DATA QUALIFICATION ACTIVITIES FOR BWIP
BP	3.6	READINESS REVIEW
BP	4.1	PREPARATION AND CONTROL OF PROCUREMENT DOCUMENTS
BP	4.2	CONTRACTOR INITIATED PROCUREMENTS
BP	5.1	PROCEDURE DEVELOPMENT
BP	6.1	PREPARATION AND RELEASE OF AMC DOCUMENTS
BP	6.2	CONTROLLED DOCUMENTS ISSUED TO THE AMC DIVISION AND STAFF
BP	6.3	REVIEW OF AND APPROVAL OF EXTERNAL DOCUMENTS
BP	7.1	SUPPLIER EVALUATION, SELECTION AND VERIFICATION
BP	7.2	SUPPLIER FURNISHED RECORDS
BP	15.1	PROCESSING CONTRACTOR NCRS AND UNUSUAL OCCURRENCES
BP	15.2	TREND ANALYSIS
BP	16.1	CORRECTIVE ACTION
BP	17.1	QUALITY RECORDS
BP	18.1	AUDIT AND SURVEILLANCE PLANNING
BP	18.4	AUDITOR QUALIFICATIONS
BP	18.5	SURVEILLANCE OF PROJECT ACTIVITIES
BP	18.6	QUALITY ASSURANCE AUDITS

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
1 Basic		1.0
1S-1, Sect. 2.1, 2.2		1.2.2
1S-1, Sect. 2.3		1.2.6
	1.1, Sent. 1	1.3, 1.3.2, 1.3.3, Append A
	1.1, Sent. 2	1.3.1, 1.3.2, 2.2.1, Fig. 1-1, 1-2, 1-3, 1-4
	1.2	1.2
1S-1, Sect. 3.1	1.3	1.2, 1.3.1, 1.3.2, 1.4
1S-1, Sect. 3.2		1.2
	1.4, Sent. 1, 2	1.2.2, 1.3.2, 18.1
	1.4, Sent. 3	1.2.2, 2.2.1, 18.0
	1.5	1.3.1
	1.6	1.2, Fig. 1-3
	1.7	1.2, Fig. 1-2, 1-3, 1-4
	1.8	1.2.4, 1.2.5, 2.2.1
	1.9	1.2
	1.10	1.2.3, 1.3, 1.3.3, Append A
	1.11	1.2.3, 1.2.4, 10.2, 10.3
	1.12a, b, c	1.2.2

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
	1.12d	1.2.6
	1.13	1.2.7
	1.14	QAP Policy Statement
	1.15	1.3.1, 1.3.2, 1.3.3
2 Basic		2.0
	2.1	2.0
	2.2	3.2
	2.3	2.2.2
	2.4	5.2
	2.5	2.0, 2.2.3
	2.6	2.2.2
	2.7	2.4
	2.8a	2.3.1
	2.8b	2.3.3
	2.8c	2.3.4
	2.8d	2.3.2
	2.8e	2.3.3
2S-1, 2S-2		2.3.3, 10.2
2S-3		2.3.3, 18.4
2S-4		2.3.1, 2.3.2, 18.4
3 Basic		3.0
3S-1, Sect. 2		3.2, 3.3, 3.4, 3.5
3S-1, Sect. 3		3.3, 3.4

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
	3.1	3.1, 2.2.3
	3.2	Site Characterization Plan, Sect. 8.6
	3.3	3.3, 3.4
	3.4	3.1
3S-1, Sect. 6	3.5	3.7
	3.6	3.41
3S-1, Sect. 4	3.7	3.4
	3.8	3.5
	3.9	3.3.2, 3.4, 3.5
3S-1, Sect. 5	3.10	3.6
3S-1, Sect. 7		17.1
4 Basic		4.0
4S-1, Sect. 2		4.1
4S-1, Sect. 3	4.1	4.1c, e
	4.2	4.1
5 Basic		5.0
	5.1	5.1, 5.2, 3.4, 3.4.1
	5.2	5.5
6 Basic		6.0
6S-1		6.1
	6.1	6.1
	6.2	6.1, 6.4

TABLE 2-2
REQUIREMENTS MATRIX

HOA-1-1986	NRC REVIEW PLAN	OAP
	6.3	5.6, 6.1e
	6.4	6.1g
	6.5	6.1i
	6.6	6.1j
7 Basic		7.0
	7.1	7.0
7S-1, Sect. 2		7.1
7S-1, Sect. 3	7.2	7.2, 7.3.1, 7.3.2
7S-1, Sect. 4		7.0
7S-1, Sect 5		7.2
7S-1, Sect. 6, 7, 9	7.3	7.4
7S-1, Sect. 8	7.4	7.3.2
	7.5	11.4
7S-1, Sect. 10		2.2.3
8 Basic		8.0
	8.1	8.0
	8.2	8.0
	8.3	8.0
8S-1		8.0
	8.4	8.0
9 Basic		9.0
9S-1, Sect. 2, 3	9.1	9.1, 9.2
	9.2	9.2

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
	9.3	9.2
	9.4	9.3
	9.5	9.3
10 Basic		10.0
	10.1	10.1
10S-1, Sect. 2	10.2	10.2, 10.3
	10.3	10.2
10S-1, Sect. 3, 4	10.4	10.4
10S-1, Sect. 5	10.5	10.4
	10.6	10.5, 10.6
10S-1, Sect. 6		10.1, 10.5
11 Basic		11.0
11S-1, Sect. 2		11.2
	11.1, Sent. 1	11.1
	11.1, Sent. 2	11.2, 11.5
	11.1, Sent. 3	11.5
	11.2	11.2
	11.3	11.3
11S-1, Sect. 3	11.4	11.6
11S-1, Sect. 4, 5	11.5	11.7
12 Basic		12.0
	12.1	12.1
	12.2	12.1, 12.2

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	OAP
12S-1		12.1
	12.3	12.1, 12.2
	12.4	12.1
	12.5	12.1
	12.6	12.1
	12.7	12.1
13 Basic, 13S-1		13.0
	13.1	13.0
	13.2	13.0
14 Basic		14.0
	14.1	14.0
15 Basic		15.0
	15.1	15.1, 15.2, 15.3
15S-1, Sect. 2, 3	15.2	15.1, 15.2, 15.3
15S-1, Sect 4	15.3	15.1, 15.2, 15.3
	15.4	15.4
16. Basic		16.0
	16.1	16.1
	16.2	16.1, 15.4 Append. A
	16.3	16.1
	16.4	16.0
17 Basic		17.0
17S-1, Sect. 2, 3, 5		17.1

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
17S-1, Sect. 4		17.3
	17.1	17.1
	17.2	17.1
	17.3	10.6, 11.7
	17.4	17.1
18 Basic		18.0
	18.1	18.1
18S-1, Sect. 2	-18.2	18.3
18S-1, Sect. 3	18.3	18.2, 18.5
18S-1, Sect. 5	18.4	18.6, 18.7
18S-1, Sect. 4	18.5	18.4, 18.5, 18.6
18S-1, Sect. 6, 7	18.6	18.3, 18.13
18S-1, Sect. 7	18.7	18.13
	18.8	18.13

**TABLE 2-3. BASALT WASTE ISOLATION PROJECT QUALITY ASSURANCE PROGRAM
RESPONSIBILITY MATRIX**

Criteria	Responsibilities				
	DOE-RL	IC	A-E	CM	SUPP
1.0 Organization	P,R	S,R	S	S	S
2.0 Quality Assurance program	P,A,R	S,R	S	S	S
3.0 Design Control	P,A,R	S,A,R	S,A,R	S	S
4.0 Procurement document control	P,A,R	S,A,R	S	S,A,R	S
5.0 Instructions, procedures, and drawings	P,A,R	S,A,R	S,A,R	S	S
6.0 Document control	P,A,R	S,A,R	S,A,R	S	S
7.0 Control of purchased items and services	P,R	S,A,R	S	S,A,R	S
8.0 Identification and control of items	P,A,R	S,A,R		S	S
9.0 Control of processes	P,R	S,A,R	S	S,A	S,A
10.0 Inspection	P,R	S,A,R		S,A	S,A
11.0 Test control	P,R	S,A,R	S	S	S,A
12.0 Control of measuring and testing equipment	P,R	S,A,R		S,A	S,A
13.0 Handling, storage, and shipping	P,R	S,A,R		S	S
14.0 Inspection, test, and operating status	P,R	S,R		S	S
15.0 Control of nonconforming items	P,A,R	S,A,R	S,A,R	S	S
16.0 Corrective action	P,A,R	S,A,R	S,A,R	S	S
17.0 Quality Assurance records	P,R	S,A,R	S	S	S
18.0 Audits	P,A,R	S,A,R	S,R	S,R	S,R

Responsible organizations:

- DOE-RL** - U.S. Department of Energy-Richland Operations Office, AMC
- IC** - Integrating Contractor
- CM** - Construction Manager
- SUPP** - Support Contractor/Lab/Supplier
- A-E** - Architect-Engineer

Responsibility:

- P** - Primary
- S** - Support
- A** - Approve
- R** - Review/audit

3.0 DESIGN CONTROL

3.1 POLICY

Project design controls include not only controls traditionally used to ensure correct translation of design inputs including applicable regulatory requirements and design bases into designs but controls to ensure adequacy and validity of site characterization results and design bases. Plans and strategies, acquisition, reduction and analysis of data during site characterization, and subsequent system analyses, are construed as activities important to safety or waste isolation and are governed by controls described herein.

Project participants shall include provisions in their design control procedures for (a) documenting design errors and deficiencies upon discovery, and (b) ensuring that resulting corrections are properly reflected across all affected design interfaces.

3.2 COMPUTER SOFTWARE

Computer software for technical computer codes important to safety or waste isolation is to be controlled by participants' procedures consistent with guidelines established in NUREG 0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. These controls will be applied throughout all phases of the project.

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION

3.3.1 Design Control versus Test Control

The processes of identifying data needs, planning data acquisition work and sequence, and experiment design (i.e., preparation of the necessary "test procedures") for the Basalt Waste Isolation Project are associated with (a) establishing how much of the "as built design" of the site must be determined, (b) how and in what sequence the "as-built" characterization is to be done, and (c) what processes of data acquisition best assure the validity of such exploration and measurement. Therefore, the activities of data acquisition (test) planning and data acquisition (test) procedure generation require the same generic controls that more conventional downstream design activities require. Supplement 9, Reliability of Data, to the OGR QA Plan provides methods of determining usability of data previously developed for use in support of site characterization activities.

While preparation, review and approval of data acquisition planning and procedure generation are controlled under the design control provisions of the QA program, actual performance of the experiments, measurement, collection, etc., for

acquiring data is controlled under applicable provisions of Section 11.0, TEST CONTROL.

3.3.2 Existing Data

A considerable body of data relevant to site characterization (e.g., geotechnical, climatological, etc.) has been accumulated during activities predating establishment of the Basalt Waste Isolation Project and/or data acquired without qualified management controls in effect. The level of qualification of such existing data for site characterization purposes will be established on a case by case basis.

Criteria for determining data qualification levels will be developed by the Project, with due regard to relevant NRC and/or OGR guidance, utilizing appropriate direction provided in Supplement 9, Reliability of Data, to the OGR/QA Plan. (AMC technical and quality personnel will monitor this activity as prescribed in AMC Procedure BP 3.5, Data Qualification Activities for BWIP).

3.3.3 Current Data

Reduction and analysis of data collected during Project site characterization, or of prior data that has since been qualified, will be performed under controls specified in approved participant procedures. Such procedures will provide, as appropriate to the nature of the data reduction and/or analysis at issue, for:

- a. Documentation of assumptions, calculations, computer codes used, and intermediate results, as applicable,
- b. Independent review of the reduced data or completed analysis, to include consideration of appropriateness of assumptions and approaches, if applicable, and a check on reasonableness of calculation results (using simplified alternate calculations if necessary),
- c. Peer review if the reduction or analysis of the approach or technique is untried or goes beyond the existing state-of-the-art,
- d. Clear identification of results or conclusions requiring subsequent confirmation by additional exploration or research, or completion of on-going work, and
- e. Verification of effective implementation of applicable controls (by audit, surveillance, etc.).

3.3.4 Published Studies

Exploration or research results reported in the literature may be used as background, evidence of consensus, or explicit support for site characterization conclusions. When used in direct support of conclusions, such application shall be controlled by participant procedures that provide criteria for such use such as Supplement 9, Reliability of Data, of the OGR QA plan.

3.4 DESIGN CONTROLS FOR SITE CHARACTERIZATION STUDIES AND DESIGN OF EQUIPMENT, FACILITY, WASTE FORM AND WASTE PACKAGING

Participants responsible for strategy or test planning, test procedures, site characterization studies and/or for the design of (a) facilities or equipment that could subsequently be utilized if the site is selected as a repository site, (b) of equipment whose characteristics could affect validity of site characterization, or (c) conceptual designs upon which site characterization approaches or analyses shall be based, shall perform such activities in accordance with approved procedures that provide the following controls:

- a. Traceable documentation of design inputs, Design Bases, Regulatory Requirements, and the rationale for design decisions,
- b. Documentation of design assumptions, including rationale,
- c. Approved and correct computer software and controls,
- d. Competent checking and independent review,
- e. Approval by designated authority,
- f. Documented independent design verification,
- g. Control of design interfaces,
- h. Control of design changes equivalent to the controls applied to original design, and
- i. Review of design drawings, specification, criteria, and analyses by personnel of the cognizant QA organization to ensure compliance with governing procedures and QA program requirements.

3.4.1 Design Verification by Formal Design Review

Formal design review consists of documented traceable review performed by qualified personnel who are independent of those who performed the work or the checking, but who have technical expertise at least equivalent to that required to have performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluations of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

3.4.2 Design Verification by Testing

Verification by testing is intended to establish the ability of some or all features of the design to perform the intended function(s) under the most adverse design conditions. In simulating design conditions, appropriate provisions shall be made to assess potential effects of simultaneous occurrences of adverse conditions expected to reinforce each other if they were to occur simultaneously (such as seismic events and outbreak of fire).

Where testing reveals design (or fabrication) deficiencies, the testing shall be repeated after correction of the deficiency(ies).

Where only part of the design is verified by test, the remainder of the design shall be verified by other methods.

3.4.3 Design Verification by Alternate Calculations

Design calculations may be verified by use of other calculational approaches. Alternate calculations may be made by simplified methods verifying that results of the formal calculations are reasonable.

3.4.4 Design Verification by Similarity

Where all or portions of a design is/are verified by similarity to prior designs, verification shall establish that (1) conditions under which the prior design operated were the same as, or more severe than, relevant conditions in which the present design will operate, (2) the prior design operated or was tested under the most adverse combination of design conditions applicable to the present design, (3) the designer has determined and appropriately accounted for any deficiencies discovered during operation of the prior design, and (4) the design characteristic features or attributes that are not identical are verified by one or more of the methods described above.

3.5 PEER REVIEW

Where site characterization and/or other design activities involve the use of new, unusual or controversial approaches or techniques, or are beyond the state of the art, or where established review criteria for analytical results or technical conclusions do not exist, peer review will be conducted to reach a consensus among qualified, independent persons possessing expertise in the applicable discipline or disciplines. Documentation of peer review will include a record of issues addressed during the review, resolution of relevant questions and comments including minority opinions not resolved, and the relationship between reviewers' qualifications and the subject of the review.

3.6 DESIGN CHANGES

Design changes including field changes require technical controls commensurate with controls exercised on the original design, including review by the design organization who was responsible for the original design (unless otherwise specified by DOE). Design change controls shall include nonconformances to design requirements dispositioned use-as-is or repair. In addition, design changes that might entail significant impact to Project concept, cost, schedules or safety apportionments must be submitted for Project Change Control Board approval and may result in procedure changes or additional training. DOE AMC processes changes in accordance with procedure BP 3.2, "Disposition of Change Requests."

3.7 DESIGN INTERFACES

Significant design interfaces exist among Project participants who are assigned responsibility for portions of the design. The Integrating Contractor is responsible for assuring that such interfaces are clearly defined by those participants and that interfacing design organizations maintain up-to-date procedures for clear and timely communication across interfaces.

3.8 REVIEW PLAN

It is intended that a general plan and schedule be developed and continually updated to show the technical and readiness reviews that are to be accomplished for site characterization and design activities. The Integrating Contractor is responsible for obtaining and integrating the necessary information for this plan on a project-wide basis, and to verify completion.

3.9 AMC COGNIZANCE

3.9.1 DOE-RL AMC Technical Surveillance

AMC personnel exercise regular and frequent surveillance within their areas of expertise over technical work being performed by Project participants (ref. AMC Procedures BP 2.2, Work Progress and Design Reviews and BP 18.5, Surveillance of Project Activities). Technical surveillance includes:

- a. Confirmation that approaches conform to recognized practice within the discipline, or to practice evaluated and endorsed via the peer review process,
- b. Confirmation that in-process results reasonably proceed from the assumptions and approaches being used, and
- c. Evaluation of technical effectiveness of controls applied to collection, reduction and analysis of supporting data or studies.

3.9.2 DOE-RL AMC Participation in Peer Reviews

AMC technical personnel will be involved in the peer review process in two ways. The cognizant AMC individual will participate in or observe selected peer reviews convened by project participants, and any AMC technical individuals may initiate peer reviews if they have reason to believe Project work in their areas of expertise meets one or more of the peer review criteria of Section 3.5 of this QAP (ref. AMC Procedure BP 3.3, Peer Review).

3.9.3 Document Review

AMC technical personnel review technical documents (such as test reports, analyses, reports of study results, etc.) for appropriateness of approach, reasonableness of conclusions, clarity and evidence of necessary supporting inputs (ref. AMC Procedures BP 6.3, Review of and Approval of External Documents and BP 2.8, Control of and Release of Licensing Documents). Such reviews and subsequent approval are to be accomplished prior to initiation of affected follow-on work unless provisional go-ahead is authorized explicitly on an exception basis.

3.9.4 Documented Review Meetings

Any member of the AMC staff may initiate a documented review meeting to resolve a concern. Typically, a documented review meeting is convened if a member of the technical staff feels that too many controversial issues have surfaced during a peer review or has unresolved questions after reviewing a technical document generated by one of the project participants (ref. AMC procedure BP-3.1, PROJECT REVIEWS).

3.9.5 AMC QS Division Audit and Surveillance of Design Controls

Quality Systems Division performs audits and surveillance of project design controls in accordance with approved AMC procedures, as described in Section 18.0 of this QAP.

3.9.6 Readiness Reviews

Readiness Review are systematic documented reviews of the readiness for startup and/or continued intended use of a facility, process, or activity. Readiness Reviews are typically conducted before proceeding beyond established project milestones, and prior to initiation of a major work activity or event.

The AMC establishes Readiness Review Program requirements, including applicable QA requirements as a minimum, in the Readiness Review Program Plan. The AMC coordinates Readiness Review activities among the DOE-OGR, the Integrating Contractor (IC), the NRC, States and Indian Tribes, as necessary. The AMC approves internal and IC Readiness Review documents, and concurs with Hold Points established in the Project Schedule by the IC. AMC internal activities associated with Readiness Reviews are conducted in accordance with BP 3.6, Readiness Review.

The IC develops the Readiness Review Program Plan (RRPP) and subordinate documents implementing the requirements established in the RRPP. The IC interprets and directs the application of Readiness Review requirements in-house, for Direct Funded Contractors, and for the IC's subcontractors in accordance with their internal implementation procedures.

The execution of Readiness Reviews and the development, review, approval, and changes to associated documentation packages are controlled in accordance with written procedures and instructions.

4.0 PROCUREMENT DOCUMENT CONTROLS

4.1 PROJECT PARTICIPANTS

Procurement document controls in the Project shall ensure that the responsible participant communicates needs and requirements clearly and accurately to the supplier. Project participants are required to establish and implement administrative procedures for the preparation and control of documents that specify technical and quality assurance requirements for purchased items or services. These procedures will include provisions and identify responsibilities for the following:

- a. Procurement planning,
- b. Preparation, review, approval and control of procurement documents,
- c. Review of procurement documents by the participant's QA personnel to determine that applicable regulatory requirements, design bases (where applicable), and other requirements are referenced or included in the procurement documents; that adequate accept/reject criteria and plans for acceptance are included where appropriate; that an appropriate supplier QA program has been specified; and that the procurement documents have been prepared in accordance with the applicable procedure(s).
- d. Bid evaluation, with participation by the initiator and/or QA (as applicable) for bids that restate or interpret technical and/or quality assurance requirements,
- e. Review of, and concurrence with, the supplier QA program prior to initiation of supplier work subject to program requirements.

For controls related to procurement of instrumentation or equipment used for data collection under conditions in which failure or malfunction during collection of data might not be detectable, see Section 11.4.

4.2 INTEGRATING CONTRACTOR ROLE

The Integrating Contractor will evaluate selected procurement document packages prepared by other Project participants during audits and surveillances of those participants' QA program implementation.

4.3 AMC EVALUATION ROLE

AMC QS Division will review selected procurement document packages prepared by Project participants, including those prepared by the Integrating Contractor, during QA audits and surveillances of Project activities. For AMC initiated procurements, AMC Procedure BP 4.1, Preparation and Control of Procurement Documents is complied with.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Project activities are prescribed by, and performed in accordance with, written instructions, procedures and/or drawings appropriate to the work. Such procedures, instructions and drawings shall be reviewed for accuracy and adequacy by personnel who are competent in the subject matter and by QA for program compliance. Section 3.4 defines the requirements for reviewers of design documents and Section 6.4 covers instructions and procedures.

5.1 ADMINISTRATIVE PROCEDURES

Administrative procedures are documents that define management controls and control systems, establish responsibilities and authorities for exercising them, and specify the approved overall methodology. The Project is governed by two basic categories of administrative procedures: (1) Procedures that define and direct operation of the Project management system, covering such areas as the work breakdown system, the various project baselines, etc. are reviewed as stated in 5.0, and (2) procedures that define and direct controls and control systems making up the Project quality assurance program. Requirements of this section, relative to administrative procedures, apply to the second category, which are designated "QA administrative procedures".

Each participating entity (i.e., government agency, public institution or civilian contractor such as USGS, states, universities, and national labs) in the Project is responsible to prepare and implement QA administrative procedures necessary to implement its approved QA Plan (QA program description).

5.2 TECHNICAL PROCEDURES

Project technical work is prescribed by, and performed in accordance with, detailed procedures (e.g., laboratory procedures, special process procedures, test procedures, etc.). Each participant is responsible for assuring that such procedures are prepared, issued and used. Controls required by the quality assurance program are incorporated at applicable points in these procedures. Technical procedures require review by the participant's QA personnel prior to use to verify that the necessary control features have been included.

5.3 INSTRUCTIONS

Written instructions are ordinarily detailed sequences of steps, descriptive material specifying how an activity is to be performed, statements of actions necessary to carry out a nonconformance disposition, inspection checklists, etc.

5.4 DRAWINGS

Certain kinds of tasks can be performed correctly by appropriately trained or experienced personnel from drawings, schematics or sketches. Typical examples include machining, sheet metal forming, pipe fitting, electrical installation, etc.

5.5 ACCEPTANCE CRITERIA

Documents that prescribe Project work shall include criteria by which acceptability of completed work can be determined, both by those who perform and supervise the work and those who independently verify acceptability. It is recognized that the acceptability of much site characterization work will not be amenable to quantitative specification; for such work, qualitative criteria shall be identified.

5.6 USE AND AVAILABILITY

The requirement for written instructions, procedures and drawings arises from the need to ensure that proper instruction is provided, to enable verification of correct performance, and to establish lasting records of what was done. Credibility of the record requires that the documentation of performance corresponds to intended actions and methodology. Actual quality of performance depends on suitable assurance of the quality of instruction, faithful performance to instructions, and appropriate application of relevant controls.

The need for physical presence of written instructions where the worker is performing a specified job is a function of task complexity, ability to verify work quality, related skill of the worker, etc. As a minimum for any activity within the scope of the project quality assurance program, applicable written instructions shall be readily available to the worker, and project personnel are to ensure (a) that they perform their work in accordance with the applicable instructions and (b) that their work meets established requirements before being submitted as completed.

Physical presence of applicable instructional direction is mandatory where the complexity of the work, or the importance of a specific sequence of steps, introduces risk into performance from memory; monotony or other factors create a risk of overlooking steps or violating safety requirements; or subsequent examination of the work cannot reliably detect incorrect or omitted steps.

5.7 AMC PREPARATION OF BASALT PROCEDURES (BPs)

Preparation of procedures for use within AMC Divisions is controlled by AMC Procedure BP 5.1, Procedure Development.

6.0 DOCUMENT CONTROL

6.1 CONTROL ELEMENTS

All Project participants are required to maintain document control systems for documents that direct or affect work within the scope of the Project QA program. These document control systems are required to provide for:

- a. Identification of documents to be controlled,
- b. Identification of responsibility assignments for preparing, reviewing, approving and issuing documents,
- c. Review of documents and document changes for adequacy, completeness and correctness prior to approval and issuance,
- d. Coordination and control of interface documents,
- e. Availability of correct and applicable documents at the work place,
- f. Ascertaining that proper documents are being used,
- g. Ensuring that obsolete or superseded documents are not available for inadvertent use,
- h. Establishment and maintenance of up-to-date distribution lists,
- i. An effective way for document users to determine whether a document is current and in effect, and
- j. Explicit identification and control of documents that are released prior to required verification, and of any Project data resulting from the use of such unverified documents prior to their verification.

6.2 AMC DOCUMENT CONTROL

Document control within the AMC Divisions is exercised in accordance with AMC Procedures BP 6.1, Preparation and Release of AMC Documents and BP 6.2, Controlled Documents Issued to the AMC Staff. The applicable controls specified in Section 6.1 are implemented in these AMC procedures.

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL

6.3.1 AMC QA Documents

The BWI Project QA Plan, the BOARD and implementing AMC QA administrative procedures (ref. Table 2-1 of this QAP) require OGR review and approval.

6.3.2 Integrating Contractor, Construction Management Contractor and Architect/Engineer Documents

QA program descriptions and implementing QA administrative procedures prepared by the Integrating Contractor, Construction Manager and Architect/Engineer require AMC approval.

6.3.3 Other Participants' Documents

Other participating organizations are required to submit their QA Plans and implementing QA administrative procedures for review and approval by the next higher participant in the project hierarchy (see Figure 1-3). However, DOE-RL's AMC will review and approve QA program descriptions, QA administrative procedures and any major or substantive changes thereto for other government agencies performing Project work under Memoranda of Understanding (MOU) with the DOE, and for public institutions performing Project work on direct contract with the DOE.

6.3.4 Technical Documents

Technical reports prepared by project participants as a basis for, or as part of, BWI site characterization, waste form, waste package design, or repository design, require AMC review and approval (ref. Project Management Plan and System Engineering Management Plan).

6.4 REVIEW AND APPROVAL PROCESS

Document review may be accomplished by competent, independent reviewers on an individual review basis, or in formal document review meetings. In either process, reviewer comments and the resolutions of comments are required to be documented for the record, and document approval requires determination by the approver(s) that all comments have been resolved satisfactorily.

Controlled documents require review by the cognizant QA organization for concurrence with quality-related aspects.

6.5 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS

Controlled documents reaching the AMC, or sent out of the AMC, are controlled in accordance with AMC Procedures BP 1.8, Correspondence Control, BP 6.1, Preparation and Release of AMC Documents, and BP 6.2, Controlled Documents Issued to AMC Staff. Controls include logging, updating of distribution lists and document indices, and a formal receipt acknowledgment system to assure superseded documents are replaced in a timely manner.

6.6 CONFIGURATION MANAGEMENT

"Configuration" is defined in DOE Order 4700.1 (3/6/87) as the "functional and/or physical characteristics of hardware and/or software as set forth in technical documentation and achieved in a product." The Project Baseline (comprised of technical, cost, and schedule baselines) is set forth in designated documents which uniquely define the approved project "configuration" at any point in time. The control of these descriptive documents is exercised through "Configuration Management," which is defined in DOE Order 4700.1 as "the systematic evaluation, coordination, approval (or disapproval), documentation, and implementation, and audit of all approved changes in the configuration of a product after formal establishment of its configuration identification."

Configuration Management uses the applicable document control requirements when changes are made to baseline documentation, since the project configuration is defined in written documents. The AMC and project participants execute Configuration Management through compliance with plans and implementing procedures developed by the Integrating Contractor. The AMC approves the Configuration Management Plan.

Continued or repeat procurement from active suppliers or suppliers who have previously been used for BWI Project work will be based in part on evaluation of performance of such previous work.

Where DOE-RL AMC contracts directly (via DOE-RL Procurement Division) for items or services within the scope of the BWI Project QA program, supplier selection and evaluation is accomplished in accordance with AMC Procedure BP 7.1, Supplier Evaluation, Selection and Verification.

7.3 VERIFICATION

7.3.1 Verification of Work in Progress

The extent and nature of verification activities to be accomplished for procured items or services within the scope of the BWI Project QA program will be planned at the outset. Such verification shall include mandatory hold points for inspection or witnessing, where appropriate, and surveillance and/or audit. Mandatory hold points for inspection and witnessing are determined by engineering and/or QA when work authorization documents are reviewed for release. In-progress inspection, witnessing and surveillance will include review of the status of required documentation.

7.3.2 Acceptance

Acceptance of completed items or services is accomplished as follows:

a. Items and materials - one or a combination of:

- (1) Receipt inspection
- (2) Certificate of conformance
- (3) Source inspection, surveillance and/or audit
- (4) Post-installation testing

b. Services: In-progress audit and surveillance as appropriate and review/approval of the completed service(s) (including technical reports, completed studies, etc.).

NOTE: Audits/surveillance alone may not be used as a basis for acceptance of items, materials, or services.

The procuring participant's QA organization shall verify that required documentation is received and complies with procurement QA requirements. Acceptability of results of technical services (such as studies, analyses, etc.) will be determined by the organization initiating the procurement.

Where certificates of conformance are to be accepted, the cognizant QA organization verifies by audit, surveillance and/or inspections that the supplier's system for substantiating such certification is valid as implemented.

7.4 SUPPLIER-FURNISHED DOCUMENTATION

Project participants are required to include provision in procurements within the scope of the Project QA program for the following supplier furnished documentation:

- a. Documentation that identifies the purchased service and the specific procurement requirements met (e.g., codes, standards and specifications),
- b. Documentation identifying any procurement requirements that have not been met, and
- c. A description of any nonconformances from the procurement requirements that have been dispositioned "accept as is" or "repair".

Participant procedures for receipt of purchased items or services shall include explicit provisions for verifying that such documentation is delivered and is acceptable.

7.5 AMC CONTROL OF PURCHASED ITEMS AND SERVICES

DOE occupies the role of owner on the BWI Project. Project work is accomplished on contracts between DOE and major contractors, interdepartment agreements between DOE and other federal government agencies, various contractual arrangements with non-federal public agencies and institutions, and subcontracts issued by major contractors. The entire Project, therefore, comprises a DOE procurement network.

DOE-RL's AMC is responsible for administering that entire procurement network, for specifying the necessary QA program, and for ensuring that delivered items, materials and services comply with applicable quality assurance requirements. Compliance with applicable provisions of the QA program described in this QA Plan is a condition of all BWI Project procurement contracts. Direct procurements within the scope of the BWI Project QA program, initiated by AMC, are managed by AMC under AMC Procedures BP 4.1, Preparation and Control of Procurement Documents; BP 7.1, Supplier Evaluation, Selection and Verification; and BP 7.2, Supplier Furnished Records. Nonconforming items or services the Integrating Contractor proposes to disposition "accept as is" or "repair" (or to disposition in a way that fits the definition of either of those two dispositions) are reviewed and approved or disapproved by AMC personnel in accordance with AMC Procedure BP 15.1, Processing Contractor NCRs and Unusual Occurrences.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES

Items, materials and samples are identified and controlled on the BWI Project in order to ensure (a) that the history of items and materials is fully known from the time of receipt to the point of use, and that traceability is maintained to the project records, and (b) that samples are traceable from the sampling point to the point of consumption or long-term storage. Provision will be made for documenting in the project records the installation, consumption or other use of any Q-listed item or material (including samples) in such a manner that it will be possible at any later time to reestablish the identity (and therefore, the history) of any such item, material or sample, given its final location or use. (Note: Continued traceability of samples in storage is a part of records management.)

Each project participant is responsible for identification and control of items, materials and/or samples in their custody. The Integrating Contractor provides overall Project direction for identification and control systems. Each participant's procedures for identification and control of samples (where the participant has custody of samples at any point in their life) provide traceability from the samples to applicable documentation such as drawings, specifications, purchase orders, drilling logs, photographs (where used), test records, inspection documents, and nonconformance reports as applicable. These procedures also provide for verification and documentation of correct sample identification prior to the release of samples for use or analysis, and preclude assignment of a single identifier to multiple discrete samples. In situations involving subdivision of a sample, identification of the individual items resulting from the subdivision shall be readily traceable to the original sample.

The Integrating Contractor is responsible for ensuring project wide controls in this area by monitoring and verifications, and AMC QS Division verifies effectiveness of contracts by surveillance and audit.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SPECIAL PROCESS - DEFINITION

A special process is one whose outcome cannot be fully characterized by nondestructive methods (i.e., where not all characteristics of the finished item can be evaluated by direct inspection, or direct inspection is disadvantageous).

9.2 IDENTIFICATION AND QUALIFICATION

Special processes used on the BWI Project are explicitly identified in appropriate QA program documents (QAP or QA-related administrative procedures), and each participant shall develop and maintain a list of those procedures that are considered to fall within the scope defined by Section 9.1, above. Special processes are required to be in compliance with applicable codes, standards, specifications, and QA procedures. Participants shall provide copies of their special process lists to the integrating contractor who will maintain and distribute a controlled listing of special processes used by the participants on the project. The procedures that specify how individual special processes are to be performed are qualified by demonstration that, when performed as specified, the process yields required results. Special process personnel are qualified by training (where appropriate) and demonstration that they can perform the process(es) with the desired results. Where equipment affects the outcome of a special process, the equipment is similarly qualified. The responsible participant's QA Plan shall describe the role the QA organization plays in qualification of special process procedures, personnel and/or equipment.

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES

Where validity of site characterization depends on precise control of processes, procedures will include provisions for in-process documentation of process and parameters in such a manner as to enable after-the-fact reconstruction of affected work.

In particular, records of process, personnel and equipment qualification will be maintained.

9.4 STANDARD "SPECIAL PROCESSES"

It is recognized that site characterization will involve laboratory processes (chemical analyses, for example) for which standard techniques have been developed within the scientific community and whose reliability has been demonstrated by broad usage. Such processes are not expected to require formal qualification within the Project. Independent verification that special processes are performed in accordance with the specified process procedure will be

planned and accomplished on the basis of approved guidelines developed by the responsible participant.

The Integrating Contractors QA organization shall monitor and periodically verify that appropriate controls are in place. AMC QS Division will audit and perform surveillances to verify control effectiveness.

10.0 INSPECTION

10.1 INSPECTION ACTIVITIES

The following categories of inspection activities will be conducted as applicable during BWI site characterization:

- a. Source inspection during designated procurements,
- b. Receipt inspection for procured items and materials,
- c. In-process and acceptance inspections during and after fabrication, construction, installation, test or modification work performed by Project participants, and
- d. Inspection of samples.

Acceptance of results of technical studies, design activities, etc., is not an "inspection" activity as discussed here. See Section 7.0 of this QAP for acceptance of such procured services.

10.2 INSPECTOR QUALIFICATION

Formal inspection is performed either by inspectors reporting to a participant's QA organization or, where appropriate, by personnel possessing particular expertise. QA personnel performing inspection functions will be qualified in accordance with ANSI/ASME NQA-1-1986 Supplement 2S-1 and Appendix 2A-1, Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel. (The use of SNT-TC-1A-1980 Qualified Level I NDE inspectors for inspection acceptance is not allowed for the BWI Project). Where experts are required for special inspections, QA in concert with the technical organization determines the inspection requirements and QA evaluates individual qualifications and provides the necessary QA training to ensure the individual can perform the inspections, use the inspection equipment, and document the inspection results. The qualification records of inspection personnel are reviewed by the participant QA organization. Participants may have inspection personnel or they may contract for inspection services.

10.3 RESPONSIBILITIES

Inspection responsibility is assigned to those participants performing activities identified in the first paragraph of Section 10.0. The Integrating Contractor requires project-wide standardization of certain inspection practices and formats to facilitate processing and later use of results and is responsible for ensuring the effectiveness of Project inspection activities. Participating contractors who perform inspections shall perform audits and surveillances of inspection activities.

AMC QS Division verifies that Project inspection activities are achieving intended results through audit and surveillance.

10.4 INSPECTION PROCEDURES

Project inspection is performed in accordance with procedures or checklists, or with explicit inspection steps in the work procedures prepared by the participating contractors. Regardless of the vehicle, such instructions are reviewed and approved by authorized QA personnel prior to use.

Inspection instructions shall provide, as necessary, for mandatory hold and/or witness points beyond which work cannot proceed until the required inspection or witnessing has been accomplished. In addition, inspection instructions are expected to provide for:

- a. Identification of the characteristics and/or activities to be inspected,
- b. The method(s) or inspection to be used,
- c. Identification of the individual(s) or groups(s) responsible for performing the inspection,
- d. Identification of required prerequisites (including required procedures, drawings, and specifications and revisions) and working conditions for the work to be inspected,
- e. A means for recording inspector or data recorder identity and the results of the inspection operation,
- f. Specification of measuring and test equipment required to perform the inspection, as well as accuracy requirements, and
- g. Acceptance and rejection criteria or reference to the requirements document(s) (such as drawings) that specify these criteria, and
- h. Date of inspection.

10.5 INSPECTION RESULTS

Participants whose activities include work requiring inspection will establish and implement procedural requirements for documentation of inspection results and for documented evaluation of the acceptability of results.

10.6 DOCUMENTATION AND RECORDS

Verification that activities have been accomplished in accordance with, and that their results conform to, established requirements is documented as performed and is retained as part of the formal Project record.

11.0 TEST CONTROL

11.1 TEST ACTIVITIES

In addition to testing accomplished in traditional projects, BWI Project activities conducted for the purpose of acquiring physical data for site characterization (such as sample collection, sample analysis, tests of rock behavior or hydrologic dynamics, etc.) are considered site characterization test activities. Such data acquisition activities will be performed with controls applied to traditional testing, such as procedures, controlled selection and use of measuring and test equipment, verification that specified prerequisites (when applicable) are met, etc. Where the course of action has to be determined as acquisition proceeds, based on ongoing results, it is expected that the need will be recognized during planning and that provisions will be made for field decisions and or other appropriate actions. The intent is to ensure a controlled degree of necessary flexibility.

11.2 TEST PLANS AND PROCEDURES REVIEW

Testing requirements are derived basically from information requirements specified in NRC's 10 CFR 60, DOE's site characterization guidelines in 10 CFR 960 and the issues identified in the geologic repository program Mission Plan. The four major issues identified in the Mission Plan have been translated into more detailed issues directly applicable to characterization of the basalt waste isolation site. Information needs strategy is established in response to those site-specific issues and iterative results of performance assessment studies and conceptual design.

Test planning and test procedures are to be reviewed and approved in accordance with controls established in response to Section 3.0, DESIGN CONTROL, of this QAP. That is, planning for data acquisition and preparation of data acquisition procedures are primary links in the definition of inputs to subsequent design and are, therefore, in the earliest phase of the design process. The planning activity and procedure preparation, review and approval are to be handled under the same controls as those applied to all other design phases.

11.3 UNCERTAINTIES AND ERROR

To the extent practicable, test planning shall include (a) identification of potential sources of error and/or uncertainty, and (b) analyses of the degree of uncertainty or error these sources could produce in the test results. Parameters that need to be measured and/or controlled to minimize such uncertainties or error, and to assure adequate control of the test, are expected to be addressed explicitly in test procedures.

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION

For instrumentation and/or equipment used in data collection, Project participants shall consider whether failure or malfunction of the instrumentation during test will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, (a) technical and quality procurement requirements will be selected specifically to minimize the likelihood of undetectable anomalies, and (b) test planning and procedures will include any special provisions for equipment/instrumentation configuration, installation and use that can further reduce risk of undetectable failure or malfunction.

11.5 PERSONNEL QUALIFICATION

Project participants are required to establish appropriate descriptions of the qualifications required of personnel who perform site characterization testing. These qualification descriptions may be stated in the form of the minimum qualifications required for personnel to fill specific positions. Participant management shall assure that personnel assignments to testing duties are consistent with the individual's qualifications or that explicit plans are in place and are implemented to bring the individual's qualifications into conformance.

11.6 TEST PROCEDURE CONTENT

Test procedures shall include as appropriate the following elements:

- a. Requirements and acceptance limits, including precision and accuracy, contained in applicable documents.
- b. Test prerequisites such as calibrated instrumentation, presence of specified test equipment and instrumentation, completeness and/or acceptability of item or condition to be tested, specified environmental conditions, and provision for data collection and storage. For tests of long duration, it is expected that specific provisions will be made for instrumentation whose calibration interval is shorter than expected test duration. Such provisions are to be designed to ensure validity of data throughout the test.
- c. Instructions for performing the test.
- d. Mandatory inspection and/or witness points (as required).

- e. Acceptance and/or rejection criteria, including required levels of precision and accuracy. (Note: "Accept/reject criteria" means that those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output which, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)
- f. Methods of data analysis (which may, however, appear in data analysis procedures other than the procedures used for performing the testing).
- g. Methods of documenting or otherwise recording test data and results.
- h. Provisions for assuring and documenting the fact that test prerequisites were met.

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE

Project participants shall assure that test results are evaluated and their acceptability determined by the responsible individual(s) or group(s), as indicated in applicable subsections of Section 3 of this plan. Test records shall include the following information where applicable:

- a. A description of the type of observation,
- b. The date and results of the test,
- c. Information related to conditions adverse to quality,
- d. Data recorder identify,
- e. Evidence as to acceptability of results, and
- f. Action taken to resolve any discrepancies noted.

11.8 DOE-RL AMC TEST CONTROL RESPONSIBILITIES

AMC will verify by technical surveillance, QA surveillance and QA audit that the Integrating Contractor's direction and management is producing effective test controls throughout the project.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

12.1 CALIBRATION PROGRAM

The Integrating Contractor is responsible for ensuring that adequate calibration control systems are implemented for M&TE to be used on the project. Participating contractors whose work includes use of M&TE devices or systems used to calibrate, measure, gauge, test, inspect, control, or to acquire data for process control in order to determine compliance with design, specifications, or technical requirements shall implement a calibration program for their own equipment. These systems shall provide for use of calibration standards traceable to nationally recognized standards; selection of M&TE on the basis of application requirements; tagging or other appropriate and effective means of knowing calibration status of individual items of M&TE; calibration intervals based on M&TE characteristics and usage; repair or replacement of M&TE found to be damaged or consistently outside allowable calibration limits; and reevaluation of results obtained by use of M&TE subsequently determined to be out of calibration.

When a nationally recognized standard does not exist, the basis for calibration is documented and reviewed. Where beyond the state-of-the-art or untried methods are being employed for calibration, an evaluation shall be made to determine if a peer review of the proposed method is required by the organization that established the calibration requirements. Participants shall describe in their QA administrative procedures the types of M&TE that are subject to a calibration program. This section does not apply to such devices as watches, rulers, tape measures, levels, etc., where normal commercial practice provides adequate accuracy.

12.2 QA INVOLVEMENT

Cognizant QA organizations within the Project are responsible for verifying that the calibration controls established and implemented by their parent organizations are adequate and effective. QA involvement includes review of, and concurrence with, calibration program procedures, as well as audit and surveillance of calibration activities.

12.3 DOE AMC OVERVIEW

AMC QS Division verifies effectiveness of the Integrating Contractor's management of the calibration control system by surveillance and audit.

13.0 HANDLING, STORAGE AND SHIPPING OF ITEMS, MATERIALS AND SAMPLES

Each Project participant whose tasks include receipt, processing or storage of items, materials or samples within the scope of the BWI Project QA program is required to establish and implement controls that protect them from loss, damage or deterioration. Participants' QA organizations shall monitor their programs to assure controls are in place.

These procedures shall require that specific handling, storage, preservation, packaging and shipping instructions be prepared by knowledgeable, responsible individuals, and that such activities be performed in accordance with approved instructions by suitably trained personnel. Where appropriate, qualification of special lifting equipment, slings and hoists is to be addressed explicitly.

The Integrating Contractor is responsible for ensuring project-wide controls in this area by audits and surveillances, and AMC QS Division verifies effectiveness of these controls by surveillance and audit.

14.0 INSPECTION, TEST AND OPERATING STATUS

Controls for maintaining and indicating the status of BWI Project inspections, test and operations are established and implemented for the purpose of:

- a. Ensuring that required inspections or tests, or required inspection or test steps, are not inadvertently bypassed, and
- b. Ensuring that personnel working on, or in the vicinity of, site characterization test or operating equipment are aware of the operating status of the equipment.

Project participants are required to establish and implement procedures that provide for use of status indicators (such as tags, markings, area postings, etc., as appropriate) to show inspection, test and/or operating status. In addition, logs, status boards or other suitable administrative controls are required where knowledge of status is required at locations remote from the actual inspection, test or operation activity.

The Integrating Contractor's QA organization shall monitor and periodically verify that appropriate controls are in place. AMC QS Division will audit and perform surveillances to verify control effectiveness.

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES

15.1 IDENTIFICATION AND CONTROL

Each project participant is required to identify any nonconforming item, material or sample by marking, tagging or other appropriate means immediately upon detection of the nonconformance. Such identification shall provide clear indication of the nonconforming condition of the item, material or sample to anyone who might otherwise process or use it. Measures shall include segregation where practical.

Any nonconformance is required to be documented upon discovery and reported promptly for evaluation and disposition. Project participants shall establish and implement systems for tracking and segregating nonconforming items until disposition has been accomplished, and for preventing inadvertent use of such items. Corrective action taken to prevent recurrence of nonconformances shall be documented.

15.2 EVALUATION AND DISPOSITION

Each participant's procedure(s) for control of nonconformances is/are required to provide for authorized, knowledgeable individuals to evaluate the significance and project implications of the nonconformance; to determine what disposition is to be made of the nonconforming item, material or sample; to provide signed appropriate instructions for carrying out the specified disposition; and to specify accept/reject criteria (where applicable) for verifying that the specified disposition has been accomplished correctly. Personnel responsible for the QA function for the participant shall participate in the evaluation and disposition process for nonconformances.

Technical justification for the acceptability of a nonconforming item, dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.

Decisions to use the nonconforming item, material or sample as is, or to restore it to usable condition without returning it to fully conforming condition, require technical review and approval by the responsible design organization. The technical organization of the next higher level of project participation also reviews use-as-is and repair dispositions for acceptability. The QA organization checks for compliance with established requirements through audits and surveillances.

Standard repair procedures may be prequalified and utilized for repairs after initial technical review and approval at the next

higher level of project participation, and used in dispositioning subsequent nonconformances.

15.3 ACCOMPLISHMENT OF DISPOSITIONS

Each participant's procedure(s) for control of nonconforming items, materials or samples is/are required to contain provisions for documented verification that disposition of such items, materials or samples is carried out in accordance with instructions and meets the specified accept/reject criteria.

15.4 TRENDS

The participants shall establish systems for monitoring and analyzing nonconformance reports for trends to help to determine root cause and to initiate appropriate action where the need is indicated. AMC review of nonconformance reports submitted by the Integrating Contractor is accomplished in accordance with AMC Procedure BP 15.1, Processing Contractor NCRs and Unusual Occurrences. Trends are determined and monitored in accordance with AMC Procedure BP 15.2, Trend Analysis. The AMC QS Division Director evaluates trend reports and notifies the BWIP Project Manager of significant nonconformance trend information.

16.0 CORRECTIVE ACTION

Corrective action on the BWI Project consists of (a) action to correct observed conditions that do not conform to specified requirements, and (b) action to prevent recurrence. Significant quality problems are defined as significant or recurring nonconformance or adverse condition which if uncorrected could have a serious effect on safety or waste isolation, could adversely affect the validity or credibility of site characterization conclusions, could endanger project personnel or property, or could have a major impact on project costs or schedules or affect safety, reliability or performance.

16.1 CORRECTIVE ACTION PROGRAM

The Integrating Contractor is responsible for establishing and ensuring implementation of a project-wide program for formal corrective action to prevent recurrence of significant problems. The program is expected to provide for the following:

- a. Evaluation of participant reported problems to determine significance, including potential implications to previously completed Project work,
- b. Investigation to determine the root cause of problems determined to be significant,
- c. Action to eliminate or compensate for the identified root cause,
- d. QA verification that defined preventive action is accomplished, and
- e. QA verification that the preventive action actually prevents recurrence.

AMC conducts corrective action in accordance with AMC Procedure BP 16.1, Corrective Action.

17.0 RECORDS MANAGEMENT

17.1 RECORDS MANAGEMENT SYSTEM

The Integrating Contractor is responsible for definition and operation of the BWI Project records management system. Quality Assurance requirements governing generation and control of records are incorporated into the Integrating Contractor's implementing procedures, which apply to all project participants. Documents and items (such as core samples, etc.) that are to become part of the formal record are transmitted directly to the Integrating Contractor for the necessary processing and storage.

Further policy direction for quality assurance records has been established by DOE-HQ through the Office of Geologic Repositories (OGR) as specified in OGR/B-3 Supplement No. 4, Quality Assurance Records. The Records Program shall include those records important to safety or waste isolation and which are required for site characterization, subsequent licensing or in operation of a repository. Completed records shall be transferred to permanent storage in a timely manner. Interim storage pending transfer shall be in (a) one hour fire rated cabinets, (b) in dual storage or (c) in metal files protected by an automatic electronic monitored dry fire protection system in a room or building. Record retention classification and disposition planning will be established after the first site is selected and licensed as a high-level waste repository, based upon guidance provided in OGR/B-3, Supplement No. 4.

Geotechnical samples will not be stored in accordance with the requirements for storage of QA records (NQA-1, Supplement 17S-1, Section 4.4.1). Samples will be afforded archival controls and protection in a building for the period during which additional examination or analysis by DOE or the NRC may be needed. No provision in the storage system will prevent or mitigate the natural time-dependent deterioration processes inherent to the sample materials that will destroy or substantially change sample properties, so they may not lend credibility to previous test results or analysis.

Organizational responsibilities for elements of the overall records management system are specified in appropriate participant procedures. The participants' QA organizations shall audit and perform surveillances of their own Records Program. In addition, the Integrating Contractor's QA manager shall have audits and surveillances of the participants' and of BRMC's Record Programs performed.

17.2 DOE-RL AMC RECORDS

DOE AMC generated material is submitted to the record in accordance with AMC Procedure BP 17.1, Quality Records.

17.3 ARCHIVAL FACILITY

Project records other than geotechnical samples in long-term storage shall be kept in a facility that meets all applicable requirements relative to record protection from deterioration and disaster.

17.4 RECORDS PROGRAM OVERVIEW

AMC QS Division shall evaluate the effectiveness of the controls of BRMC by surveillance and audit.

18.0 AUDIT AND SURVEILLANCE

18.1 AUDIT - GENERAL

With specific exceptions identified herein, all participants in the BWI Project are required to establish and maintain formal internal QA audit programs that comply with requirements stated in the BQARD and this document. Participants who award subcontracts for project work (thus establishing subtier participants) are required to conduct external audits of the QA programs of the subtier participants for whom they are responsible. The Integrating Contractor, in his project management role, is also required to schedule and conduct audits of all other major contractors, including the Construction Management Contractor and the Architect/Engineer.

Audits performed by the AMC QS Division will normally include participation by appropriate technical advisors, who will verify adequacy of technical processes employed to assure the validity and correctness of technical work.

AMC QS Division audits Project activities indicated below:

- a. Activities within the scope of this QA program performed by the BWI Division,
- b. Implementation of the Project QA program as established and managed by the Integrating Contractor, and
- c. Selected activities throughout the Project, with emphasis on performance of major contractors in their implementation of the Project QA program as it applies to them and on effectiveness of contractor audit programs.

In addition, QS Division auditors accompany audit teams of the Integrating Contractor and other major contractors on selected audits to observe audit performance and evaluate effectiveness of contractor audit processes.

QS Division is audited by the ES&H QA Branch or by third party auditors under the auspices of ES&H QA at regular intervals.

18.2 AUDIT PROGRAM CONTENT

QA audit within the BWI Project addresses the following questions:

- a. Is the audited participant carrying out his approved QA program?
- b. Are the controls and/or control systems defined in the audited participant's QA program working effectively?

- c. Does the record provide convincing objective evidence that the controls and/or control systems have been, and are being, rigorously applied (i.e., that a rigorous forensic record is being compiled)?
- d. Does the audited participant exhibit an acceptable degree of procedural discipline?
- e. Are the technical measures used to determine validity and correctness of scientific/engineering approaches and results adequate? (This does not include subjective analysis of peer review activities.)

18.3 AUDIT SCHEDULING

Every Project participant who is required to conduct a QA audit program is expected to develop, maintain and implement an approved audit schedule and to update the schedule periodically.

Audit schedules are based on planned and ongoing Project work, and the safety importance of the activities being performed. Schedules are required to provide for (a) verification early in the life of a discrete task or work phase that approved controls are in place and are being applied, and (b) verification at appropriate later points in the life of the task or work phase that comprehensive, credible evidence exists to demonstrate control effectiveness, and (c) judicious use of technical participants on audit teams to verify the appropriateness and adequacy of technical approaches being employed on samples of activities being performed in their areas of expertise.

The audit scheduling process is required to consider surveillance results as an important factor. That is, surveillance and audit are regarded as complementary methods of assessing QA program effectiveness and credibility. Although formal updates to audit schedules are required to be issued at regular intervals, surveillance results are evaluated on a continuing basis for indications (a) that scheduled audits should be rescheduled, or should have their scope or direction changed, or (b) that additional audits should be scheduled.

Special audits will be scheduled in the event of (a) major changes to a participant's QA program or organization, or (b) discovery of major areas of concern.

Participants are required to submit audit schedules, and schedule changes that occur between regular issues of updated schedules, to the next higher participant in the Project hierarchy. Change submittals are expected to include the rationale for the reported change(s).

18.4 AUDITOR QUALIFICATION

The use of a certified lead auditor as team leader for every QA audit is a formal Project requirement. Lead auditor qualification complies with the requirements of NQA-1-1986, Supplement 2S-3 and Appendix 2A-3 as specified in the BQARD.

The team leader shall participate actively in selection of auditors to staff the team, and is responsible for assuring that every team member is competent to perform his or her assigned portions of the audit by virtue of prior experience and/or specific, documented orientation or training during the audit preparation phase. In addition, the team leader is expected to ascertain that members of the audit team are independent with respect to activities they will audit (i.e., that no audit team member audits an activity for which he or she was directly responsible).

The team leader is also responsible for coordinating the selection and assignment (by appropriate technical managers) of technical participants.

18.5 AUDIT PREPARATION

As a minimum, preparation for individual audits is expected to include study of auditee procedures applicable to the activities to be audited, evaluation of relevant surveillance results, relevant corrective action history, results of previous audits of the same activities, review of trend data, and review of the current status of the work.

18.6 AUDIT PERFORMANCE

Audits are performed to check lists or procedures prepared or identified during audit preparation and will include compliance and product oriented auditing. Conditions observed during performance of a part of the audit may open additional areas of interest or may warrant a change of emphasis. However, if such conditions are outside the scope of the audit, it is expected that the auditor will bring them to the attention of the audit team leader, who will refer them to the proper individual or organization for investigation or other appropriate action. Such out-of-scope conditions are not expected to interfere with proper accomplishment of the objectives of the audit in work.

Audit performance will include adequate documentation of the evidence examined and conditions observed so that a sound basis exists for conclusions that are drawn and reported.

18.7 AUDIT REPORTS

Audit results are to be reported to the audited activity, upper management of the audited organization(s), and upper management of the auditing organization. Copies of audit reports will be forwarded to higher level organizations in accordance with distribution instructions issued by the AMC for Project compliance. These distribution requirements will reflect higher DOE headquarters direction.

Audit reports will explicitly recognize those QA program elements within their scope that are being implemented effectively, as well as identifying deficiencies in implementation.

18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS

It is recognized that some research and development organizations have no prior experience with internal QA audit and that it would not be an effective application of Project resources to insist on development of the audit capability. In such instances, the responsible participant at the next higher level in the Project hierarchy may elect to perform the necessary audits, or may require that a third party be engaged to do so.

Typical situations justifying this approach include the following:

- a. Academic institutions
- b. Government agencies participating under memoranda of understanding
- c. Small specialized organizations or individual contributors (such that no uninvolved staff is available for auditing)

18.9 SURVEILLANCE - GENERAL

Each Project participant who is required to conduct a QA audit program will also develop and implement an approved surveillance plan, which will be updated and reissued at periodic intervals.

Surveillance is documented observation and/or examination of work that is in progress, and surveillance results constitute a part of the formal Project record. Surveillance may include any combination of the following:

- a. Actual observation of the physical performance of work,
- b. Observation of the work place for presence of suitable conditions and adequate housekeeping and safety measures,

- c. Observation of related access control, fire prevention provisions, etc.,
- d. Review or spot checks of documents in preparation,
- e. Review or spot checks of procedures or instructions governing the work,
- f. Evaluation or verification of the presence and effectiveness of applicable controls, and
- g. Discussion with personnel performing or supervising the work.

18.10 QUALIFICATION FOR SURVEILLANCE

Surveillance of the BWI Project is performed by personnel who are knowledgeable in the kind of work they are observing. Certification of surveillance personnel qualifications is not required, but the discipline or speciality of the individual performing surveillance is expected to bear a clear relationship to the field under surveillance. QA personnel performing surveillance of controls applied to technical activities are not required to be qualified in the technical discipline(s) involved.

18.11 AMC QS DIVISION SURVEILLANCE

Surveillance performed by or for AMC QS DIVISION is controlled by AMC Procedure BP 18.5, Surveillance of Project Activities. Technical personnel participate in the planning of, and in surveillance activities as appropriate within their areas of expertise. During work progress reviews and peer review, AMC QS Division personnel perform surveillances of ongoing control activities.

18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS

Project participants are required to provide appropriate levels of surveillance over activities for which they are responsible. Surveillance activities are to address both technical and control adequacy of work in progress and are to be performed and documented in accordance with approved procedures.

18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES

18.13.1 By Audited or Surveilled Activity

Project participant activities shall address deficiencies identified by audit or surveillance with prompt, vigorous corrective action. Adverse findings identified as significant are to be investigated to determine the root

cause of the deficiency and to define action that will prevent recurrence. Results are reported promptly to the auditing or surveilling QA organization.

18.13.2 By Auditing or Surveilling Organization

The auditing or surveilling QA organization shall:

- a. Evaluate responses to significant deficiencies identified during audit or surveillance for evidence that the reported cause appears capable of having produced the observed condition(s) and that the proposed course of corrective action addresses the alleged cause in such a way as to have a high likelihood of long-term prevention of recurrence.
- b. Confirm timely implementation of approved corrective action(s).
- c. Verify that the corrective action was effective in preventing recurrence.
- d. Results of QA evaluations are provided to responsible management as described in Section 18.7.

Project participants shall maintain tracking and trending systems that will provide long term visibility of significant problems so that any recurrence will immediately be recognized and reported to appropriate management for any additional actions required. AMC trending of audit findings and concerns is performed in accordance with AMC Procedure BP 15.2 Trend Analysis.

APPENDIX A: CLARIFICATIONS TO THE NRC REVIEW PLAN

PREAMBLE

The DOE concept of project management for major acquisitions holds contractor technical processes and results to be inseparable from controls under which they are performed. These controls are integrated into an overall quality assurance program. It is essential that management responsibilities and authority relative to implementation of the quality assurance program and verification of its effectiveness be clearly delineated. In particular, it is important to distinguish between direct controls and the "quality assurance functions", as defined in Criterion I of 10 CFR 50 Appendix B; i.e., "(a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as by checking, auditing and inspection, that activities affecting the safety related functions have been correctly performed."

The listed clarifications to the NRC Review Plan reflect the following perception of responsibilities:

1. Almost all controls that make up the quality assurance program are exercised by line organizations of the participant contractors. Nothing in the working of regulatory requirements or DOE QA program descriptions should give the appearance of relieving the highest line official of responsibility for effective implementation of those controls.
2. The highest ranking DOE QA official on the project should be held accountable for QA functions, as defined in Criterion I of 10 CFR 50 Appendix B. That official should be at a level in the organization that provides sufficient authority so that he or she can deal directly and effectively with the top line official and so that communication concerning status and effectiveness of the QA program produces timely, appropriate line action.

CLARIFICATIONS TO NRC REVIEW PLAN

1. NRC REVIEW PLAN SECTION 1.1

"The responsibility for the overall program is retained and exercised by the DOE at a level that 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."

Responsibility for overall QA program policy and direction is exercised by DOE Headquarters and the Office of Geologic Repositories. Within the Basalt Waste Isolation Project field office, project management is exercised through DOE/RL AMC Basalt Waste Isolation Division technical staff monitoring (surveillance) and review. Surveillance includes evaluation of contractor technical performance and of the effectiveness of controls under which the work is performed. The BWI Division technical staff is normally involved in direct project work, but exercises technically oriented management functions with line organizations performing quality affecting activities. Thus, verification of proper performance of work is not limited to the DOE-RL AMC QS Division as the BWI Division also does verification of technical adequacy in their technical management role.

6. NRC REVIEW PLAN, SECTION 3.6

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

Clarification

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

10. NRC REVIEW PLAN, SECTION 14.1

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

Clarification

Procedures will be established to assure that inspection, test and operating status is clearly indicated by means of markings, tagging, boundary markers, etc., as appropriate to the nature of the equipment or natural region affected and of the inspection, test or operation involved.

11. NRC REVIEW PLAN, SECTION 16.2

"Corrective action is documented and initiated following a nonconformance to preclude recurrence..."

Clarification

Nonconformances will be evaluated by trend analysis for additional corrective action as appropriate. Evaluation will involve consideration of such factors as cost of remedial action for repetitive occurrence, nuisance value of repetitions, potential impact of repeated occurrences on more significant aspects of the work, potential for repeated occurrences to produce a negative perception of overall control effectiveness and cost to isolate cause(s) and implement preventive action(s).

12. 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."

Clarification

Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition will be documented and reported to immediate management and upper levels of management for review and assessment. Conditions adverse to quality will be considered significant if they are determined to have a potential adverse impact on safety or waste isolation or on the integrity of the record relative to safety or waste isolation.



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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAR 9 1987

Mr. James Knight, Director
Siting, Licensing, and Quality Assurance Division
Office of Geologic Repositories
Office of Civilian Radioactive Waste Management
U.S. Department of Energy RW-20
Washington, DC 20545

Dear Mr. Knight:

Your letter of July 17, 1986 to the NRC provided a number of DOE QA plans for NRC staff review. Several of these reviews have been furnished to you in letters dated August 25 and November 21, 1986 (NNWSI QA Plan NVO-196-17), and January 28, 1987 (OGR QA Plan OGR-B-3). The purpose of this letter is to transmit staff review comments on the remaining plans, which are in the following attachments:

- Attachment 1 Basalt Waste Isolation Division
QA Plan, Revision 1, April 15, 1986
- Attachment 2 Basalt Quality Assurance
Requirements Document (BQARD),
Revision 0, January 1986
- Attachment 3 Salt Repository Project Office
QA Plan, Revision 0, November 26, 1985

As part of our overall review of the QA program prior to site characterization, we have commented or will be commenting on the QA plans for OGR, the project offices, Rockwell, Battelle, and several NNWSI participants. Novel or unique-QA procedures will also be reviewed in detail. In order for the DOE to achieve a fully qualified program prior to the start of site characterization, it will be necessary that these staff reviews be completed and comments resolved. We believe it would be helpful if a planning meeting could be held in the near future to discuss the status of the DOE QA Plans and NRC reviews of them.

As we have noted in the past, it is important to recognize the limits of the review of the QA program plans. The extent that the program is actually used throughout the high-level waste repository program as a management tool as opposed to being put in place merely to satisfy the NRC requirement cannot be measured through a QA program plan review. In the several cases where serious construction quality problems occurred at nuclear power plants, QA program plans had been reviewed and found acceptable by the NRC as meeting the requirements of Appendix B of 10 CFR Part 50. However, these programs were not properly implemented. The QA program plan review provides only a portion of what is necessary to develop confidence that work will be done adequately--that is, to assure that adequate information on the quality of work implementation is being developed for management and being met in a demonstrable fashion. A most important indicator of the successful implementation of these plans will

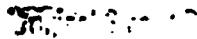
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be the detailed, results-oriented technical reviews that will be performed by the NRC staff as work progresses.

Questions on the enclosed comments or arrangements for a meeting between our staffs should be referred to James Kennedy of my staff on 427-4786.

Sincerely,


John J. Linehan, Acting Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:
As stated

cc: C. Newton, OGR
L. Olson, BWIP
J. Neff, SRPO
D. Vieth, NNWSI

REQUEST FOR ADDITIONAL INFORMATION
BASALT WASTE ISOLATION PROJECT QUALITY ASSURANCE PLAN
REVISION 1, APRIL 15, 1986

1. The BWI Project Quality Assurance Plan was written prior to the following NRC June 1986 draft generic technical positions (GTPs):
 - a. Peer review.
 - b. Qualification of existing data.
 - c. Items and activities subject to QA requirements.

An evaluation should be made against the draft guidance of these GTPs, and differences between the plan and the draft GTPs should be addressed.

2. Expressions such as "are expected to" or "is expected that" are found throughout the plan. Change these expressions to "shall" or justify not doing so.
3. Section 1.3 and Appendix A of the plan describe QA responsibilities within the BWI Division. Identify who (by position title) in the Richland Operations Office is responsible for the overall BWI program. Clarify the meaning of the dashed lines, arrowheads, and ellipses on Figure 1.3 of the plan. Also indicate what ES&H stands for on Figure 1.3 and in Section 1.5 of the plan. (1.1)*
4. Discuss how the Integrating Contractor avoids conflict of interest in its roles of project management and project participant. Clarify whether the Integrating Contractor, the Architect/Engineer, the Construction Manager, and other participants under direct contract to DOE for BWI Project work report to DOE-HQ, DOE-RL, or DOE-BWI Division. (1.3)
5. Section 1.2.2 of the plan indicates the BWI Division verifies effective implementation of the QA program. Clarify that this includes at least an annual audit of the Integrating Contractor. (1.4)
6. Sections 1.4 and 1.5 of the plan discuss QA interface with DOE-HQ and interdivision interface within DOE-RL respectively. Similarly, discuss the DOE-RL interface with Project participants. (1.6)

* The number in parenthesis after an RAI refers to the specific guidance in the NRC review plan.

7. Clarify whether the Director, BWI Division, reports through the Office of Commercial Nuclear Waste (Section 1.3.1) or the Office of Civilian Nuclear Waste (Figure 1-2). Identify the onsite and offsite organizational elements which function under QA program controls or justify not doing so. Show the ES&H Division, the Procurement Division, and the Personnel Division on an organization chart. (1.7)
8. Describe measures which ensure that DOE-RL's BWI Division Quality Systems Branch Chief is involved in the aspects of the BWI Project that affect safety and/or waste isolation and how the extent of DOE-RL QA controls is determined. (1.8)
9. Identify a management position within DOE-RL, the Integrating Contractor, Architect/Engineer, and Construction Manager organizations that retains overall authority and responsibility for the applicable QA program. Describe the management, CA, and technical experience and knowledge requirements for these positions. Verify that each of these positions has the following characteristics:
 - a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
 - b. Has effective communication channels with other senior management positions.
 - c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.
 - d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10)
10. Describe measures which ensure that 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.Describe how these actions are accomplished. (1.12)

11. Section 1.2.6 of the plan addresses stop work. Clarify the retention time of records of stop work requests. (1.12)
12. Identify items and activities covered by the QA program. Section 2.0 of the plan indicates that analytical processes are used to determine importance to safety and/or waste isolation. Clarify whether importance to safety and importance to waste isolation are defined as numerical performance objectives and standards. Justify why not if not. (2.1)
13. Section 3.2 of the plan indicates that Supplement 6 of the OGR QA plan addresses computer software control. Update Section 3.2 to reflect the fact that Supplement 6 of the OGR plan no longer addresses computer software. (2.2)
14. Section 2.4 of the plan indicates a management team assesses effectiveness of the overall Project QA program. Clarify that the management team is composed of personnel above or outside the DCE-PL organization. (2.7)
15. Section 3.1 of the plan indicates that design controls include those used to ensure the correct translation of design inputs into designs. Describe the controls which ensure that applicable regulatory requirements and design bases are reflected in design, procurement, and procedural documents. Also, describe measures which ensure that performance goals are specified for repository subsystems and components to support the establishment of data gathering and analysis needs. Discuss the timeliness of specifying these requirements. At the latest, planned performance allocation should be addressed in the SCP consistent with agreements reached in NRC/DOE meetings of April 17, 1981 and September 26 and 27, 1985 on this matter. (3.2)
16. Describe measures which ensure that (1) errors and deficiencies in approved design and design information documents are documented and (2) action is taken to ensure that all errors and deficiencies are corrected. (3.4)
17. Section 3.4 of the plan addresses design verification, and it includes in Section 3.4.4, "Design Verification by Similarity," an addition to the 3 methods of 10 CFR 50 Appendix B. This method would be acceptable if a fourth condition was added: (4) the design characteristics (attributes, features) that are not identical are identified and verified in a manner other than by similarity. Add such a condition or justify not doing so. Also, describe measures which ensure that design checking, which includes such things as confirmation of the numerical accuracy and computations and the accuracy of data input to computer codes, will be performed. (Confirmation that the correct computer code has been used is part of design verification.) Design verification should be performed by persons other than those performing design checking. Clarify whether personnel performing design verification can be associated with the responsible design organization. (3.7)

18. Clarify whether procedures prescribe the extent of documentation required for design verification. (3.9)
19. Section 3.6 of the plan addresses design changes. Clarify whether a configuration control system is in place such that design changes, including field changes, are analyzed to ensure they are required, are subject to the same design controls as the original design, are communicated to all affected groups and individuals, and are considered for changes to procedures and training. (3.10)
20. Section 5.0 of the plan refers to personnel "who meet the independence criteria specified in Section 3.4 of this QAP." Clarify what these criteria are.
21. Section 5.2 of the plan requires review of technical procedures by QA personnel. Clarify whether DOL-PL requires such review of administrative procedures (Categories 1 and 2 per Section 5.1 of the plan), instructions, and drawings. Also clarify whether "each participating entity in the Project" as specified in Section 5.0 of the plan is the same as "each Project participant" which is used elsewhere in the plan. (5.1)
22. Describe the scope of the DOE-RL document control program and identify the types of documents controlled by this program. Section 6.1 of the plan describes what the BWI Division requires of all Project participants in the area of document control. Clarify that the BWI Division requires the same of DOE-RL. This clarification should be made, as appropriate, throughout the plan since page v of the plan indicates that "all project participants" does not include the BWI Division of DOE-RL. (Section 4.1 and 7.0 are examples where clarification is required.) (6.1)
23. Describe measures which ensure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner. (6.4)
24. Section 7.3.1 and 10.4 of the plan address mandatory hold points for inspection or witnessing and use the term "where appropriate." Identify the organization(s) that determine when these (and similar) activities are appropriate. (7.1 and 10.5)
25. Describe the BWI Division Quality Systems Branch and other DOE-RL organizational responsibilities for qualification of special processes, equipment, and personnel. Provide examples of processes during site characterization that will be classified as special processes and those that will not. (9.2)
26. Clarify that special processes (standard or not standard) are required to be in conformance with applicable codes, standards, QA procedures, and specifications. The last sentence of Section 9.2 of the plan requires that participant's QA Plan describes QA's role in special processes. Clarify whether the BWI Division requires involvement of QA organizations. (9.3)

28. Section 7.5 of the plan indicates that DOE-RL's BWI Division is responsible for ensuring that delivered items and materials comply with applicable QA requirements, but Section 10 assigns inspection to Project participants. Describe how the BWI division meets the responsibility noted from Section 7.5 without performing inspections. Indicate how the BWI Division participates in determining when inspections are required and in defining how and when inspections are performed. (10.1)
29. Section 10.2 of the plan addresses inspector qualification and permits inspections by personnel outside QA organizations. Clarify that inspections are accomplished by individuals or groups who do not have direct responsibility for performing the work being inspected. The inspection function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity. (10.2)
30. Section 10.2 also refers to personnel with "particular" or "special" expertise. Describe QA's involvement in determining the expertise required commensurate with the technical complexity of the inspector function and the acceptability of the qualifications of the inspector. Also clarify that the qualifications and certifications of inspectors (both in and outside QA) are documented and kept current. Section 10.2 uses the term, "participant's QA inspection function." Clarify whether this is the same as the participant's QA organization. (10.2)
31. Describe measures which ensure that, when practicable, tests of structures, systems, and components shall be at conditions which simulate both normal and anticipated off-normal operations. (11.5)
32. Describe the scope of the QA program for the control of M&TE and identify the types of equipment to be controlled. (12.1)
33. Sections 12, 13, and 14 of the plan appear somewhat inconsistent. Sections 12 and 13 make the Integrating Contractor responsible for the controls, but 14 doesn't. Sections 13 and 14 address each Project participant, but 12 doesn't. Section 12 addresses cognizant QA organizational responsibilities, but 13 and 14 don't. Sections 12 and 13 specify surveillance and audit by DOE BWI Division QS, but 14 doesn't. Clarify these sections to eliminate these apparent inconsistencies, and describe how the involved organizations will meet their assigned responsibilities.
34. Describe measures which ensure that nonconforming items and samples are segregated from those which are acceptable. (15.1)
35. Section 15.2 of the plan requires that "use-as-is" and "repair" dispositions receive technical review and approval at the next higher level of project participation. Describe QA responsibilities regarding this review and approval. (15.2)

36. Section 15.1 of the plan requires that each nonconformance be documented. Clarify that nonconformance documentation identifies the item, describes the nonconformance, shows the disposition of the nonconformance, and includes signature approval of the disposition. (15.3)
37. Section 15.4 of the plan states that "The Project" will monitor and analyze nonconformance trends on a Project-wide basis. Identify what organization is responsible for these activities. Clarify that the trend analyses are used to help identify root causes of nonconformances. Identify the management level of DOE responsible to review and assess significant results of the nonconformance trend information. (15.4)
38. Describe measures which ensure that the significance of each nonconformance is assessed to determine whether corrective action is required to prevent recurrence. Identify the organization responsible for this assessment. (16.2)
39. Describe the scope of the record program. That is, identify by type of data what records will be maintained within the records management system. (17.1)
40. Describe the responsibilities of the project participants' QA organizations in the records management system. (17.2)
41. Section 17.3 of the plan addresses an archival facility for long-term storage of project records. Describe record storage facilities to be used prior to the availability of such a facility. (17.4)
42. Section 18.3 of the plan addresses audit scheduling. Clarify that audit scheduling considers the safety importance of the activities being performed. (18.2)
43. Section 18.13.2 of the plan addresses follow-on activities by auditing organizations. Clarify that these include analysis of audit data by the QA organization with the results being reported to responsible management for review, assessment, and appropriate action. (18.4)
44. Describe measures which ensure that audited organizations describe in a formal report the corrective action to be taken to address adverse audit findings and that this report is submitted to responsible management and the auditing organization. (18.7)
45. Clarify that technical audits which provide a comprehensive independent verification and evaluation of procedures and activities affecting quality are included in the audit program, that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited, and that audit team leaders are from the QA organization. (18.9)

46. Appendix A of the plan gives exceptions/clarifications to the NRC review plan. The following comments result from the staff review of Appendix A:
- a. The last sentence of clarification item 1 states that QA program controls are exercised by line functions. Clarify whether "line functions" refer to BWI Division personnel. If so, identify these line functions with the organization shown in Figure 1-2 of the plan. If not, identify what is meant by "line functions." Also clarify whether the "QA program controls" are the surveillances performed by BWI Division technical personnel as described in Section 18 of the plan. If not, clarify what is meant by QA program controls.
 - b. Clarification item 2 states that qualified individual(s) or organizational element(s) will be identified within DOE's organization, prior to initiation of activities, as responsible for assuring that delegated work meets established quality standards. Identify such individual(s) or organizational element(s) with this responsibility for ongoing delegated work. (1.5)
 - c. Clarification item 3 indicates that DOE will identify a DOE management position that retains overall authority and responsibility for: (1) performing QA functions relative to direct quality affecting activities within DOE, (2) verifying effectiveness of quality-related controls applicable to quality affecting work performed by DOE personnel, and (3) verifying proper performance of QA functions within contractor QA programs. Clarify who (by position title) has these responsibilities within DOE-RL for the BWI Project.
 - d. Clarification item 4 indicates that both DOE and contractor verification of conformance to established requirements may be performed by people outside the QA organization. When this is the case, clarify that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
 - e. The last sentence of clarification item 7 states: "Geological data acquisition "testing" is not considered to belong to the "special process" category for purposes of process demonstration. Explain the QA significance of this statement.
 - f. Clarification item 9 is acceptable if only "samples" will require handling, preservation, storage, etc; i.e., if no structures, systems, components, or other materials are involved. If this is not the case, delete this clarification or justify not doing so.

Enclosure
Page 8

- g. Section 16.0 of the plan defines significant problems, and Appendix A of the plan describes significant conditions adverse to quality. Rectify these terms and their definitions or justify not doing so. (16.4)

REQUEST FOR ADDITIONAL INFORMATION
BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT (BQARD)
REVISION 0, January 1986

1. A statement used throughout BQARD is: "Therefore, the intent of this requirement will be met if implemented as stated." As a requirements document, BQARD should address meeting a requirement rather than meeting "the intent" of a requirement. Also, requirements document should use "shall" instead of "will" or "may". Further, the term "if implemented" should be clarified as was done on Sheet 3 under Criterion 3. Therefore the quoted statement should read: "Therefore, this requirement shall be implemented as stated," or words to that effect.
2. Sheet 10 under Criterion 2 addresses requirements for personnel performing quality-related activities. For these personnel (the "doers"), reference is made to NRC's Review Plan items 2.8a, c, and d. Item 2.8e, "Qualified personnel are certified in accordance with applicable codes and standards," should also be referenced as some of these personnel (welders, for example) require certification. The second sentence under item 1 should read: "Therefore, this requirement shall be met by implementing the requirements of 2.8a, c, d, and e as stated."
3. The note on Sheet 12 under Criterion 2 indicates that test inspectors (i.e., inspectors of testing activities) can be "... assigned to the testing organization and designated by the testing supervisor to be an in-process Inspector...." Clarify that "in-process Inspectors" do not have direct responsibility for performing the work being verified. The quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
4. The note on Sheet 7 under Criterion 3 limits the use of the word "validating" to the context of computer codes. The definition of validation from NUREG-0856 should be expanded to: "Assurance that a model is a correct representation of the process or system for which it is intended." Note that the definition of verification in ANSI N45.2.11 expands the definition in NUREG-0856 in a similar fashion.
5. The first paragraph on Sheet 1 under Criterion 4 states that site characterization participants have the option of controlling procurement activities per the requirements of either Criterion 4 or Criterion 7. While there may be some duplication in these criteria, there are also differing requirements, and the requirements of both criteria should be met.
6. The last paragraph on Sheet 2 under Criterion 4 states that construction participants have the option of using either the Site Characterization Criterion 4 or NQA-1 Basic Requirement 4 and Supplement 4S-1. Here again there are differing requirements, all of which should be met. The

proviso at the end of this paragraph does not appear to address this. A comparable comment applies to Criteria 5 through 18.

7. Supplements 4S-1 and 7S-1 of NQA-1 do not address the involvement of the QA organization in the various activities. The NRC Review Plan Sections 4.2 and 7.2 do. BQARD should require that these sections of the review plan be met. (See Sheet 3 under Criterion 4 and Sheet 3 under Criterion 7.)
8. The second paragraph on Sheet 1 under Criterion 9 implies that tests conducted per Criterion 11 do not require qualified procedures, qualified equipment, qualified personnel, and monitoring of process variables. This implication should be eliminated.
9. The first sentence under BWIP Project Implementation on Sheet 2 under Criterion 9 indicates that the NRC has "reworded" Criterion 9. The NRC has not reworded Criterion 9, and this sentence should be deleted or revised. A similar problem exists on Sheet 10 under Criterion 10, Sheets 7 and 9 under Criterion 11, Sheet 2 under Criterion 12, Sheet 2 of Criterion 14, Sheet 4 of Criterion 16, and on Sheets 5 and 6 under Criterion 18.
10. The discussion of inspection on Sheets 1 and 2 under Criterion 10 needs clarification. The first sentence indicates inspection is an "independent verification," but the third paragraph indicates that in-process inspections may be performed by the supervisor of the activity. We agree that the doer's supervisor is directly responsible for the work, and we believe that supervisors can and should make (or have made) in-process checks (i.e., nonindependent verification) and final checks before having work inspected. We do not agree that a doer's supervisor has the independence required to perform inspections, and the discussion should be revised to reflect this. Note that some work may require inspection during processing, some may require checking, and some may require neither.

The first sentence on Sheet 2 under Criterion 10 states: "Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusion," indicating a personal inspector vs. line supervisor relationship which is not desirable. The inspector's responsibility is neither to confirm nor deny "the adequacy of the supervisor's conclusion," and the sentence should be deleted or revised. Finally, clarify the significance of the parenthetical words in the third and fourth paragraphs under Criterion 10.
11. Sheet 6 under Criterion 10 indicates that Section 8 of 10S-1 of NQA-1 will be implemented to ensure that inspection results are documented and evaluated and that their acceptability is determined by a responsible individual. Beyond documentation, Section 8 does not appear to address this guidance. Clarify.
12. Explain the last sentence on Sheet 10 under Criterion 10 which states: "For the BWIP project, refer to the PMP/SEMP for identification of the BWIP designated inspectors."

13. Item C on Sheet 4 under Criterion 11 addresses the fact that QA should, as a minimum, audit the test program. Item C should specify that this will be done.
14. Under Criterion 11, BOARD should address whether testing will test the item under conditions which will be present during normal and anticipated off-normal operation when practicable.
15. The last paragraph on Sheet 8 under Criterion 11 states, "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." Test records should meet both Section 17.3 of the NRC Review Plan and paragraph 5 of supplement 11S-1 of NQA-1, and the paragraph should be so clarified.
16. Under criterion 12, clarify that both technical and QA programmatic audits are performed and that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.

BASALT WASTE ISOLATION PROJECT

**BASALT QUALITY ASSURANCE
REQUIREMENTS DOCUMENT**

(BOARD)

DRAFT REVISION 3
MARCH 1987

DOCUMENT MONITOR:

T. H. Davies, Quality Systems Division Date
Basalt Waste Isolation Division
U.S. Department of Energy - Richland, WA

REVIEWED:

R. P. Saget, Quality Systems Director Date
Basalt Waste Isolation Division
U.S. Department of Energy - Richland, WA

APPROVED:

J. H. Anttonen, Assistant Manager Date
Commercial Nuclear Waste
U.S. Department of Energy - Richland, WA

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.)

DRAFT

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-11st 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 right column, entitled "BWIP Project Implementation," provides a discussion of the intent of the criteria requirements in implementing the elements that comprise a viable system. This part of each criterion is guidance and does not contain any DOE, NQA-1, or NRC requirements. It is recognized there may be other equally acceptable methods of meeting the requirements.

The second part of each criterion begins with the 10 CFR 50 Appendix B criterion listed in the left column with the discrete QA requirements that shall apply during site characterization. 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-1-1986 Supplements which are applicable to and not in conflict with 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. 10 CFR 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. QA Management Policies and Requirements, OCRWM, October 1985 (DOE/RW/0032)
 - e. QA Plan for High-Level Radioactive Waste Repositories, OGR/B-3, Rev. 1, August 1986 and supplements
 - f. DOE Order 5700.6B, "Quality Assurance" and DOE-RL Order 5700.1A, "Quality Assurance"
 - g. DOE Order 4700.1, "Project Management System"
 - h. ANSI/ASME NQA-1 1986
 - i. Federal Acquisition Regulation (FAR) Part 46, "Quality Assurance"
 - j. DOE Order 5000.3, Unusual Occurrence Reporting System.
4. UTILIZATION OF NQA-1 WITHIN THE BQARD. QA Programs that 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, the 18 NQA-1 Basic Requirements, the NQA-1 supplements, and the NRC Review Plan, to define QA Program requirements. Further, certain NQA-1 appendices identified as nonmandatory 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 BQARD.** The following documents are not included within and will be distributed separately from the BQARD:
 - a. "Q-1ist" Methodology, except by reference to OGR/B-3, Supplement 3.
 - b. "Graded QA" Methodology, except by reference to OGR/B-3, Supplement 8.
 - 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-1ist
 - 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 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 that have been incorporated by reference within the appropriate criterion where other requirements did not provide this information.

7. **REVISION STATUS OF BQARD.** Revisions to the BQARD will be made by individual page revision. Each page will have a page number and revision number. The Table of Contents will identify individual pages by title or criterion number, indicating page number, revision number, and issue 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 (e.g., before the Site Characterization Plan was issued). An important question concerns 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 ability 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 is 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 (e.g., 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 that describes the methods, test anomalies, and other test characteristics 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 effort 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 committee on Nuclear Quality Assurance (NQA) 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.

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**BOARD
CRITERION 1: ORGANIZATION
REVISION 0 (sheet 1 of 13)**

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish requirements for critical areas of each participant contractor's organization in order to ensure that project activities are accomplished within a defined and controlled organizational structure. The criterion requires a defined organizational structure that 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>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 1. 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 1. Deviations, and the alternate method of providing equivalent control, will be documented.</p> <p>NOTE: "Contractor" as used in this BOARD refers to all contractors, subcontractors, vendors, consultants, agents or agencies, and institutions performing work covered by the quality assurance program.</p>

BQARD

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>The applicant shall be responsible for the establishment and execution of the quality assurance program.</p> <p>HRC REVIEW PLAN SECTION 1.1</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 1.1 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 1S-1, Section 2.1 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 13)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 1.2</p> <p>DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</p> <p>NRC REVIEW PLAN SECTION 1.3</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 1.4</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 1.2 through 1.6 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 1S-1, Section 2.2 of NQA-1-1986 shall be implemented.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1986 shall be implemented.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 1S-1, Section 2 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 13)

Requirement	BWIP Project Implementation
<p data-bbox="130 356 562 393">NRC REVIEW PLAN SECTION 1.5</p> <p data-bbox="130 419 1003 546">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.</p> <p data-bbox="130 574 562 611">NRC REVIEW PLAN SECTION 1.6</p> <p data-bbox="130 637 982 736">Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</p>	<p data-bbox="1052 419 1965 513">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1052 637 1934 736">This requirement shall be implemented as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1986 shall be implemented.</p>

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 13)

Requirement	BNIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 1.7</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 1.9</p> <p>DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.</p> <p>NRC REVIEW PLAN SECTION 1.10</p> <p>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:</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Sections 1.7, 1.9, 1.10, and 1.15 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement shall be implemented as stated. In addition, Supplement IS-1, Section 3 of NQA-1-1986 shall be implemented.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BQARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 6 of 13)

Requirement	BWIP Project Implementation
<p>b. Has effective communication channels with other senior management positions.</p> <p>c. Has responsibility for approval of QA manual(s), changes thereto, and interpretations thereof.</p> <p>d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.</p> <p>NRC REVIEW PLAN SECTION 1.15</p> <p>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.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 7 of 13)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>These activities include both the performing functions of attaining quality objectives and the quality assurance functions.</p> <p>NRC REVIEW PLAN SECTION 1.8</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 1.8 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement IS-1, Section 2 of NQA-1-1986 shall be implemented. The requirements and methodology for formulating a Q-List and application of Graded QA are delineated in OGR/B-3, Supplements 3 and 8.</p>

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CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
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Requirement	BWIP Project Implementation
<p>REQUIREMENT 6: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 1.12</p> <p>Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:</p> <ul style="list-style-type: none">a. Identify quality problems.b. Initiate, recommend, or provide solutions through designated channels.c. Verify implementation of solutions.d. Stop unsatisfactory work. <p>The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.</p> <p>NRC REVIEW PLAN SECTION 1.13</p> <p>Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 1.12, 1.13, and 1.14 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, this requirement is also addressed in NQA-1-1986, Basic Requirement 1.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
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Requirement	BWIP Project Implementation
<p data-bbox="157 365 591 393">NRC REVIEW PLAN SECTION 1.14</p> <p data-bbox="157 426 1008 488">Policies regarding the implementation of the QA program are documented and made mandatory.</p>	<p data-bbox="1087 426 1847 513">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 11 of 13)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 7: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 1.15 of the NRC Review Plan (see sheet 6 of this criterion). In addition, this requirement shall be implemented in accordance with NQA-1-1986, Basic Requirement 1.</p>

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CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 12 of 13)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 8: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 1S-1, Section 3 of NQA-1-1986 shall be implemented.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 9: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement IS-1, Section 3 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM
REVISION 1 (sheet 1 of 19)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>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 ensure the adequacy of the completed repository facility. Consequently, each BWIP participant shall establish a complementary 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.</p> <p>In addition, NQA-1-1986 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.</p> <p>The NRC makes a distinction between (1) administrative QA procedures and (2) detailed technical or implementing procedures. Quality assurance administrative procedures provide instructions for implementation and application of the 18 criteria of 10 CFR Part 50 Appendix B. These apply to all technical program areas (e.g., procedures for test plan development). The detailed technical</p>

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CRITERION 2: QUALITY ASSURANCE PROGRAM
REVISION 0 (sheet 2 of 19)

Requirement	BWIP Project Implementation
	<p>(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).</p> <p>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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>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.</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.5</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.6</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 2.5 and 2.6 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>The methodology for formulating a Q-List and the application of a Graded QA Program and the requirements imposed by Headquarters-OGR are as delineated in the Quality Assurance Plan for High-Level Radioactive Waste Repositories (OGR/B-3), Supplements 3 and 8.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.3</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.4</p> <p>The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.</p> <p>The term "quality-related" refers to the quality of items "important to safety" or "important to waste isolation."</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 2.3 and 2.4 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.1</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 2.1 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>The methodology for formulating a Q-List is imposed by Headquarters-OGR as delineated in the QA Plan for High-Level Radioactive Waste Repositories (OGR/B-3), Supplement 3.</p>

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CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 6 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.2</p> <p>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."</p>	<p>The requirements and methodology for formulating a Q-List and application of Graded QA are contained in the Headquarters-OGR QA Plan for High-Level Radioactive Waste Repositories (OGR/B-3), Supplements 3 and 8.</p> <p>For site characterization, additional guidance has been provided in Section 2.2 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated. (This is incorporated in Criterion 3 controls.)</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 7 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 5: 10 CFR 50 APPENDIX B</p> <p>Activities affecting quality shall be accomplished under suitably controlled conditions.</p>	<p>This requirement shall be implemented in accordance with NQA-1-1986, Basic Requirement 2.</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 8 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 6: 10 CFR 50 APPENDIX B</p> <p>Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.</p>	<p>This requirement shall be implemented in accordance with NQA-1-1986, Basic Requirement 2.</p>

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 9 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 7: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be implemented in accordance with NQA-1-1986, Basic Requirement 2.</p>

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CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 10 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 8: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.8</p> <p>Indoctrination, training, and qualification in programs are established such that:</p> <ol style="list-style-type: none"> 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. 	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 2.8 of the NRC Review Plan.</p> <ol style="list-style-type: none"> 1. NQA-1-1986 addresses personnel <u>performing</u> quality-related activities in Basic Requirement 2 and Supplement 2S-4. This requirement shall be met by implementing the requirements of 2.8a, c, d, and when applicable, e, in cases such as welder certification, etc., as stated. Additional requirements are specified in OGR/B-3, Supplement 1, Section 5.0. 2. For personnel <u>verifying</u> quality-related activities, Requirements a, b, c, d, and e shall be implemented. NQA-1-1986 provides supplemental guidance as follows: <ul style="list-style-type: none"> Design Reviewers - Supplement 3S-1, Section 4 Inspectors - Supplements 2S-1 and/or 2S-2 Auditors - Supplement 2S-3 Indoctrination and Training - Supplement 2S-4. <p>Note that the Review Plan Criterion 3.8 provides qualification standards for peer reviewers.</p> <p>In addition, the prospective lead auditor shall have verifiable evidence that a minimum of 10 credits under the following score system have been accumulated (DOE-RL).</p> <ol style="list-style-type: none"> 1. <u>Education (4 Credits Maximum)</u> <ul style="list-style-type: none"> Associate degree from an accredited institution: score one (1) credit, or if the degree is in

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CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 11 of 19)

Requirement	BWIP Project Implementation
	<p>engineering, physical sciences, mathematics, or quality assurance, score two (2) credits; or 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.</p> <p>2. <u>Experience (9 Credits Maximum)</u></p> <p>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.</p> <p>If two (2) years of this experience have been in the nuclear field, score one (1) additional credit; or</p> <p>If two (2) years of this experience have been in quality assurance, score two (2) additional credits; or</p> <p>If two (2) years of this experience have been in auditing, score three (3) additional credits; or</p> <p>If two (2) years of this experience have been in nuclear quality assurance, score three (3) additional credits; or</p> <p>If two (2) years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.</p>

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CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 0 (sheet 12 of 19)

Requirement	BWIP Project Implementation
	<p>3. <u>Other Credentials of Professional Competence</u> (2 Credits Maximum)</p> <p>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.</p> <p>4. <u>Rights of Management (2 Credits Maximum)</u></p> <p>The lead auditor's employer may grant up to two (2) credits for other performance factors applicable to auditing that 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.</p> <p>The sample form shown in NQA-1 may be utilized as a record of lead auditor qualification.</p> <p>In addition, the following requirements on the qualifications of inspection and test (verification) personnel are made mandatory (DOE-RL):</p> <p>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 them, 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.</p>

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CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 1 (sheet 13 of 19)

Requirement	BWIP Project Implementation
	<p>"In-process inspectors" shall have no direct responsibility in performing the work being inspected/verified. The inspection function may be part of the line organization provided the QA organization performs periodic surveillance to verify sufficient independence from the individuals who performed the activity.</p> <p>1. FUNCTIONAL QUALIFICATIONS</p> <p>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.</p> <p>1.1 Level I Personnel Capabilities</p> <p>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.</p> <p>1.2 Level II Personnel Capabilities</p> <p>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</p>

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 1 (sheet 14 of 19)

Requirement	BWIP Project Implementation
	<p>personnel; and in evaluating the validity and acceptability of inspection and test results.</p> <p>1.3 Level III Personnel Capabilities</p> <p>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.</p> <p>2. EDUCATION AND EXPERIENCE QUALIFICATIONS</p> <p>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 that 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.</p> <p>2.1 Level I</p> <p>2.1.1 Two years of related experience in equivalent inspection or testing activities; or</p>

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CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
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Requirement	BWIP Project Implementation
	<p>2.1.2 High school graduation and six months of related experience in equivalent inspection or testing activities; or</p> <p>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.</p> <p>2.2 Level II</p> <p>2.2.1 One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or</p> <p>2.2.2 High school graduation plus three years of related experience in equivalent inspection or testing activities; or</p> <p>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</p> <p>2.2.4 Graduation from a four-year college plus six months of related experience in equivalent inspection or testing activities.</p> <p>2.3 Level III</p> <p>2.3.1 Six years of satisfactory performance as a Level II in the corresponding inspection or test category or class; or</p> <p>2.3.2 High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 1 (sheet 16 of 19)

Requirement	BWIP Project Implementation
	<p>eight years of experience in equivalent inspection or testing activities with at least two years as Level II and with at least two years 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</p> <p>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</p> <p>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.</p>

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 17 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 9: 10 CFR 50 APPENDIX B</p> <p>The applicant shall regularly review the status and adequacy of the quality assurance program.</p>	<p>This requirement shall 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.</p> <p>In addition, management assessments of the QA program shall be implemented as specified in OGR/B-3, QA Plan, Section 4.4.</p>

BQARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
DRAFT REVISION 3 (sheet 18 of 19)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 10: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 2.7</p> <p>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:</p> <ul style="list-style-type: none"> 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. 	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 2.7 of the NRC Review Plan.</p> <p>Additional requirements for the overview of QA activities are specified in OGR/B-3, Supplement 2.</p> <p>This requirement is addressed in NQA-1-1986, Basic Requirement 2. Therefore, this requirement shall be implemented as stated.</p> <p>Also refer to Criterion 15, Requirement 2 and Criterion 16, Requirement 1.</p> <p>In addition, participants shall submit audit schedules, schedule revisions, and audit reports to the integrating contractor (HQ-OGR).</p> <p>Management assessments shall be conducted at least annually for determining (a) the effectiveness of the system of management controls that are established to achieve and ensure quality and (b) the adequacy of resources and personnel provided to the QA program. Management shall verify that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program. Copies of the report of management assessments generated by participant contractors shall be provided to DOE-RL.</p>

BOARD
CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION
REVISION 1 (sheet 19 of 19)

Requirement	BWIP Project Implementation
	<p>Management assessments shall be performed by HQ-OGR, the project offices and their major contractors. Each organization shall develop its internal procedures for the planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations (OGR/B-3 QA Plan, Section 4.4).</p>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the requirements for controls over the repository design activities in order to ensure that (a) design products to be used during site characterization data collection/testing/analysis (e.g., 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is to establish the requirements for controls over the repository definitive design processes, in order to ensure 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.</p> <p>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.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.1</p> <p>The definitions of <u>design</u>, <u>design information</u>, and <u>design activities</u> used in the design control program are as defined in this section. The term <u>design</u> refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). <u>Design information</u> and <u>design activities</u> refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data 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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Sections 3.1 and 3.2 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>Requirements for the control of the reliability of data for geologic repository projects, specifically when those data were collected and/or analyzed prior to a QA program being in place, shall be as specified in OGR/B-3, Supplement 9.</p>

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

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 3.2</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 3S-1, Sections 2, 3, and 7 of NQA-1-1986 shall be implemented.</p> <p>In addition, performance assessment and allocation, and changes thereto, based on data analysis results, shall be controlled in accordance with the applicable requirements of the System Engineering Management Plan. (DOE-RL)</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.6</p> <p>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.</p>	<p>This requirement shall be met by implementing NQA-1-1986, Supplement 3S-1, Section 2.</p> <p>For site characterization, additional guidance has been provided in Section 3.6 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be met by implementing NQA-1-1986, Supplement 3S-1.</p> <p>In addition, requirements for the methodology for formulating a Q-List are as specified in OGR/B-3, Supplement 3.</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 6 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations.</p> <p>NRC REVIEW PLAN SECTION 3.5</p> <p>Interface controls among organizations or groups involved in design development and other design activities are described.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance in Section 3.5 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 3S-1, Section 6 of NQA-1-1986 shall be implemented.</p>

BQARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 7 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 5: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.3</p> <p>Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.</p>	<p>This requirement shall be met by implementing Supplement 3S-1, Section 6 of NQA-1-1986.</p> <p>For site characterization, the NRC has provided additional guidance in Section 3.3 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated. In addition, design/engineering "holds" shall be included (DOE-RL).</p> <p>Note the use of the word "validating." It pertains 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, to provide assurance that a model is a correct representation of the process or system for which it is intended.</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 8 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 6: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.4</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.8</p> <p>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.</p>	<p>This requirement shall be met by implementing the requirements of NQA-1-1986, Supplement 3S-1, Section 4.</p> <p>For site characterization, the NRC has provided additional guidance in Sections 3.4 and 3.8 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing the requirements of NQA-1-1986, Supplement 3S-1, Section 5.</p> <p>This method of design verification is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>In addition, requirements for the control of peer reviews conducted for geologic repository projects shall be as specified in OGR/B-3, Supplement 7.</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 9 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 7: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.7</p> <p>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:</p> <ul style="list-style-type: none"> (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. <p>It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.</p> <p>NRC REVIEW PLAN SECTION 3.9</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Sections 3.7 and 3.9 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 3S-1, Section 4 of NQA-1-1986 shall be implemented.</p> <p>This requirement shall be met by implementing the requirements of NQA-1-1986, Supplement 3S-1.</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 10 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT B: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be met by implementing the requirements of Supplement 3S-1, Subsection 4.2.3 of NQA-1-1986.</p> <p>Refer to Criterion 11 for additional information.</p>

BOARD
CRITERION 3: DESIGN CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 11 of 12)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 9: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented to the level of detail apparent in the requirement. Additional guidance is provided in NQA-1-1986, Appendix 3A-1.</p> <p>In addition, the word "reactor" is deleted and the words "high level waste disposal" added in its stead (DOE-RL).</p> <p>In addition, the delineation of appropriate acceptance limits for inspections and tests (site characterization testing) shall be directly relatable to the design input that must be confirmed via performance of the test (DOE-RL).</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 10: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 3.10</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Section 3.10 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 3S-1, Section 5 of NQA-1-1986 shall be implemented.</p> <p>NOTE: "Configuration Management and Change Control" shall comply with DOE Order 4700.1, Part C, "Configuration Management and Change Control."</p>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the requirements for the control of Procurement Documents including content, in order to ensure that only correct and complete Procurement Documents are utilized by BWIP. This Criterion and 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.)</p> <p>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 (e.g., RFP's, contract modifications). 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</p>

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

Requirement	BWIP Project Implementation
	<p>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.</p> <p>Note that Criterion 6, "Document Control," NRC Review Plan 6.5, identifies Procurement Documents for inclusion within a document control system.</p> <p>Note that Procurement Document changes (i.e., contract modifications) that result from unsatisfactory supplier performance may be considered "significant conditions adverse to quality" and shall be documented as required by Criterion 16, NRC Review Plan Section 16.4.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

BOARD
CRITERION 4: PROCUREMENT DOCUMENT - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 4.2</p> <p>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.</p>	<p>This requirement shall be met by implementing NQA-1-1986, Basic Requirement 4 and Supplement 4S-1.</p> <p>For site characterization, additional guidance has been provided in Section 4.2 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated.</p> <p>In addition, Sections 2, 3, and 4 of Supplement 4S-1 and Supplement 7S-1, Sections 1, 3, 4, and 5 of NQA-1-1986, shall be implemented for activity (2).</p>

BOARD
CRITERION 4: PROCUREMENT DOCUMENT - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 4.1</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 4.1 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 4S-1, Sections 2 and 3 of NQA-1-1986 shall be implemented.</p> <p>Note that Federal Acquisition Regulations (FAR's) may require acceptance inspections if the procurement includes turnover of tangible, capital equipment to the purchaser.</p> <p>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.</p>

BOARD
CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS
REVISION 2 (sheet 1 of 3)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>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 ensure that activities are performed correctly, and if required, can be reproduced at a later date.</p> <p>NOTE: NQA-1 Supplement S-1 makes a distinction between "Procedure" and "Qualified Procedure," which is "an approved procedure <u>that has been demonstrated</u> 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 5.1</p> <p>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).</p>	<p>This requirement is addressed in NQA-1-1986, Basic Requirement 5.</p> <p>For site characterization, additional guidance has been provided in Section 5.1 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.</p> <p>NRC REVIEW PLAN SECTION 5.2</p> <p>Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality-related activities have been satisfactorily accomplished.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 5.2 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing NQA-1-1986, Basic Requirement 5.</p>

BOARD
CRITERION 6: DOCUMENT CONTROL
REVISION 2 (sheet 1 of 4)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the requirements for the control of project quality-affecting documents, in order to ensure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.</p> <p>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 ensures adequate control over case-by-case changes to controlled documents, if deviations/waivers are to be used.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be implemented as stated in NQA-1-1986, Basic Requirement 6 and Supplement 6S-1.</p> <p>Additional guidance has been provided in Sections 6.1, 6.2, 5.5, and 6.6 of the NRC Review Plan.</p>
<p>NRC REVIEW PLAN SECTION 6.1</p> <p>The scope of the document control program is described, and the types of controlled documents are identified.</p>	<p>This requirement shall be met by implementing all requirements in NQA-1-1986, Supplement 6S-1, Sections 1 and 2, provided the requirement to describe the scope of the document control program is addressed.</p>
<p>NRC REVIEW PLAN SECTION 6.2</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, NQA-1-1986, Supplement 6S-1 shall be implemented.</p>
<p>NRC REVIEW PLAN SECTION 6.5</p> <p>A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>
<p>NRC REVIEW PLAN SECTION 6.6</p> <p>When documents which require verification are released prior to verification, they are so identified and controlled.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated, and in addition, any project data resulting from application of the unverified document shall be clearly identified (DOE-RL).</p>

BOARD
CRITERION 6: DOCUMENT CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 6.3</p> <p>Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed <u>prior</u> to commencing the work.</p> <p>NRC REVIEW PLAN SECTION 6.4</p> <p>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.</p>	<p>This requirement shall be implemented as stated in NQA-1-1986, Supplement 6S-1, Section 1.</p> <p>Additional guidance has been provided in Sections 6.3 and 6.4 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be met by implementing Supplement 6S-1, Section 3 of NQA-1-1986.</p> <p>In addition, change controls shall comply with DOE Order 4700.1, Part C, "Configuration Management and Change Control."</p>

BOARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES
REVISION 2 (sheet 1 of 7)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the minimum requirements for control of purchased material, equipment and services, to ensure 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.</p> <p>Procedures shall be written to provide for: (a) source evaluation and selection, (b) inspection of items at the source or 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.</p> <p>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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 7.1</p> <p>Organization responsibilities are described for the control of purchased material, equipment, and services.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 7.1 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing Supplement 7S-1, Section 2 of NQA-1-1986.</p> <p>In addition, receiving inspection requirements may be minimized for items packaged for preservation at the supplier's 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).</p>

BOARD-
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION

DRAFT

REVISION 3 (sheet 4 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 7.3</p> <p>The organization providing materials, equipment, or services furnishes the following records to the purchaser:</p> <ul style="list-style-type: none">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." <p>The procedure for review and acceptance of these documents should be described in the purchaser's QA program.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 7.3 of the NRC Review Plan.</p> <p>The words "repository site" shall be substituted where appropriate.</p> <p>This requirement shall be met by implementing Supplement 7S-1, Section 8 of NQA-1-1986.</p> <p>This requirement shall be met by implementing Supplement 7S-1, Sections 8 and 9 of NQA-1-1986.</p> <p>This requirement shall be met by implementing Supplement 7S-1, Section 9, Subsection (b) of NQA-1-1986.</p> <p>This requirement shall be met by implementing Supplement 7S-1, Sections 5, 6, 7, and 9 of NQA-1-1986.</p>

BOARD
CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated, with the words "repository site" substituted where appropriate.</p> <p>Refer to Criteria 17 for additional records retention requirements.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 5: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 7.4</p> <p>Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.</p> <p>NRC REVIEW PLAN SECTION 7.5</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Sections 7.4 and 7.5 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 7S-1, Section 8.2.1 of NQA-1-1986 shall be implemented.</p> <p>This requirement shall be met during the selection and use of equipment for data collection activities under Criterion 11, for use with Criterion 3.</p> <p>While preparation, review, and approval of data acquisition planning and procedure generation are controlled under the design control provisions of the QA program, actual performance of the experiments, measurement, collection, etc., for acquiring data is controlled under applicable provisions of Section 11.0, Test Control.</p>

BOARD

**CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION
REVISION 1 (sheet 7 of 7)**

Requirement	BWIP Project Implementation
	<p>For instrumentation and/or equipment used in data collection, project participants are expected to consider whether failure or malfunction of the instrumentation during test will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, (a) technical and quality procurement requirements shall be selected specifically to minimize the likelihood of undetectable anomalies, and (b) test planning and procedures shall include any special provisions for equipment/instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.</p>

BQARD
CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS
REVISION 2 (sheet 1 of 4)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the requirements for identification and control of samples in order to ensure 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>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 ensure that only correct materials, parts, and components are utilized.</p>

BOARD

CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 3 (sheet 2 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies.</p> <p>NRC REVIEW PLAN SECTION 8.1</p> <p>Controls are established and described to identify and control samples. The description should include organization responsibilities.</p> <p>NRC REVIEW PLAN SECTION 8.3</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 8S-1 of NQA-1-1986 shall be implemented.</p> <p>For site characterization, additional guidance has been provided in section 8.1 and 8.3 of the NRC Review Plan.</p> <p>This requirement is addressed in NQA-1-1986, Supplement 8S-1, under the term "Items."</p> <p>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).</p> <p>This requirement shall be met by implementing NQA-1-1986, Supplement 8S-1.</p>

BOARD

CRITERION 8: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 8.2</p> <p>Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 8.2 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing NQA-1-1986, Supplement 8S-1.</p>

BQARD

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.</p> <p>NRC REVIEW PLAN SECTION 8.4</p> <p>Correct identification of samples is verified and documented prior to release for use or analysis.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 8.4 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>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).</p>

BOARD
CRITERION 9: CONTROL OF SPECIAL PROCESSES
REVISION 2 (sheet 1 of 3)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of the criterion during site characterization is to establish the minimum requirements for the control of special processes, in order to ensure that site characterization processes where direct inspection is impossible or disadvantageous produce results that are demonstrably valid through the use of other accepted assurance techniques.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 9.1</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 9.2</p> <p>Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.</p> <p>NRC REVIEW PLAN SECTION 9.3</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Sections 9.1 through 9.5 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 9S-1 of NQA-1-1986 shall be implemented.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="142 338 562 371">NRC REVIEW PLAN SECTION 9.4</p> <p data-bbox="142 404 945 503">Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.</p> <p data-bbox="142 528 562 561">NRC REVIEW PLAN SECTION 9.5</p> <p data-bbox="142 586 945 685">Qualifications records of procedures, equipment, and personnel associated with special processes are established and maintained.</p>	<p data-bbox="1066 404 1837 470">This requirement shall be met by implementation of NQA-1-1986, Supplement 9S-1, Section 3.</p> <p data-bbox="1066 586 1879 685">This requirement shall be implemented as stated. In addition, Supplement 9S-1, Section 3.3 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 10: INSPECTION
REVISION 2 (sheet 1 of 9)

Requirement	BWIP Project Implementation
	<p data-bbox="1381 343 1713 373" style="text-align: center;">Site Characterization</p> <p data-bbox="1104 406 2003 591">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.</p> <p data-bbox="1104 624 2003 935">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 ensure 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.</p> <p data-bbox="1104 968 2003 1443">For site characterization data gathering activities (e.g., laboratory testing and analysis), a combination of inspection and special process methods may be better suited to provide reliability of the data gathered. Since the quality of the end result cannot be directly measured or inspected (there is no acceptance criteria for testing results), the control of testing may be similar to the controls of special processes (i.e., procedures approved prior to use through technical and/or peer reviews; testing personnel qualified through experience, education and training; equipment "qualified" through calibration; and monitoring of performance of the test). Data subjected to an independent technical and/or peer review will constitute a final verification of the data's validity.</p>

BOARD
CRITERION 10: INSPECTION
REVISION 2 (sheet 2 of 9)

Requirement	BWIP Project Implementation
	<p>Final inspections shall be performed by qualified personnel not reporting directly to the immediate supervisors who are responsible for performing the work being inspected. 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.</p> <p>All project personnel, particularly project inspection personnel, shall be advised that the phrase "acceptance inspection" has a specific contractual meaning and must be used with discretion. In addition, inspection planners and those producing inspection procedures shall ensure they are aware of and responsive to Federal Acquisition Regulations pertaining to inspections.</p> <p>Potentially Licenseable Construction</p> <p>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.</p>

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 3 (sheet 3 of 9)

DRAFT

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 10.1</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>In addition, the program shall be operative and provide input to the design documents and procurement documents used during site characterization (DOE-RL).</p> <p>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).</p> <p>For site characterization, additional guidance has been provided in Section 10.1 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 10S-1, Sections 4, 5.1, 6, and 7 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 9)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>Such inspection shall be performed by individuals other than those who performed the activity being inspected.</p> <p>NRC REVIEW PLAN SECTION 10.2</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 10.3</p> <p>A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Sections 10.2, 10.3, and 10.6 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>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, and limitations on the authority, of the inspecting contractor (DOE Order 6410.1).</p> <p>This requirement shall be implemented as stated. In addition, Supplement IOS-1, Section 2.2 of NQA-1-1986 shall be implemented.</p> <p>Certification of inspection personnel shall be met by implementation of NQA-1-1986, Supplement 2S-1 and Appendix 2A-1.</p>

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 9)

Requirement	BWIP Project Implementation
<p data-bbox="153 667 587 698">NRC REVIEW PLAN SECTION 10.6</p> <p data-bbox="153 728 953 819">Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.</p>	<p data-bbox="1076 355 1959 632">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).</p> <p data-bbox="1076 723 1832 786">This requirement shall be met by implementing Supplement 10S-1, Sections 6 and 8 of NQA-1-1986.</p> <p data-bbox="1076 816 1959 943">In addition, each inspection shall be documented, and all inspection results pertaining to an activity shall be furnished to the reviewer of the resultant data (Criterion 3) (DOE-RL).</p>

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 6 of 9)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality.</p> <p>NRC REVIEW PLAN SECTION 10.4</p> <p>Inspection procedures, instructions, or checklists provide for the following:</p> <ul style="list-style-type: none">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.	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 10.4 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 10S-1, Section 8 of NQA-1-1986 shall be implemented.</p>

BQARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 7 of 9)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided.</p>	<p>This requirement shall be met by implementation of NQA-1-1986, Supplement 10S-1, Section 5.</p> <p>Inspection of certain defined special processes shall be met by implementation of Criterion 9.</p>

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 8 of 9)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 5: 10 CFR 50 APPENDIX B</p> <p>Both inspection and process monitoring shall be provided when control is inadequate without both.</p>	<p>This requirement shall be met by implementation of Supplement 10S-1, Section 5 of NQA-1-1986.</p>

BOARD
CRITERION 10: INSPECTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 9 of 9)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 6: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 10.5</p> <p>Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.</p>	<p>This requirement shall be met by implementing supplement 10S-1, Section 3 of NQA-1-1986.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement as shown in Section 10.5 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing Supplement 10S-1, Section 3 of NQA-1-1986.</p>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>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 ensure 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 ensure 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.</p> <p>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.</p> <p>NOTE: The requirements of this criterion may be selectively applied to "exploratory" testing, upon issuance of an NRC Generic Technical Position.</p>

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

Requirement	BWIP Project Implementation
	<p>Potentially Licenseable Construction</p> <p>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.</p>

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 8)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 11.1</p> <p>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.</p>	<p>This requirement shall be met by implementing the requirements of NQA-1-1986, Supplement 11S-1 as further defined herein.</p> <p>Additional guidance has been provided in Sections 11.1, 11.2, and 11.3 of the NRC Review Plan.</p> <p>A. The first sentence of this requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be met by implementing the guidance provided in figure 3 of the NRC Review Plan, as summarized below.</p> <p>1. A Test Control Program Plan shall be developed which defines program requirements based on:</p> <ul style="list-style-type: none"> a. Site issues b. Information needs c. Program objectives. <p>This plan shall include:</p> <ul style="list-style-type: none"> a. Purpose b. Scope c. Description of work d. Specific requirements e. Interfaces f. Equipment and facilities g. Milestones.

BQARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 8)

Requirement	BWIP Project Implementation
	<p>Individual test plans shall be developed which define how needed information will be gathered. These plans shall include, as appropriate, the following:</p> <ul style="list-style-type: none">a. Test objectivesb. Scope of testsc. Justificationd. Test descriptionse. Expected resultsf. Listing of required technical implementing proceduresg. Responsibilities/personnelh. Schedulei. Format of reportsj. Referencesk. List of applicable QA administrative proceduresl. List of required QA technical procedures. <p>B. The second sentence of this requirement is not specifically addressed in NQA-1-1986, Supplement 11S-1. Therefore, Requirement "(a)" of this sentence shall be implemented as stated, and Requirement "(b)" of this sentence shall be implemented in Criterion 2.</p> <p>C. The requirement of sentence three is that the quality assurance organization shall, as a minimum, audit these functions in accordance with the requirements of Criterion 18, "Audits."</p>

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 8)

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 11.2</p> <p>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).</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated. See Criterion 3 for the detailed interpretation of NRC Review Plan, Sections 3.7, 3.8, and 3.9.</p>
<p>NRC REVIEW PLAN SECTION 11.3</p> <p>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.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>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.</p>

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 6 of 8)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be met by implementing all the requirements of NQA-1-1986, Supplement 11S-1 Section 2, with the following modification made:</p> <p>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 (e.g., 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).</p>

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 7 of 8)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 11.4</p> <p>Test procedures or instructions provide for the following:</p> <ul style="list-style-type: none"> 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. 	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in the NRC Review Plan Section 11.4.</p> <p>This requirement is not specifically addressed in NQA-1-1986, in the detail given in the NRC Review Plan. Therefore, this requirement shall be implemented as stated.</p> <p>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 the identified acceptance limits, or other nonconformances with respect to a test procedure, shall be dispositioned utilizing Criterion 15, "Nonconformances" (DOE-RL).</p>

BOARD
CRITERION 11: TEST CONTROL - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 8 of 8)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>Test results shall be documented and evaluated to assure that test requirements have been satisfied.</p> <p>NRC REVIEW PLAN SECTION 11.5</p> <p>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).</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Section 11.5 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing NQA-1-1986, Supplement 11S-1, paragraph 4, provided: the words "as described in Criterion 3" are added after the "responsible party."</p> <p>The requirement for test records shall be met by implementing the requirements of the NRC Review Plan Section 17.3, and the requirements of NQA-1-1986, Supplement 11S-1, paragraph 5.</p> <p>In addition, document requirements for experiment and research for geologic repository projects are specified in OGR/B-3, Supplement 5, Section 5.0.</p>

BOARD
CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT
REVISION 2 (sheet 1 of 4)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the controls necessary over measuring and test equipment, in order to ensure 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

BOARD

CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT - FOR SITE CHARACTERIZATION
REVISION 3 (sheet 2 of 4)

DRAFT

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 12.1</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 12.2</p> <p>QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 12S-1, Section 4 of NQA-1-1986 shall be implemented.</p> <p>For site characterization, additional guidance has been provided in Sections 12.1 through 12.7 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 12: CONTROL OF MEASURING AND TEST EQUIPMENT - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 12.3</p> <p>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.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>
<p>NRC REVIEW PLAN SECTION 12.4</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 12S-1, Section 5 of NQA-1-1986 shall be implemented.</p>
<p>NRC REVIEW PLAN SECTION 12.5</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 12S-1, Sections 2, 3, and 4 of NQA-1-1986 shall be implemented.</p>

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

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 12.6</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 12S-1, Section 3.1 of NQA-1-1986 shall be implemented.</p> <p>In sentence 2 of the supplement section the words "the basis for calibration shall be documented" shall be deleted and the words "provisions are established to document acceptability of the calibration standard used" shall be added in their place, which only serves as a clarification.</p>
<p>NRC REVIEW PLAN SECTION 12.7</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 12S-1, Section 3.2 of NQA-1-1986 shall be implemented.</p> <p>In addition, refer to Criterion 15 for documentation requirements (DOE-RL).</p>

BOARD
CRITERION 13: HANDLING, SHIPPING AND STORAGE
REVISION 2 (sheet 1 of 3)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>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 ensure 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 (e.g., environmental and geological samples taken during site characterization). This criterion may also have applicability to other critical site characterization items. Note Test Procedure Requirements.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization: that 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.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 13.1</p> <p>Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 13.1 of the NRC Review Plan.</p> <p>This requirement shall be met by implementation of Supplement 13S-1, Sections 2, 3, and 4 of NQA-1-1986, with the clarification of changing the words "sampling, handling" to "sample handling,".</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 13.2</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 13.2 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 13S-1, Sections 3.1 and 3.2 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 14: INSPECTION, TEST AND OPERATING STATUS
REVISION 2 (sheet 1 of 4)

Requirement	BNIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>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 ensure 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is similar to its intent during site characterization.</p>

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

Requirement	BNIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 14.1</p> <p>Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Section 14.1 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing NQA-1-1986, Basic Requirement 14.</p> <p>In addition, procedures shall be established to ensure that inspection, test, and operating status is clearly indicated by means of markings, tagging, boundary markers, etc., as appropriate to the nature of the equipment or natural region affected and of the inspection, test or operation involved.</p> <p>In addition, procedures shall be established to control the issuance and use of unique marking devices (e.g., stamps, tags, labels) to ensure traceability to the individual or to the specific activity utilizing the marking device (DOE-RL).</p>

BQARD
CRITERION 14: INSPECTION, TEST AND OPERATING STATUS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement is addressed in NQA-1-1986, Basic Requirement 14.</p>

BOARD

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement is addressed in NQA-1-1986, Basic Requirement 14.</p>

BOARD
CRITERION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS
REVISION 2 (sheet 1 of 4)

Requirement	BWIP Project Implementation
	<p>The intent of this criterion during site characterization is to establish the minimum requirements for controlling project nonconformances, to ensure 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.</p> <p>Refer to NQA-1-1986 Supplement S-1 for Nonconformance definition. Note that procedural deficiencies are included.</p> <p>"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 need to be made.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 15.1</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 15.1 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing NQA-1-1986, Supplement 15S-1.</p>

BOARD
CRITERION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.</p> <p>NRC REVIEW PLAN SECTION 15.2</p> <p>QA responsibilities related to nonconformance control are described.</p> <p>NRC REVIEW PLAN SECTION 15.3</p> <p>Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.</p> <p>NRC REVIEW PLAN SECTION 15.4</p> <p>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.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 15S-1, Sections 2, 3, and 4 of NQA-1-1986 shall be implemented.</p> <p>For site characterization, additional guidance has been provided in Sections 15.1, 15.2, 15.3, and 15.4 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is also addressed in NQA-1-1986, Basic Requirement 15.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented consistent with Criterion 16.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.</p>	<p>This requirement shall be implemented as stated. In addition, Supplement 15S-1, Sections 4.4 and 4.5 of NQA-1-1986 shall be implemented.</p>

BOARD
CRITERION 16: CORRECTIVE ACTION
REVISION 2 (sheet 1 of 4)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the minimum requirements for controlling project corrective actions, to ensure that conditions adverse to quality are identified and corrected in a timely manner. Each project participant shall identify the need for corrective action, ensure 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.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 16.1</p> <p>Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.</p> <p>NRC REVIEW PLAN SECTION 16.2</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 16.3</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Sections 16.1, 16.2, and 16.3 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 16: CORRECTIVE ACTION - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 4)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p>	<p>This requirement shall be met by implementing NQA-1-1986, Basic Requirement 16.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 16.4</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Section 16.4 of the NRC Review Plan.</p> <p>This requirement is also addressed in NQA-1-1986, Basic Requirement 16.</p> <p>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).</p> <p>In addition, significant conditions adverse to quality shall require an Unusual Occurrence Report (HQ-OCRWM).</p> <p><u>Unusual Occurrence Reporting.</u> Contractors are required to report any significant event that results in any deviation from the planned or expected behavior of an activity or operation of course of events that 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).</p> <p>In addition, significant conditions adverse to quality shall be reported to <u>both</u> the integrating contractor and DOE-RL QSD as soon as possible but not later than five calendar days from the date of occurrence (DOE-RL).</p>

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS
REVISION 2 (sheet 1 of 7)

Requirement	BWIP Project Implementation
	<p style="text-align: center;">Site Characterization</p> <p>The intent of this criterion during site characterization is to establish the requirements for control of project records, to ensure that documents and samples that furnish evidence of activities affecting quality remain valid and retrievable.</p> <p>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 records, 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.</p> <p>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).</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="67 343 630 376">REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p data-bbox="67 404 829 470">Sufficient records shall be maintained to furnish evidence of activities affecting quality.</p> <p data-bbox="67 531 504 564">NRC REVIEW PLAN SECTION 17.2</p> <p data-bbox="67 591 892 690">QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.</p>	<p data-bbox="991 399 1732 432">This requirement shall be implemented as stated.</p> <p data-bbox="991 591 1753 690">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 17.1</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 17.1 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>In addition, each participant shall establish a definitive list of documents that are to become quality assurance records (DOE-RL).</p> <p>In addition, each participant's records program shall be consistent with the project Records Management Plan (HQ-OGR).</p> <p>Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations shall be retained as lifetime QA records. (OGR/B-3, Supplement 1, Section 5.7)</p> <p>Additional requirements for the control of QA records are specified in OGR/B-3, Supplement 4.</p>

BQARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>The records shall also include closely related data such as qualifications of personnel, procedures, and equipment.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated, and as required by OGR/B-3, Supplement 5.</p>

BQARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 17.3</p> <p>Inspection and test records contain the following where applicable:</p> <ul style="list-style-type: none">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.	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, additional guidance has been provided in Section 17.3 of the NRC Review Plan.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>In addition, the inspection record shall be identifiable with the test activity inspected, and the person evaluating test or inspection results shall be identified (DOE-RL).</p>

BQARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 6 of 7)

Requirement	DWIP Project Implementation
<p>REQUIREMENT 5: 10 CFR 50 APPENDIX B</p> <p>Records shall be identifiable and retrievable.</p>	<p>This requirement shall be met by implementing Supplement 17S-1, Sections 2 and 5 of NQA-1-1986, provided participants record storage facility is consistent with Requirement 17.4.</p>

BOARD
CRITERION 17: QUALITY ASSURANCE RECORDS - FOR SITE CHARACTERIZATION

DRAFT
REVISION 3 (sheet 7 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 6: 10 CFR 50 APPENDIX B</p> <p>Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.</p> <p>NRC REVIEW PLAN SECTION 17.4</p> <p>Suitable facilities for the storage of records are described and utilized.</p>	<p>This requirement shall be met by implementing Supplement 17S-1, Sections 2, 3, 4, and 6 of NQA-1-1986.</p> <p>For site characterization, additional guidance has been provided in Section 17.4 of the NRC Review Plan.</p> <p>This requirement shall be met by implementing Supplement 17S-1, Section 4 of NQA-1-1986.</p>

BQARD
CRITERION 18: AUDITS
REVISION 2 (sheet 1 of 7)

Requirement	BWIP Project Implementation
	<p>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 ensure that the management feedback information contained in BWIP audit reports is timely, impartial, and correct.</p> <p>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.</p> <p>After confirmation of QA program implementation, audits performed within BWIP shall place emphasis upon verification of the achievement of quality in project end products.</p> <p style="text-align: center;">Potentially Licenseable Construction</p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p>REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 18.1</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 18.2</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>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.</p> <p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>This requirement shall 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-1-1986.</p> <p>In addition, frequency of regularly scheduled internal and external audits shall be based on evaluation of all applicable and active elements of the quality assurance programs. These evaluations shall include an assessment of the effectiveness of the applicable and active elements of the program based on such information as the following (DOE-RL):</p> <ul style="list-style-type: none"> (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).

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 3 of 7)

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 18.3</p> <p>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.</p>	<p>Regularly scheduled audits shall be supplemented by additional audits for one of the reasons given below:</p> <ul style="list-style-type: none"> (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 (e.g., 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. <p>This requirement shall be met by implementing Supplement 18S-1, Section 4 of NQA-1-1986.</p> <p>In addition, all audits 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).</p> <p>In addition, participants shall submit audit schedules, audit schedule revisions, and audit reports to the integrating contractor (HQ-OGR).</p>

BOARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 4 of 7)

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 18.6</p> <p>A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>In addition, each audit report shall include an "Executive Summary" of the audit findings (HQ-OCRWM).</p>
<p>NRC REVIEW PLAN SECTION 18.7</p> <p>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.</p>	<p>This requirement shall be met by implementing Supplement 18S-1, Section 6 of NQA-1-1986.</p>
<p>NRC REVIEW PLAN SECTION 18.8</p> <p>In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.</p>	<p>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p>In addition, the impact of the findings on completed work shall be evaluated (DOE-RI).</p>

BQARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 2 (sheet 5 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p>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.</p> <p>NRC REVIEW PLAN SECTION 18.5</p> <p>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.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Section 18.5 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. In addition, Supplement 18S-1, Sections 3.1, 3.2, and 3.3 of NQA-1-1986 shall be implemented.</p> <p>In addition, auditor orientation shall 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).</p>

DRAFT

BOARD
CRITERION 18: AUDITS - FOR SITE CHARACTERIZATION
REVISION 3 (sheet 6 of 7)

Requirement	BWIP Project Implementation
<p>REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p>Audit results shall be documented and reviewed by management having responsibility in the area audited.</p> <p>NRC REVIEW PLAN SECTION 18.4</p> <p>Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.</p>	<p>This requirement shall be implemented as stated.</p> <p>For site characterization, the NRC has provided additional guidance for this requirement in Section 18.4 of the NRC Review Plan.</p> <p>This requirement shall be implemented as stated. The auditee's and auditor's organizations shall respond to this requirement and to Requirement 18.6. In addition, Supplement 18S-1, Section 5 of NQA-1-1986 shall be implemented.</p>

Requirement

BWIP Project Implementation

REQUIREMENT 4: 10 CFR 50 APPENDIX B

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

This requirement shall be met by implementing Supplement 18S-1, Sections 6 and 7 of NQA-1-1986.

Audit records shall comply with Supplement 18S-1, Section 8 of NQA-1-1986.

Enclosure 1

Question 1 - Memorandum Page 1, 3rd Paragraph

The second page of the introduction to BQARD states: "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." This appears to conflict with the QA management requirements expressed by OCRWM in its October 1985 document, "Quality Assurance Management Policies and Requirements." Section 5.2 of that document states: "...ANSI/ASME NQA-1 is the basic QA requirements standard for the (Civilian Radioactive Waste Management Program...". Although the NRC has not endorsed NQA-1 for use on the Program, BWI Division should be asked to explain, as a point of information, why the NQA-1 supplements are not utilized in their entirety in BQARD.

Response: All supplements of NQA-1-1986 are referenced in the BQARD. Page 2 of 3, paragraph 4 of the BQARD has been modified to reflect this.

"UTILIZATION OF NQA-1 WITHIN THE BQARD. QA Programs that 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, the 18 NQA-1 Basic Requirements, the NQA-1 supplements, and the NRC Review Plan, to define QA Program requirements."

Question 2 - Memorandum Page 1, 4th Paragraph

Sheet 6 under Criterion 7 states that the guidance given in NRC Review Plan, Section 7.5, is on hold by DOE-RL until receipt of NRC clarification. Section 7.5 reads as follows: "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." We are unaware of any request for clarification of this, but this item should be on the agenda for the meeting proposed above.

Response: The statement of the NRC Review Plan, Section 7.5 being on hold by DOE-RL was deleted in Revision 2.

Comments from the Request for Additional Information

Comment 1: A statement used throughout BQARD is "Therefore, the intent of this requirement will be met if implemented as stated." As a requirements document, BQARD should address meeting a requirement rather than meeting "the intent" of a requirement. Also, requirements documents should use "shall" instead of "will" or "may". Further, the term "if

implemented" should be clarified as was done on Sheet 3 under Criterion 3. Therefore the quoted statement should read: "Therefore, this requirement shall be implemented as stated." or words to that effect.

Response: The following generic changes have been made throughout the document:

- a) The statements have been changed to read:
"This requirement shall be implemented as stated."
- b) The words "will" and "may" have been changed to "shall".

Comment 2: Sheet 10 under Criterion 2 addresses requirements for personnel performing quality-related activities. For these personnel (the "doers"), reference is made to the NRC's Review Plan items 2.8a, c, and d. Item 2.8e, "Qualified personnel are certified in accordance with applicable codes and standards", should also be referenced as some of these personnel (welders, for example) require certification. The second sentence under item 1 should read: "Therefore, this requirement shall be met by implementing the requirements of 2.8a, c, d, and e as stated."

Response: Criterion 2, Sheet 10 of 19, Sentence changed to read: "...2.8a, c, d, and, when applicable, e, in cases such as welder certification, etc., as stated."

Comment 3: The note on Sheet 12 under Criterion 2 indicates that test inspectors (i.e., inspectors of testing activities) can be "...assigned to the testing organization and designated by the testing supervisor to be an in-process Inspector...". Clarify that "in-process Inspectors" do not have direct responsibility for performing the work being verified. The quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.

Response: The following paragraph has been added to Criterion 2, Sheet 13 of 19:

Comment 3 (continued)

"In-process inspectors" shall have no direct responsibility in performing the work being inspected/verified. The inspection function may be part of the line organization provided the QA organization performs periodic surveillance to verify sufficient independence from the individuals who performed the activity."

Comment 4: The note on Sheet 7 under Criterion 3 limits the use of the word "validating" to the context of computer codes. The definition of validation from NUREG-0856 should be expanded to: "Assurance that a model is a correct representation of the process or system for which it is intended." Note the definition of verification in ANSI N45.2.11 expands the definition in NUREG-0856 in a similar fashion.

Response: The following has been added to the note of Criterion 3, Sheet 7 of 12: "...computer codes, to provide assurance that a model is a correct representation of the process or system for which it is intended".

Comment 5: The first paragraph on Sheet 1 under Criterion 4 states that site characterization participants have the option of controlling procurement activities per the requirements of either Criterion 4 or Criterion 7. While there may be some duplication in these criteria, there are also differing requirements, and the requirements of both criteria should be met.

Response: On Sheet 1 of 4, Criterion 4, the words: "Also, at the option of the participant," have been deleted and the statement now reads: "This Criterion and Criterion 7 shall establish...".

Comment 6: The last paragraph on Sheet 2 under Criterion 4 states that construction participants have the option of using either the Site Characterization Criterion 4 or NQA-1 Basic Requirement 4 and Supplement 4S-1. Here again there are differing requirements, all of which should be met. The proviso at the end of this paragraph does not appear to address this. A comparable comment applies to Criteria 5 through 18.

Response: For Criterion 4 through 18, the last sentence in the paragraph giving participants this option has been deleted.

Comment 7: Supplements 4S-1 and 7S-1 of NQA-1 do not address the involvement of the QA organization in the various activities.

Comment 7 (continued)

The NRC Review Plan, Sections 4.2 and 7.2 do. BQARD should require that these sections of the review plan be met. (See Sheet 3 under Criterion 4 and Sheet 3 under Criterion 7.

Response: Criterion 4, Sheet 3 of 4 and Criterion 7, sheet 3 of 7 have been revised.

Comment 8: The second paragraph on Sheet 1 under Criterion 9 implies that tests conducted per Criterion 11 do not require qualified procedures, qualified personnel, and monitoring of process variables. This implication should be eliminated.

Response: This paragraph has been deleted.

Comment 9: The first sentence under BWIP Project Implementation on Sheet 2 under Criterion 9 indicates that the NRC has "reworded" Criterion 9. The NRC has not reworded Criterion 9, and this sentence should be deleted or revised. A similar problem exists on Sheet 10 under Criterion 10, Sheets 7 and 9 under Criterion 11, Sheet 2 under Criterion 12, Sheet 2 of Criterion 14, Sheet 4 of Criterion 16 and on Sheets 5 and 6 under Criterion 18.

Response: In all cases, the word "reworded" has been deleted and the phrase "provided additional guidance" inserted.

Comment 10:
(paragraph 1) The discussion of inspection on Sheets 1 and 2 under Criterion 10 needs clarification. The first sentence indicates inspection is an "independent verification," but the third paragraph indicates that in-process inspections may be performed by the supervisor of the activity. We agree that the doer's supervisor is directly responsible for the work, and we believe that supervisors can and should make (or have made) in-process checks (i.e., nonindependent verification) and final checks before having work inspected. We do not agree that a doer's supervisor has the independence required to perform inspections, and the discussion should be revised to reflect this. Note that some work may require inspection during processing, some may require checking, and some may require neither.

Response: The paragraph in question has been changed to read:

"Final inspections shall be performed by qualified personnel not reporting directly to the immediate supervisors who are responsible for performing the work being inspected. Final inspections should be

Comment 10 (continued)

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."

Comment 10 (paragraph 2)

The first sentence on Sheet 2 under Criterion 10 states: "Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusion," indicating a personnel inspector vs. line supervisor relationship which is not desirable. The inspector's responsibility is neither to confirm nor deny "the adequacy of the supervisor's conclusion," and the sentence should be deleted or revised. Finally, clarify the significance of the parenthetical words in the third and fourth paragraphs under Criterion 10.

Response: The first sentence on Sheet 2 of 10, Criterion 10 has been deleted. In addition, the parenthetical words in the third and fourth paragraphs of Criterion 10 have been deleted.

Comment 11: Sheet 6 under Criterion 10 indicates that Section 8 of 10S-1 of NQA-1 will be implemented to ensure that inspection results are documented and evaluated and that their acceptability is determined by a responsible individual. Beyond documentation, Section 8 does not appear to address this guidance. Clarify.

Response: Reference to Section 6 of NQA-1-1986, Supplement 10S-1 has been added on Sheet 5 under Criterion 10.

Comment 12: Explain the last sentence on Sheet 10 under Criterion 10 which states: "For the BWIP Project, refer to the PMP/SEMP for identification of BWIP designated inspectors."

Response: Sentence has been deleted.

Comment 13: Item C on Sheet 4 under Criterion 11 addresses the fact that QA should, as a minimum, audit the test program. Item C should specify that this will be done.

Response: "Should" has been changed to "shall" in this sentence.

Comment 14: Under Criterion 11, BQARD should address whether testing will test the item under conditions which will be present during normal and anticipated off-normal operation when practicable.

Comment 14 (continued)

Comment 14 (continued)

Response: Not incorporated. This wording is not deemed applicable to site characterization and for items (e.g., equipment for the proposed repository), it is covered under Criterion 3, Sheet 10 of 12, Requirement 8.

Comment 15: The last paragraph on Sheet 8 under Criterion 11 states, "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." Test records should meet both Section 17.3 of the NRC Review Plan and paragraph 5 of supplement 11S-1 of NQA-1, and the paragraph should be so clarified.

Response: This paragraph has been revised to read as follows:

"The requirement for test records shall be met by implementing the requirements of the NRC Review Plan, Section 17.3, and the requirements of NQA-1-1986, Supplement 11S-1, paragraph 5."

Comment 16: Under Criterion 18, clarify that both technical and QA programmatic audits are performed and that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.

Response: Not incorporated. This requirement is addressed in the BWIP QA Plan and it is not appropriate to incorporate this into the BQARD as it is not a federally mandated requirement.

The BWIP Quality Assurance Plan (DOE/RL 86-6) requires audits to address:

"Are the technical measures used to determine validity and correctness of scientific/engineering approaches and results adequate? (This does not include subjective analysis of peer review activities.)"

In addition, the following is quoted from the same document:

"Audit schedules are based on planned and ongoing Project work. Schedules are required to provide for (a) verification early in the life of a discrete task or work phase that approved controls are in place and are being applied, and (b) verification at appropriate later points in life of the task or work phase that comprehensive, credible evidence exists to demonstrate control

Comment 16 (continued)

effectiveness, and (c) judicious use of technical participants on all audit teams to verify the appropriateness and adequacy of technical approaches being employed on samples of activities being performed in their areas of expertise."

REQUEST FOR ADDITIONAL INFORMATION
BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT (BOARD)
REVISION 0, January 1986

1. A statement used throughout BOARD is: "Therefore, the intent of this requirement will be met if implemented as stated." As a requirements document, BOARD should address meeting a requirement rather than meeting "the intent" of a requirement. Also, requirements document should use "shall" instead of "will" or "may". Further, the term "if implemented" should be clarified as was done on Sheet 3 under Criterion 3. Therefore the quoted statement should read: "Therefore, this requirement shall be implemented as stated," or words to that effect.
2. Sheet 10 under Criterion 2 addresses requirements for personnel performing quality-related activities. For these personnel (the "doers"), reference is made to NRC's Review Plan items 2.8a, c, and d. Item 2.8e, "Qualified personnel are certified in accordance with applicable codes and standards," should also be referenced as some of these personnel (welders, for example) require certification. The second sentence under item 1 should read: "Therefore, this requirement shall be met by implementing the requirements of 2.8a, c, d, and e as stated."
3. The note on Sheet 12 under Criterion 2 indicates that test inspectors (i.e., inspectors of testing activities) can be "... assigned to the testing organization and designated by the testing supervisor to be an in-process Inspector...." Clarify that "in-process Inspectors" do not have direct responsibility for performing the work being verified. The quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
4. The note on Sheet 7 under Criterion 3 limits the use of the word "validating" to the context of computer codes. The definition of validation from NUREG-0856 should be expanded to: "Assurance that a model is a correct representation of the process or system for which it is intended." Note that the definition of verification in ANSI N45.2.11 expands the definition in NUREG-0856 in a similar fashion.
5. The first paragraph on Sheet 1 under Criterion 4 states that site characterization participants have the option of controlling procurement activities per the requirements of either Criterion 4 or Criterion 7. While there may be some duplication in these criteria, there are also differing requirements, and the requirements of both criteria should be met.
6. The last paragraph on Sheet 2 under Criterion 4 states that construction participants have the option of using either the Site Characterization Criterion 4 or NQA-1 Basic Requirement 4 and Supplement 4S-1. Here again there are differing requirements, all of which should be met. The

proviso at the end of this paragraph does not appear to address this. A comparable comment applies to Criteria 5 through 18.

7. Supplements 4S-1 and 7S-1 of NQA-1 do not address the involvement of the QA organization in the various activities. The NRC Review Plan Sections 4.2 and 7.2 do. BQARD should require that these sections of the review plan be met. (See Sheet 3 under Criterion 4 and Sheet 3 under Criterion 7.)
8. The second paragraph on Sheet 1 under Criterion 9 implies that tests conducted per Criterion 11 do not require qualified procedures, qualified equipment, qualified personnel, and monitoring of process variables. This implication should be eliminated.
9. The first sentence under BWIP Project Implementation on Sheet 2 under Criterion 9 indicates that the NRC has "reworded" Criterion 9. The NRC has not reworded Criterion 9, and this sentence should be deleted or revised. A similar problem exists on Sheet 10 under Criterion 10, Sheets 7 and 9 under Criterion 11, Sheet 2 under Criterion 12, Sheet 2 of Criterion 14, Sheet 4 of Criterion 16, and on Sheets 5 and 6 under Criterion 18.
10. The discussion of inspection on Sheets 1 and 2 under Criterion 10 needs clarification. The first sentence indicates inspection is an "independent verification," but the third paragraph indicates that in-process inspections may be performed by the supervisor of the activity. We agree that the doer's supervisor is directly responsible for the work, and we believe that supervisors can and should make (or have made) in-process checks (i.e., nonindependent verification) and final checks before having work inspected. We do not agree that a doer's supervisor has the independence required to perform inspections, and the discussion should be revised to reflect this. Note that some work may require inspection during processing, some may require checking, and some may require neither.

The first sentence on Sheet 2 under Criterion 10 states: "Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusion," indicating a personal inspector vs. line supervisor relationship which is not desirable. The inspector's responsibility is neither to confirm nor deny "the adequacy of the supervisor's conclusion," and the sentence should be deleted or revised. Finally, clarify the significance of the parenthetical words in the third and fourth paragraphs under Criterion 10.
11. Sheet 6 under Criterion 10 indicates that Section 8 of IOS-1 of NQA-1 will be implemented to ensure that inspection results are documented and evaluated and that their acceptability is determined by a responsible individual. Beyond documentation, Section 8 does not appear to address this guidance. Clarify.
12. Explain the last sentence on Sheet 10 under Criterion 10 which states: "For the BWIP project, refer to the PMP/SEMP for identification of the BWIP designated inspectors."

13. Item C on Sheet 4 under Criterion 11 addresses the fact that QA should, as a minimum, audit the test program. Item C should specify that this will be done.
14. Under Criterion 11, BOARD should address whether testing will test the item under conditions which will be present during normal and anticipated off-normal operation when practicable.
15. The last paragraph on Sheet 8 under Criterion 11 states, "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." Test records should meet both Section 17.3 of the NRC Review Plan and paragraph 5 of supplement 11S-1 of NQA-1, and the paragraph should be so clarified.
16. Under criterion 18, clarify that both technical and QA programmatic audits are performed and that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.

RESPONSE TO NRC

**REQUEST FOR ADDITIONAL INFORMATION
BASALT WASTE ISOLATION PROJECT QUALITY ASSURANCE PLAN
REVISION 1, APRIL 15, 1986**

1. The BWI Project Quality Assurance Plan was written prior to the following NRC June 1986 draft generic technical positions (GTPs):
 - a. Peer review.
 - b. Qualification of existing data.
 - c. Items and activities subject to QA requirements.

An evaluation should be made against the draft guidance of these GTPs, and differences between the plan and the draft GTPs should be addressed.

RESPONSE (1)

Comments on these three GTPs were transmitted to the NRC on November 7, 1986. Revision 2 of the BWIP QA Plan has been issued and the guidance of OGR/B-3 Supplements 3, 7, and 9 which address these subjects has been referenced. The specific "how to" requirements are incorporated in AMC and Integrating Contractor procedures. When the GTPs are finalized the OGR/B-3 QA Plan and supplements will be evaluated for changes which will be incorporated in the BWIP QA Plan and implementing procedures, if required.

2. Expressions such as "are expected to" or "is expected that" are found throughout the plan. Change these expressions to "shall" or justify not doing so.

RESPONSE (3)

The generic "are expected to" or "is expected that" have been changed to "shall" throughout the QA Plan in Revision 3.

3. Section 1.3 and Appendix A of the plan describe QA responsibilities within the BWI Division. Identify who (by position title) in the Richland Operations Office is responsible for the overall BWI program. Clarify the meaning of the dashed lines, arrowheads, and ellipses on Figure 1.3 of the plan. Also indicate what ES&H stands for on Figure 1.3 and Section 1.5 of the plan. (1.1)*

RESPONSE (2) (3)

Section 1.3 has been completely rewritten in Revision 2 to reflect the AMC organization. The Assistant Manager for Commercial Nuclear Waste is the Project Manager and is responsible for the Basalt Waste Isolation Project. Figure 1-3 has been clarified by providing a legend. The ellipses indicate

the listed responsibilities apply to each participants' QA Manager. Figure 1-2 has been revised to show the Environmental Safety Quality Assurance and Health (ES&H) Division and Section 1.5c has been added to describe their functions on the BWIP in Revision 3.

4. Discuss how the Integrating Contractor avoids conflict of interest in its roles of project management and project participant. Clarify whether the Integrating Contractor, the Architect/Engineer, the Construction Manager, and other participants under direct contract to DOE for BWI Project work report to DOE-HQ, DOE-RL, or DOE-BWI Division. (1.3)

RESPONSE (3)

With both End Function Management and reporting of the project by Work Breakdown Structure as well as the line organization functional management; audits, surveillance and verifications by the IC QA organization includes both end function management and line organizations. We do not see a conflict within the Integrating Contractor's functions. The project is also managed by DOE and the activities are subject to technical review by the BWI Division and audits and surveillance by Quality Systems Division. The Direct Funded Contractors report technically to the AMC and contractually through the PRO Division, both of which are parts of DOE-RL.

5. Section 1.2.2 of the plan indicates the BWI Division verifies effective implementation of the QA program. Clarify that this includes at least an annual audit of the Integrating Contractor. (1.4)

RESPONSE (3)

Section 1.2.2 of Revision 3 has been clarified to reflect that annual audits and surveillances are performed by the AMC Quality Systems Division.

6. Sections 1.4 and 1.5 of the plan discuss QA interface with DOE-HQ and interdivision interface within DOE-RL respectively. Similarly, discuss the DOE-RL interface with Project participants. (1.6)

RESPONSE (2)

Sections 1.2, 1.3, 1.4 and 1.5 in Revision 2 have been completely rewritten to reflect the DOE-RL AMC organization and project interfaces. The QA Program responsibilities and functions for the Project Manager and the two division directors have been listed specifically.

7. Clarify whether the Director, BWI Division, reports through the Office of Commercial Nuclear Waste (Section 1.3.1) or the Office of Civilian Nuclear Waste (Figure 1-2). Identify the onsite and offsite organizational elements which function under QA program controls of justify not doing so. Show the ES&H Division, the Procurement Division, and the Personnel Division on an organization chart. (1.7)

RESPONSE (2,3)

The directors of Basalt Waste Isolation Division and the Quality Systems Division report to the Assistant Manager for Commercial Nuclear Waste (AMC). Figure 1-2 has been modified to reflect all of the DOE-RL divisions that support the project. Section 1.2.4 has been revised to indicate that the Architect/Engineer is the only offsite organization. This was initially corrected in Revision 2 with further modification in Revision 3.

8. Describe measures which ensure that DOE-RL's BWI Division Quality Systems Branch Chief is involved in the aspects of the BWI Project that affect safety and/or waste isolation and how the extent of DOE-RL QA controls is determined. (1.8)

RESPONSE (2)

Section 1.3 and 1.3.3 in Revision 2 describes the function of the Director, Quality Systems Division. This QA Plan applies to items and activities important to safety and waste isolation. The extent of QA controls are further delineated within the Basalt Procedures.

9. Identify a management position within DOE-RL, the Integrating Contractor, Architect/Engineer, and Construction Manager organizations that retains overall authority and responsibility for the applicable QA program. Describe the management, QA, and technical experience and knowledge requirements for these positions. Verify that each of these positions has the following characteristics:
 - a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
 - b. Has effective communication channels with other senior management positions.
 - c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.
 - d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10)

RESPONSE (2)

DOE-RL's Assistant Manager for Commercial Nuclear Waste (AMC) manages and directs the Basalt Waste Isolation Project. The Director, AMC Quality Systems Division exercises the direct line authority in the BWIP for QA functions. In the case of the Integrating Contractor, the Architect/Engineer and Construction Management Contractor, the project manager has overall authority for work performed and each has a QA Manager responsible for their QA program. Figure 1-3 depicts the BWIP QA Program Management Responsibilities. The

positions are at the same or higher organization level as the line manager directly responsible for performing activities affecting quality and in each case they are sufficiently independent of cost and schedule. This is described for DOE-RL in Section 1.3 Revision 2 and in the DOE approved QA Plans of the Integrating Contractor, the Architect Engineer, and the Construction Management Contractor.

In each case, the management, QA, or technical experience or knowledge for the QA managers has been established by the responsible organizations. Position requirements for the Quality Systems Division Director is established by the BWIP Project Manager. In each case, the QA Managers along with the Project Managers have approval authority for QA Manuals, changes and interpretation. In addition, the Director AMC Quality Systems Division provides policy guidance in interpretation between the Basalt Quality Assurance Requirements Document and implementing details as prescribed within the QA plan.

10. Describe measures which ensure that 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.

Describe how these actions are accomplished. (1.12)

RESPONSE (3)

Section 1.2.2 in Revision 3 has been rewritten to state this requirement and to indicate that within AMC, procedures BP 3.1, PROJECT REVIEWS and BP 2.7, APPEALS ON QUALITY CONCERNS, are established so that quality, technical, and administrative personnel have avenues to identify problems, provide recommendations and verify implementation of solutions. The participating contractors have established similar controls.

11. Section 1.2.6 of the plan addresses stop work. Clarify the retention time of records of stop work requests. (1.12)

RESPONSE (3)

A sentence has been added in Section 1.2.6, Revision 3 as follows: "(STOP WORK DOCUMENTS) and resulting corrective actions become project records which are forwarded to the BRMC for retention."

Within AMC, Procedure BP 1.11, STOP WORK includes provisions for lifetime record retention.

12. Identify items and activities covered by the QA Program. Section 2.0 of the plan indicates that analytical processes are used to determine

importance to safety and/or waste isolation. Clarify whether importance to safety and importance to waste isolation are defined as numerical performance objectives and standards. Justify why not if not. (2.1)

RESPONSE (3)

Section 2.0, second paragraph, in Revision 3, has been modified to read as follows:

Importance to safety and waste isolation is determined by analytical processes involving failure modes and effects analysis, and fault tree analysis, which develop numerical performance objectives and standards, and incorporation of scientific and engineering judgement. The process is described in the Project's Performance Assessment Plan. Project QA organizations are involved in the process at all appropriate points. These iterative processes provide the basis for the Project Q-list, and provide important inputs to assignment of items and activities to quality levels within the Graded QA program.

13. Section 3.2 of the plan indicates that Supplement 6 of the OGR QA plan addresses computer software control. Update Section 3.2 to reflect the fact that Supplement 6 of the OGR plan no longer addresses computer software. (2.2)

RESPONSE (2)

This correction was made in Revision 2 of the BWIP QA Plan.

14. Section 2.4 of the plan indicates a management team assesses effectiveness of the overall Project QA program. Clarify that the management team is composed of personnel above or outside the DOE-RL QA organization. (2.7)

RESPONSE (3)

Section 2.4, first paragraph, Revision 3, has been modified as follows:

At intervals determined by the AMC, but not exceeding one year, a management team above or outside the Quality Systems Division assesses effectiveness of the overall Project QA program. The structure of the assessment team and mechanics of the assessment process are addressed by an approved procedure. (AMC Procedure BP 2.1, Quality Assurance Program Assessment describes how DOE-RL performs management assessments.)

15. Section 3.1 of the plan indicates that design controls include those used to ensure the correct translation of design inputs into designs. Describe the controls which ensure that applicable regulatory requirements and design bases are reflected in design, procurement, and procedural documents. Also, describe measures which ensure that performance goals are specified for repository subsystems and components

to support the establishment of data gathering and analysis needs. Discuss the timeliness of specifying these requirements. At the latest, planned performance allocation should be addressed in the SCP consistent with agreements reached in NRC/DOE meetings of April 17, 1981 and September 26 and 27, 1985 on this matter. (3.2)

RESPONSE (3)

The first sentence of Section 3.1 in Revision 3 has been reworded as follows:

Project design controls include not only controls traditionally used to ensure correct translation of design inputs including applicable regulatory requirements and design bases into designs but controls to ensure adequacy and validity of site characterization results and design bases.

Sections 3.3 and 3.4 prescribe methods used for determining data needs and analysis and the required controls.

Performance allocation and timeliness of specifying data needs are described in the SCP and are in concert with DOE and NRC agreements, which are reflected in Study Plans and Engineering Plans which are prepared and executed to approved procedures. The QA Plan is not the appropriate document to present Engineering and Scientific plans and schedules.

16. Describe measures which ensure that (1) errors and deficiencies in approved design and design information documents are documented and (2) action is taken to ensure that all errors and deficiencies are corrected. (3.4)

RESPONSE (2)

Section 3.1, second paragraph in Revision 2 reads as follows:

Project participants shall include provisions in their design control procedures for (a) documenting design errors and deficiencies upon discovery, and (b) ensuring that resulting corrections are properly reflected across all affected design interfaces.

17. Section 3.4 of the plan addresses design verification, and it includes in Section 3.4.4, "Design Verification by Similarity," an addition to the 3 methods of 10 CFR 50 Appendix B. This method would be acceptable if a fourth condition was added: (4) the design characteristics (attributes, features) that are not identical are identified and verified in a manner other than by similarity. Add such a condition or justify not doing so. Also, describe measures which ensure that design checking, which includes such things as confirmation of the numerical accuracy and computations and the accuracy of data input to computer codes, will be performed. (Confirmation that the correct computer code has been used is part of design verification.) Design verification should be performed by persons other than those performing design checking. Clarify whether personnel performing design verification can be associated with their responsible design organization. (3.7)

RESPONSE (3)

Organizationally, personnel performing design verifications are required to comply with ANSI/NQA-1 Suppl. 3S-1. Section 3.4.4 in Revision 3 has been changed to clarify the intent as follows:

Where all or portions of a design is/are verified by similarity to prior designs, verification shall establish that (1) conditions under which the prior design operated were the same as, or more severe than, relevant conditions in which the present design will operate, (2) the prior design operated or was tested under the most adverse combination of design conditions applicable to the present design, (3) the designer has determined and appropriately accounted for any deficiencies discovered during operation of the prior design, and (4) the design characteristic features or attributes that are not identical, are verified by one or more of the methods described above.

18. Clarify whether procedures prescribe the extent of documentation required for design verification. (3.9)

RESPONSE (3)

Section 3.4 in Revision 3 has been changed to read:

"f. Documented independent design verification."

The full extent of documentation is specified in the participants implementing procedures.

19. Section 3.6 of the plan addresses design changes. Clarify whether a configuration control system is in place such that design changes, including field changes, are analyzed to ensure they are required, are subject to the same design controls as the original design, are communicated to all affected groups and individuals, and are considered for changes to procedures and training. (3.10)

RESPONSE (3)

Section 3.6 in Revision 3 has been revised as follows:

Design changes including field changes require technical controls commensurate with controls exercised on the original design, including review by the design organization which was responsible for the original design (unless otherwise specified by DOE). Design change controls shall include nonconformances to design requirements dispositioned use-as-is or repair. In addition, design changes that might entail significant impact to Project concept, cost, schedules, or safety apportionments must be submitted for Project Change Control Board approval and may result in procedure changes or additional training.

DOE-RL does not perform design which has been delegated to the Integrating Contractor and Architect/Engineer. The project has issued Project Management Directives, PMD 19.6, "Baseline Change Control," and PMD 19.16, "Configuration Management," which collectively establishes requirements for how changes are processed and that a configuration management and control system will be in place for processing of all changes.

20. Section 5.0 of the plan refers to personnel "who meet the independence criteria specified in Section 3.4 of this QAP." Clarify what these criteria are.

RESPONSE (3)

Section 5.0 has been revised and clarified.

21. Section 5.2 of the plan requires review of technical procedures by QA personnel. Clarify whether DOE-RL requires such review of administrative procedures (Categories 1 and 2 per Section 5.1 of the plan), instructions, and drawings. Also clarify whether "each participating entity in the project" as specified in Section 5.0 of the plan is the same as "each Project participant" which is used elsewhere in the plan. (5.1)

RESPONSE (3)

Section 5.0 has been revised to clarify review requirements. Participating entity encompasses such organizations as NRC, USCG, Sandia Laboratories, DOE-HQ, the State of Washington where work may be done to a Memorandum of Understanding rather than a formal contract. Project participants are those organizations under contract to DOE-RL. Responsibility for approval of their QA plans and procedures is covered in Section 1.3 of Revision 2.

22. Describe the scope of the DOE-RL document control program and identify the types of documents controlled by this program. Section 6.1 of the plan describes what the BWI Division requires of all Project participants in the area of document control. Clarify that the BWI Division requires the same of DOE-RL. This clarification should be made, as appropriate, throughout the plan since page v of the plan indicates that "all project participants" does not include the BWI Division of DOE-RL. (Section 4.1 and 7.0 are examples where clarification is required.) (6.1)

RESPONSE (2)

DOE-RL AMC Document Control program covers only those documents that are produced or released by DOE. They include the Basalt Procedures, the Project Management Directives, and such documents as the Project Plan, Project Management Plan (PMP), the Systems Engineering Management Plan (SEMP), the Information Resource Management Plan (IRMP), the Basalt Quality Assurance Requirements Document (BQARD) the Basalt Waste Isolation Project Quality Assurance Plan and Procurement Documents.

In the case of DOE, the Document Control Center is operated as a satellite operation by the Integrating Contractor as specified in the Basalt procedures. - The requirements imposed upon project participants is applicable to AMC as indicated on page vii of revision 2 of the BWIP QA Plan.

23. Describe measures which ensure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner. (6.4)

RESPONSE (3)

Section 6.5, has been revised in Revision 3 to clearly specify this requirement.

24. Sections 7.3.1 and 10.4 of the plan address mandatory hold points for inspection or witnessing and use the term "where appropriate." Identify the organization(s) that determine when these (and similar) activities are appropriate. (7.1 and 10.5)

RESPONSE (3)

Section 7.3.1 of the QA Plan has been revised.

Project Participants establish witness and hold points in accordance with their procedures. Typically participant engineering and/or QA organizations specify inspection witness and hold points in work documents.

25. Describe the BWI Division Quality systems Branch and other DOE-RL organizational responsibilities for qualification of special processes, equipment, and personnel. Provide examples of processes during site characterization that will be classified as special processes and those that will not. (9.2)

RESPONSE (3)

AMC BWI and QS divisions do not specify or qualify special processes, equipment or personnel. The Participating contractors are assigned this responsibility. In addition the integrating contractor has been directed to compile and maintain a listing of special processes developed by the participating contractors. This list will be available for review at the site as it is developed. It is expected that welding of exploratory shaft liners and NDE would be considered special processes. During site characterizations such processes as analytical testing of geotechnical samples and other laboratory testing such as chemical, mechanical, thermal, electrical, or hydraulic testing to ASTM or equivalent methods would not be considered special processes.

26. Clarify that special processes (standard or not standard) are required to be in conformance with applicable codes, standards, QA procedures, and specifications. The last sentence of Section 9.2 of the plan requires that participant's QA Plan describes QA's role in special processes. Clarify whether the BWI Division requires involvement of QA organizations. (9.3)

RESPONSE (3)

Section 9.2 has been revised.

AMC requires that Project Participant's describe the role of their QA organization in their QA Plans for special processes which as a minimum would require QA review prior to use.

28. Section 7.5 of the plan indicates that DOE-RL's BWI Division is responsible for ensuring that delivered items and materials comply with applicable QA requirements, but Section 10 assigns inspection to Project participants. Describe how the BWI division meets the responsibility noted from Section 7.5 without performing inspections. Indicate how the BWI Division participates in determining when inspections are required and in defining how and when inspections are performed. (10.1)

RESPONSE (3)

DOE-RL's AMC does not perform inspections of items and materials. This responsibility has been assigned to the project participants who are responsible to have the inspections performed. AMC accepts services as described in Section 7.3.2. The integrating contractors' QA Department, and AMC's Quality Systems Division perform audits and surveillances of inspection activities as indicated in Sections 4.3 and 7.5. When inspections are required on AMC procurements, the requirements are specified in the procurement documents (AMC procedures BP 4.1, BP 7.1 and BP 7.2). The DOE-RL Procurement Division (PRO) performs direct procurements as described in Section 1.5. The PRO also contracts with the participating contractors to perform required inspections.

29. Section 10.2 of the plan addresses inspector qualification and permits inspections by personnel outside QA organization. Clarify that inspections are accomplished by individuals or groups who do not have direct responsibility for performing the work being inspected. The inspections function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity. (10.2)

RESPONSE (2)

As compliance with ANSI/ASME NQA-1, 1986 is required by this QAP in Revision 2, it specifically states that inspections are performed by individuals or groups not directly responsible for performing the work or supervising the work in Supplement 10S-1, Section 2.1. Further clarification in this section seems unnecessary. AMC has established a requirement that the inspection function be a part of the participants' QA organizations, and their QA Plans and QA administrative procedures address this.

30. Section 10.2 also refers to personnel with "particular" or "special" expertise. Describe QA's involvement in determining the expertise required commensurate with the technical complexity of the inspection function and the acceptability of the qualifications of the inspector.

Also clarify that the qualifications and certifications of inspectors (both in and outside QA) are documented and kept current. Section 10.2 uses the term, "participant's QA inspection function." Clarify whether this is the same as the participant's QA organization. (10.2)

RESPONSE (2)

Section 10.2 has been revised and clarified.

31. Describe measures which ensure that, when practicable, tests of structures, systems, and components shall be at conditions which simulate both normal and anticipated off-normal operations. (11.5)

RESPONSE (2)

Test procedures are prepared and reviewed by the responsible design organizations in accordance with Section 3.0 of this QAP as indicated in Section 11.2. If testing is being used for design verification or acceptance, such conditions as normal or off-normal operation would be included in the requirements and acceptance limits of the test procedure as indicated in Section 11.6 of the QAP. In a review of the NRC Review Plan for Quality Assurance Program for Site Characterization of High Level Waste Repositories, we were not able to find the specific requirement listed and it is considered inappropriate to incorporate further detail in the QAP.

32. Describe the scope of the QA program for the control of M&TE and identify the types of equipment to be controlled. (12.1)

RESPONSE (3)

Section 12.1 has been revised, and the role of QA is described. A listing of types of equipment to be controlled is inappropriate for this QAP.

33. Sections 12, 13, and 14 of the plan appear somewhat inconsistent. Sections 12 and 13 make the Integrating Contractor responsible for the controls, but 14 does not. Sections 13 and 14 address each Project participant, but 12 does not. Section 12 addresses cognizant QA organizational responsibilities, but 13 and 14 do not. Sections 12 and 13 specify surveillance and audit by DOE BWI Division QS, but 14 does not. Clarify these sections to eliminate these apparent inconsistencies, and describe how the involved organizations will meet their assigned responsibilities.

RESPONSE (2,3)

Section 12.1 in Revision 2 has been rewritten to reflect that other project participants use M&TE and have calibration programs. Sections 13.0 and 14.0 have been clarified and made consistent in Revision 3.

34. Describe measures which ensure that nonconforming items and samples are segregated from those which are acceptable. (15.1)

RESPONSE (2)

Section 15.1 first paragraph in Revision 2 has been clarified as follows:

Each project participant is required to identify any nonconforming item, material or sample by marking, tagging or other appropriate means immediately upon detection of the nonconformance. Such identification shall provide clear indication of the nonconforming condition of the item, material or sample to anyone who might otherwise process or use it. Measures shall include segregation where practical.

35. Section 15.2 of the plan requires that "use-as-is" and "repair" dispositions receive technical review and approval at the next higher level of project participation. Describe QA responsibilities regarding this review and approval. (15.2)

RESPONSE (2)

Section 15.2 has been revised.

36. Section 15.1 of the plan requires that each nonconformance be documented. Clarify that nonconformance documentation identifies the item, describes the nonconformance, shows the disposition of the nonconformance, and includes signature approval of the disposition. (15.3)

RESPONSE (2)

This is covered in Section 15.2.

37. Section 15.4 of the plan states that "The Project" will monitor and analyze nonconformance trends on a Project-wide basis. Identify what organization is responsible for these activities. Clarify that the trend analyses are used to help identify root causes of nonconformances. Identify the management level of DOE responsible to review and assess significant results of the nonconformance trend information. (15.4)

RESPONSE (3)

Section 15.4 in Revision 3 has been clarified as follows:

"The participants shall establish systems for monitoring and analyzing nonconformances reports for trends to help to determine root cause and to initiate appropriate action where the need is indicated. AMC review of nonconformance reports submitted by the Integrating Contractor is accomplished in accordance with AMC Procedure BP 15.1, Processing Contractor NCRs and Unusual Occurrences. Trends are determined and monitored in accordance with AMC Procedure BP 15.2, Trend Analysis. The AMC QS Division Director evaluates trend reports and notifies the BWIP Project Manager of significant nonconformance trend information."

38. Describe measures which ensure that the significance of each

nonconformance is assessed to determine whether corrective action is required to prevent recurrence. Identify the organization responsible for this assessment. (16.2)

RESPONSE (2)

The participant contractor's technical and QA organizations, determine if nonconforming conditions are significant. This assessment would normally be done by the Integrating Contractor, or the Architect/Engineer with input from the Construction Management Contractor.

The Integrating Contractor has been assigned the task of implementing a formal project-wide program for formal corrective action to prevent recurrence of significant problems in Section 16.1. In this role he will evaluate other participant reported problems to determine significance. These reports are regularly transmitted to AMC management for evaluation and assessment and to direct any required action.

39. Describe the scope of the record program. That is, identify by type of data what records will be maintained within the records management system. (17.1)

RESPONSE (3)

Section 17.1 in Revision 3 has been revised; however the specific types of records within the Records Management Program are not appropriate for a top-level document such as the QA Plan.

40. Describe the responsibilities of the project participants' QA organizations in the records management system. (17.2)

RESPONSE (3)

Sections 17.1 and 17.4 in Revision 3 requires the following:

The participating contractors' QA organizations are responsible to perform surveillances and audits of their records program. In addition, the Integrating Contractor perform surveillances and audit of the Participants and the BRMC's Record Programs.

The AMC Quality System Division evaluates the effectiveness of the controls by the Integrating Contractor by surveillances and audits.

41. Section 17.3 of the plan addresses an archival facility for long-term storage of project records. Describe record storage facilities to be used prior to the availability of such a facility. (17.4)

RESPONSE (3)

The records storage facilities presently consist of a vault in the Federal Building with 2 hour fire rated doors, metal cabinets, and a building sprinkler system. The BRMC has 2 hour fire rated cabinets for storage of

records. The silver halide films of records are stored in separate cabinets in separate buildings and prints are used for record research and retrieval. No project records have been discarded since the site investigation was initiated in 1977.

42. Section 18.3 of the plan addresses audit scheduling. Clarify that audit scheduling considers the safety importance of the activities being performed. (18.2)

RESPONSE (3)

Section 18.3, second paragraph in Revision 3, has been changed to reflect this item.

43. Section 18.13.2 of the plan addresses follow-on activities by auditing organizations. Clarify that these include analysis of audit data by the QA organization with the results being reported to responsible management for review, assessment, and appropriate action. (18.4)

RESPONSE (3)

Section 18.13.2 in Revision 3 has been clarified to specifically address this item.

44. Describe measures which ensure that audited organizations describe in a formal report the corrective action to be taken to address adverse audit findings and that the report is submitted to responsible management and the audited organization. (18.7)

RESPONSE (3)

Section 18.13.1 in Revision 3, has been clarified to address this item.

45. Clarify that technical audits which provide a comprehensive independent verification and evaluation of procedures and activities affecting quality are included in the audit program, that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited, and that audit team leaders are from the QA organization.

RESPONSE (2)

Section 18.0 has been revised.

46. Appendix A of the plan gives exceptions/clarifications to the NRC review plan. The following comments result from the staff review of Appendix A:

- a. The last sentence of clarification item 1 states that QA program controls are exercised by line functions. Clarify whether "line functions" refer to BWI Division personnel. If so, identify these line functions with the organization shown in Figure 1-2 of the

plan. If not, identify what is meant by "line functions." Also clarify whether the "QA program controls" are the surveillances performed by BWI Division technical personnel as described in Section 18 of the plan. If not, clarify what is meant by QA program controls.

RESPONSE (3)

This clarification has been revised.

- b. Clarification item 2 states that qualified individual(s) or organizational element(s) will be identified within DOE's organization, prior to initiation of activities, as responsible for assuring that delegated work meets established quality standards. Identify such individual(s) or organizational element(s) with this responsibility for ongoing work. (1.5)

RESPONSE (2)

Clarification has been deleted. QA Plan Sections 1.2 and 1.3 adequately describe requirements.

- c. Clarification item 3 indicates that DOE will identify a DOE management position that retains overall authority and responsibility for: (1) performing QA functions relative to direct quality affecting activities within DOE, (2) verifying effectiveness of quality-related controls applicable to quality affecting work performed by DOE personnel, and (3) verifying proper performance of QA functions within contractor QA programs. Clarify who (by position title) has these responsibilities within DOE-RL for the BWI Project.

RESPONSE (2)

Clarification has been deleted. QA Plan Section 1.3 describes this function.

- d. Clarification item 4 indicates that both DOE and contractor verification of conformance to established requirements may be performed by people outside the QA organization. When this is the case, clarify that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.

RESPONSE (2)

Clarification has been deleted. QA Plan Section 1.0 addresses this subject.

- e. The last sentence of clarification item 7 states: "Geological data acquisition "testing" is not considered to belong to the "special process" category for purposes of process demonstration. Explain the QA significance of this statement.

Response (2)

Clarification has been deleted. Section 9.2 addresses this subject.

- f. Clarification item 9 is acceptable if only "samples" will require handling, preservation, storage, etc; i.e., if no structures, systems, components, or other materials are involved. If this is not the case, delete this clarification or justify not doing so.

Response (2)

Clarification has been deleted. Section 13.0 of the QA Plan has been revised to address this subject.