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Department of Energy

Richland Operations Office  
P.O. Box 550  
Richland, Washington 99352

87-QSD-147

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May 18 1987  
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WM Project 10, 14, 16  
Docket No. \_\_\_\_\_  
PDR \_\_\_\_\_  
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Distribution:  
Kennedy  
Linehan  
Riddle  
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(Return to WM, 623-SS)

J. P. Knight, Director  
Siting, Licensing and  
Quality Assurance  
Office of Civilian Radioactive  
Waste Management, HQ

BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT (BOARD) DOE-RL 86-1,  
REVISION 3 (DRAFT)

The BOARD has been revised in response to the NRC's Request for Additional Information attached to USNRC memorandum from Brian K. Grimes to Robert E. Browning dated October 18, 1986, subject "Review of Basalt QA Requirements Document." The responses were discussed and verbally concurred with by James Kennedy of the NRC on March 17, 1987 and during subsequent telephone conversations.

Responses to the NRC's written questions are included as Enclosure 1. In addition, further changes and clarifications were incorporated as follows:

- o Page 2, item g, of the introduction to BOARD was changed from DOE Order 6410.1 to DOE 4700.1, "Project Management System," which supersedes and cancels 6410.1.
- o To provide clarification on the configuration control system included in Criterion 3, sheet 12 of 12, under the sub-heading "NRC Review Plan, Section 3.10" we have incorporated a note as follows:

"Configuration Management and Change Control' shall comply with DOE Order 4700.1, Part C, 'Configuration Management and Change Control.'"

- o In addition, since we feel that Criterion 6 more appropriately addresses configuration control, we have revised Criterion 6, sheet 4 of 4, by adding the following:

"In addition, change controls shall comply with DOE Order 4700.1, Part C, 'Configuration Management and Change Control.'"

Other clarifications and requirements added are as follows:

- o In Criterion 2, sheet 17 of 19, under the sub-heading "Requirement 9: 10CFR50, Appendix B" we have added the statement:

"In addition, management assessments of the QA program shall be implemented as specified in OGR/B-3, QA Plan, Section 4.4."

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5/25/87

TO : J. KENNEDY  
NRC

FROM : K. SOMMER  
HQ IOGR  
RW-24

COPY : C. NEWTON  
RW-24

DISCUSSION :

ATTACHED REVISION 3 (DRAFT)  
BWTP "BQARD" AND RESPONSE  
TO NRC'S REQUEST FOR  
ADDITIONAL INFORMATION  
(JAN. 1986) FOR YOUR  
INFORMATION / REVIEW.

BEST REGARDS

K.G.   
FOR C. NEWTON

See note to boundary  
Am. Summary  
5/25/87  
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OCRWM

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- o In Criterion 3, sheet 3 of 12, under the sub-heading "NRC Review Plan Section 3.2" we have added the following:  
  
"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."
- o In Criterion 7, sheet 4 of 7, under the sub-heading of "NRC Review Plan Section 7.3" we have revised this requirement as follows:  
  
"This requirement shall be met by implementing Supplement 7S-1, Sections 5, 6, 7, and 9 of NQA-1-1986."
- o In Criterion 10, sheet 9 of 9, under the sub-heading "Requirement 6: 10CFR50, Appendix B" we have added the following:  
  
"This requirement shall be met by implementing supplement 10S-1, Section 3, of NQA-1-1986."

Enclosure 2 is draft Revision 3 of the BOARD which incorporates the above comments as well as those in Enclosure 1. Please forward a copy of this letter with enclosures to James Kennedy of the NRC with a request that he endorse draft Revision 3 of the BOARD for use on BWIP.

Our plans are to issue Revision 3 of the BOARD to the project participants following the NRC's endorsement which we hope you can obtain in an expeditious manner. If you or the NRC have any questions or comments, please contact me or C. K. Kasch of my staff on FTS 444-5183.

Sincerely,

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

QSD:CKK  
QA79D7.BG1

- Enclosures:
1. Response to NRC Questions
  2. BOARD, Rev. 3 (DRAFT)

**J. KENNEDY, NRC, 5/25/87**  
**G. FAUST, WESTON, 5/25/87**  
**C. NEWTON, HQ/OGR, 5/25/87**

## 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. BOARD 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 (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. BOARD 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.

BASALT WASTE ISOLATION PROJECT

BASALT QUALITY ASSURANCE  
REQUIREMENTS DOCUMENT

(BQARD)

**DRAFT** REVISION 3  
MARCH 1987

DOCUMENT MONITOR:

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

REVIEWED:

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

APPROVED:

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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-list 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-list" 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-list
  - e. QA for exploratory testing (as opposed to confirmatory testing).

The attachment to this introduction provides further information on each of these subjects. Participants are advised that existing BQARD implementation direction in these five 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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**BQARD**  
**CRITERION 1: ORGANIZATION**  
**REVISION 0 (sheet 1 of 13)**

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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><b>NOTE:</b> "Contractor" as used in this BQARD refers to all contractors, subcontractors, vendors, consultants, agents or agencies, and institutions performing work covered by the quality assurance program.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="197 332 764 360"><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="197 393 1073 455">The applicant shall be responsible for the establishment and execution of the quality assurance program.</p> <p data-bbox="197 551 621 579"><b>NRC REVIEW PLAN SECTION 1.1</b></p> <p data-bbox="197 616 1087 865">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 data-bbox="1136 393 1885 421">This requirement shall be implemented as stated.</p> <p data-bbox="1136 457 2003 520">For site characterization, additional guidance has been provided in Section 1.1 of the NRC Review Plan.</p> <p data-bbox="1136 616 2045 712">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><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 1.2</b></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><b>NRC REVIEW PLAN SECTION 1.3</b></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><b>NRC REVIEW PLAN SECTION 1.4</b></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>

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

Requirement	BWIP Project Implementation
<p>NRC REVIEW PLAN SECTION 1.5</p> <p>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>This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>
<p>NRC REVIEW PLAN SECTION 1.6</p> <p>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>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 5 of 13)**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 1.7</b></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><b>NRC REVIEW PLAN SECTION 1.9</b></p> <p>DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.</p> <p><b>NRC REVIEW PLAN SECTION 1.10</b></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 1S-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>

BOARD  
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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 4: 10 CFR 50 APPENDIX B</b></p> <p>These activities include both the performing functions of attaining quality objectives and the quality assurance functions.</p> <p><b>NRC REVIEW PLAN SECTION 1.8</b></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 1S-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>

**BQARD**  
**CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION**  
**REVISION 2 (sheet 8 of 13)**

Requirement	BWIP Project Implementation
<p data-bbox="226 320 793 348"><b>REQUIREMENT 5: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="226 381 1119 571">The quality assurance functions are those of (a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed.</p> <p data-bbox="226 604 667 632"><b>NRC REVIEW PLAN SECTION 1.11</b></p> <p data-bbox="226 665 1119 822">Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for: design, item 3.7; inspections, item 10.2; and test data evaluation, item 11.5 are outlined in these sections.</p>	<p data-bbox="1165 381 1917 409">This requirement shall be implemented as stated.</p> <p data-bbox="1165 442 2032 503">For site characterization, additional guidance has been provided in Section 1.11 of the NRC Review Plan.</p> <p data-bbox="1165 665 2074 756">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 9 of 13)**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 6: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 1.12</b></p> <p>Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:</p> <ol style="list-style-type: none"> <li>a. Identify quality problems.</li> <li>b. Initiate, recommend, or provide solutions through designated channels.</li> <li>c. Verify implementation of solutions.</li> <li>d. Stop unsatisfactory work.</li> </ol> <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><b>NRC REVIEW PLAN SECTION 1.13</b></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>

**BQARD**  
**CRITERION 1: ORGANIZATION - FOR SITE CHARACTERIZATION**  
**REVISION 2 (sheet 10 of 13)**

Requirement	BWIP Project Implementation
<p data-bbox="214 332 655 360">NRC REVIEW PLAN SECTION 1.14</p> <p data-bbox="214 394 1076 455">Policies regarding the implementation of the QA program are documented and made mandatory.</p>	<p data-bbox="1157 394 1927 485">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 11 of 13)**

Requirement	BWIP Project Implementation
<p data-bbox="205 320 772 350"><b>REQUIREMENT 7: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="205 383 1083 571">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 data-bbox="1150 383 1898 413">This requirement shall be implemented as stated.</p> <p data-bbox="1150 446 2058 601">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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 8: 10 CFR 50 APPENDIX B</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><b>REQUIREMENT 9: 10 CFR 50 APPENDIX B</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 1S-1, Section 3 of NQA-1-1986 shall be implemented.</p>

BQARD  
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>

**BOARD**  
**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;"><b>Potentially Licenseable Construction</b></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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 2.5</b></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><b>NRC REVIEW PLAN SECTION 2.6</b></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><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 2.3</b></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><b>NRC REVIEW PLAN SECTION 2.4</b></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 data-bbox="226 282 793 315">REQUIREMENT 3: 10 CFR 50 APPENDIX B</p> <p data-bbox="226 345 1104 505">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 data-bbox="226 535 653 568">NRC REVIEW PLAN SECTION 2.1</p> <p data-bbox="226 598 1104 915">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 data-bbox="1171 345 1919 378">This requirement shall be implemented as stated.</p> <p data-bbox="1171 408 2032 470">For site characterization, additional guidance has been provided in Section 2.1 of the NRC Review Plan.</p> <p data-bbox="1171 598 1940 690">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1171 720 2032 849">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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 4: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 2.2</b></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 data-bbox="195 335 766 365"><b>REQUIREMENT 5: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="195 398 1076 460">Activities affecting quality shall be accomplished under suitably controlled conditions.</p>	<p data-bbox="1140 393 2023 455">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 8 of 19)**

Requirement	BWIP Project Implementation
<p data-bbox="201 327 766 360"><b>REQUIREMENT 6: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="201 393 1060 550">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 data-bbox="1140 393 2026 454">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 data-bbox="212 320 779 351"><b>REQUIREMENT 7: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="212 384 1073 508">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 data-bbox="1152 384 2034 447">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 10 of 19)**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 8: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 2.8</b></p> <p>Indoctrination, training, and qualification in programs are established such that:</p> <ol style="list-style-type: none"> <li>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.</li> <li>b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.</li> <li>c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.</li> <li>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.</li> <li>e. Qualified personnel are certified in accordance with applicable codes and standards.</li> </ol>	<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"> <li>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.</li> <li>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"> <li>Design Reviewers - Supplement 3S-1, Section 4</li> <li>Inspectors - Supplements 2S-1 and/or 2S-2</li> <li>Auditors - Supplement 2S-3</li> <li>Indoctrination and Training - Supplement 2S-4.</li> </ul> <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"> <li>1. <u>Education (4 Credits Maximum)</u> <ul style="list-style-type: none"> <li>Associate degree from an accredited institution: score one (1) credit, or if the degree is in</li> </ul> </li> </ol> </li> </ol>

**BQARD**  
**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>

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

Requirement	BWIP Project Implementation
	<p data-bbox="1161 302 1900 368"><b>3. <u>Other Credentials of Professional Competence</u></b> <b>(2 Credits Maximum)</b></p> <p data-bbox="1224 398 2053 525">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 data-bbox="1161 555 1850 588"><b>4. <u>Rights of Management</u> (2 Credits Maximum)</b></p> <p data-bbox="1224 617 2024 839">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 data-bbox="1224 868 2024 935">The sample form shown in NQA-1 may be utilized as a record of lead auditor qualification.</p> <p data-bbox="1161 964 1976 1063">In addition, the following requirements on the qualifications of inspection and test (verification) personnel are made mandatory (DOE-RL):</p> <p data-bbox="1161 1093 2053 1443"><b>NOTE:</b> 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>

**BQARD**  
**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><b>1. FUNCTIONAL QUALIFICATIONS</b></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><b>1.1 Level I Personnel Capabilities</b></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><b>1.2 Level II Personnel Capabilities</b></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>

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

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

**BOARD**  
**CRITERION 2: QUALITY ASSURANCE PROGRAM - FOR SITE CHARACTERIZATION**  
**REVISION 1 (sheet 15 of 19)**

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>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></p> <p>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>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>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 style="text-align: center;">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>

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

Requirement	BWIP Project Implementation
<p data-bbox="130 333 697 363"><b>REQUIREMENT 9: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="130 396 928 459">The applicant shall regularly review the status and adequacy of the quality assurance program.</p>	<p data-bbox="1075 393 1957 518">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 data-bbox="1075 551 1923 644">In addition, management assessments of the QA program shall be implemented as specified in OGR/B-3, QA Plan, Section 4.4.</p>

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

**DRAFT**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 10: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 2.7</b></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"> <li>a. Frequent contact with program status through reports, meetings, and/or audits.</li> <li>b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.</li> </ul>	<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>

**BQARD**  
**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>

BQARD  
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><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 3.1</b></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>

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

Requirement	BWIP Project Implementation
<p data-bbox="155 332 583 360"><b>NRC REVIEW PLAN SECTION 3.2</b></p> <p data-bbox="155 393 1033 773">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 data-bbox="1096 393 1915 484">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 data-bbox="1096 517 1995 645">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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 3.6</b></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>

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

Requirement	BWIP Project Implementation
<p data-bbox="200 332 768 360"><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="200 394 1076 550">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 data-bbox="1144 394 1959 455">This requirement shall be met by implementing NQA-1-1986, Supplement 3S-1.</p> <p data-bbox="1144 490 1910 583">In addition, requirements for the methodology for formulating a Q-List are as specified in OGR/B-3, Supplement 3.</p>

BQARD  
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><b>REQUIREMENT 5: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 3.3</b></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><b>REQUIREMENT 6: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 3.4</b></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><b>NRC REVIEW PLAN SECTION 3.8</b></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><b>REQUIREMENT 7: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 3.7</b></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"> <li>(a) The supervisor is the only technically qualified individual.</li> <li>(b) The need is individually documented and approved in advance with concurrence of the Quality Assurance manager.</li> </ul> <p>It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.</p> <p><b>NRC REVIEW PLAN SECTION 3.9</b></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>

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

Requirement	BWIP Project Implementation
<p data-bbox="191 327 758 360"><b>REQUIREMENT 8: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="191 389 1052 550">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 data-bbox="1129 384 1948 480">This requirement shall be met by implementing the requirements of Supplement 3S-1, Subsection 4.2.3 of NQA-1-1986.</p> <p data-bbox="1129 513 1902 546">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><b>REQUIREMENT 9: 10 CFR 50 APPENDIX B</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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 10: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 3.10</b></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>

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

Requirement	BWIP Project Implementation
<p data-bbox="142 327 709 360"><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="142 389 974 612">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 data-bbox="142 645 569 678"><b>NRC REVIEW PLAN SECTION 4.2</b></p> <p data-bbox="142 708 993 963">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 data-bbox="1087 384 1976 447">This requirement shall be met by implementing NQA-1-1986, Basic Requirement 4 and Supplement 4S-1.</p> <p data-bbox="1087 480 1948 543">For site characterization, additional guidance has been provided in Section 4.2 of the NRC Review Plan.</p> <p data-bbox="1087 703 1839 736">This requirement shall be implemented as stated.</p> <p data-bbox="1087 769 1965 865">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>

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

Requirement	BWIP Project Implementation
<p data-bbox="205 327 766 360"><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="205 389 1062 517">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 data-bbox="205 546 625 579"><b>NRC REVIEW PLAN SECTION 4.1</b></p> <p data-bbox="205 609 1079 963">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 data-bbox="1140 384 1892 417">This requirement shall be implemented as stated.</p> <p data-bbox="1140 447 2007 513">For site characterization, additional guidance has been provided in Section 4.1 of the NRC Review Plan.</p> <p data-bbox="1140 609 2039 703">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 data-bbox="1140 733 2007 860">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 data-bbox="1140 890 1990 1050">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>

BQARD  
**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>

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

Requirement	BWIP Project Implementation
<p data-bbox="172 332 737 360">REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p data-bbox="172 393 1020 550">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 data-bbox="172 583 600 611">NRC REVIEW PLAN SECTION 5.1</p> <p data-bbox="172 644 1037 867">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 data-bbox="1115 389 1898 450">This requirement is addressed in NQA-1-1986, Basic Requirement 5.</p> <p data-bbox="1115 484 1976 545">For site characterization, additional guidance has been provided in Section 5.1 of the NRC Review Plan.</p> <p data-bbox="1115 640 1885 735">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="163 327 730 356"><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="163 389 1024 513">Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.</p> <p data-bbox="163 546 590 576"><b>NRC REVIEW PLAN SECTION 5.2</b></p> <p data-bbox="163 609 1039 733">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 data-bbox="1104 389 1854 419">This requirement shall be implemented as stated.</p> <p data-bbox="1104 452 1969 513">For site characterization, additional guidance has been provided in Section 5.2 of the NRC Review Plan.</p> <p data-bbox="1104 612 1997 674">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;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 6.1</b></p> <p>The scope of the document control program is described, and the types of controlled documents are identified.</p> <p><b>NRC REVIEW PLAN SECTION 6.2</b></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><b>NRC REVIEW PLAN SECTION 6.5</b></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><b>NRC REVIEW PLAN SECTION 6.6</b></p> <p>When documents which require verification are released prior to verification, they are so identified and controlled.</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, 6.5, and 6.6 of the NRC Review Plan.</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>This requirement shall be implemented as stated. In addition, NQA-1-1986, Supplement 6S-1 shall be implemented.</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, and in addition, any project data resulting from application of the unverified document shall be clearly identified (DOE-RL).</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="172 318 737 348">REQUIREMENT 2: 10 CFR 50 APPENDIX B</p> <p data-bbox="172 381 1062 538">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 data-bbox="172 571 596 601">NRC REVIEW PLAN SECTION 6.3</p> <p data-bbox="172 634 1050 761">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 data-bbox="172 794 596 824">NRC REVIEW PLAN SECTION 6.4</p> <p data-bbox="172 857 1062 953">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 data-bbox="1115 376 1898 439">This requirement shall be implemented as stated in NQA-1-1986, Supplement 6S-1, Section 1.</p> <p data-bbox="1115 472 2007 535">Additional guidance has been provided in Sections 6.3 and 6.4 of the NRC Review Plan.</p> <p data-bbox="1115 634 1883 730">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1115 857 1883 953">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="123 335 691 365"><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="123 398 1021 522">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 data-bbox="1070 393 1776 455">This requirement shall be met by implementing Supplement 6S-1, Section 3 of NQA-1-1986.</p> <p data-bbox="1070 488 1872 583">In addition, change controls shall comply with DOE Order 4700.1, Part C, "Configuration Management and Change Control."</p>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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>



CRITERION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES - FOR SITE CHARACTERIZATION  
 REVISION 3 (sheet 4 of 7)

**DRAFT**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 7.3</b></p> <p>The organization providing materials, equipment, or services furnishes the following records to the purchaser:</p> <ul style="list-style-type: none"> <li>a. Documentation that identifies the service and the specific procurement requirements (e.g., codes, standards, and specifications) met.</li> <li>b. Documentation identifying any procurement requirements that have not been met.</li> <li>c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."</li> </ul> <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>

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

Requirement	BWIP Project Implementation
<p data-bbox="184 323 747 353"><b>REQUIREMENT 4: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="184 386 1024 574">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 data-bbox="1125 386 1999 508">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 data-bbox="1125 541 1957 601">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><b>REQUIREMENT 5: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 7.4</b></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><b>NRC REVIEW PLAN SECTION 7.5</b></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>

**BQARD**  
**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;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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>



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;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></p> <p>The intent of this criterion during construction is identical to its intent during site characterization.</p>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 9.1</b></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><b>NRC REVIEW PLAN SECTION 9.2</b></p> <p>Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.</p> <p><b>NRC REVIEW PLAN SECTION 9.3</b></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>

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

Requirement	BWIP Project Implementation
<p data-bbox="183 327 612 356">NRC REVIEW PLAN SECTION 9.4</p> <p data-bbox="183 389 1002 485">Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.</p> <p data-bbox="183 513 612 543">NRC REVIEW PLAN SECTION 9.5</p> <p data-bbox="183 576 1002 672">Qualifications records of procedures, equipment, and personnel associated with special processes are established and maintained.</p>	<p data-bbox="1125 384 1917 450">This requirement shall be met by implementation of NQA-1-1986, Supplement 9S-1, Section 3.</p> <p data-bbox="1125 574 1949 670">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 - FOR SITE CHARACTERIZATION  
REVISION 3 (sheet 3 of 9)

**DRAFT**

Requirement	BWIP Project Implementation
<p data-bbox="138 332 701 365">REQUIREMENT 1: 10 CFR 50 APPENDIX B</p> <p data-bbox="138 394 1024 555">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 data-bbox="138 872 579 905">NRC REVIEW PLAN SECTION 10.1</p> <p data-bbox="138 935 1016 1125">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 data-bbox="1077 394 1829 427">This requirement shall be implemented as stated.</p> <p data-bbox="1077 457 1942 551">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 data-bbox="1077 581 1990 741">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 data-bbox="1077 771 1944 837">For site characterization, additional guidance has been provided in Section 10.1 of the NRC Review Plan.</p> <p data-bbox="1077 935 1955 1029">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>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p>Such inspection shall be performed by individuals other than those who performed the activity being inspected.</p> <p><b>NRC REVIEW PLAN SECTION 10.2</b></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><b>NRC REVIEW PLAN SECTION 10.3</b></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 10S-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="136 627 577 660"><b>NRC REVIEW PLAN SECTION 10.6</b></p> <p data-bbox="136 693 955 784">Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.</p>	<p data-bbox="1071 305 1974 594">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="1071 685 1848 751">This requirement shall be met by implementing Supplement 10S-1, Sections 6 and 8 of NQA-1-1986.</p> <p data-bbox="1071 784 1974 916">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><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 10.4</b></p> <p>Inspection procedures, instructions, or checklists provide for the following:</p> <ul style="list-style-type: none"> <li>a. Identification of characteristics and activities to be inspected.</li> <li>b. A description of the method of inspection.</li> <li>c. Identification of the individuals or groups responsible for performing the inspection operation.</li> <li>d. Acceptance and rejection criteria.</li> <li>e. Identification of required procedures, drawings, and specifications and revisions.</li> <li>f. Recording inspector or data recorder and the results of the inspection operation.</li> <li>g. Specifying necessary measuring and test equipment including accuracy requirements.</li> </ul>	<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 data-bbox="107 320 674 348"><b>REQUIREMENT 4: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="107 381 968 508">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 data-bbox="1045 381 1829 442">This requirement shall be met by implementation of NQA-1-1986, Supplement 10S-1, Section 5.</p> <p data-bbox="1045 475 1927 536">Inspection of certain defined special processes shall be met by implementation of Criterion 9.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="165 332 732 365"><b>REQUIREMENT 5: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="165 393 1044 459">Both inspection and process monitoring shall be provided when control is inadequate without both.</p>	<p data-bbox="1108 393 1896 459">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 data-bbox="128 320 695 351"><b>REQUIREMENT 6: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="128 381 1008 574">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 data-bbox="128 604 569 636"><b>NRC REVIEW PLAN SECTION 10.5</b></p> <p data-bbox="128 665 1022 764">Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.</p>	<p data-bbox="1066 381 1776 444">This requirement shall be met by implementing supplement 10S-1, Section 3 of NQA-1-1986.</p> <p data-bbox="1066 474 1976 569">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 data-bbox="1066 665 1776 728">This requirement shall be met by implementing Supplement 10S-1, Section 3 of NQA-1-1986.</p>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></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>

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

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

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 11.1</b></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"> <li>a. Site issues</li> <li>b. Information needs</li> <li>c. Program objectives.</li> </ul> <p>This plan shall include:</p> <ul style="list-style-type: none"> <li>a. Purpose</li> <li>b. Scope</li> <li>c. Description of work</li> <li>d. Specific requirements</li> <li>e. Interfaces</li> <li>f. Equipment and facilities</li> <li>g. Milestones.</li> </ul>

**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"> <li>a. Test objectives</li> <li>b. Scope of tests</li> <li>c. Justification</li> <li>d. Test descriptions</li> <li>e. Expected results</li> <li>f. Listing of required technical implementing procedures</li> <li>g. Responsibilities/personnel</li> <li>h. Schedule</li> <li>i. Format of reports</li> <li>j. References</li> <li>k. List of applicable QA administrative procedures</li> <li>l. List of required QA technical procedures.</li> </ul> <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>

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

Requirement	BWIP Project Implementation
<p data-bbox="119 327 576 360"><b>NRC REVIEW PLAN SECTION 11.2</b></p> <p data-bbox="119 389 1023 488">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 data-bbox="1072 384 1953 513">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 data-bbox="119 579 576 612"><b>NRC REVIEW PLAN SECTION 11.3</b></p> <p data-bbox="119 642 981 771">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 data-bbox="1072 639 1985 738">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1072 768 1970 897">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 data-bbox="121 320 688 350"><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="121 383 970 541">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 data-bbox="1066 383 1927 475">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 data-bbox="1066 508 1978 987">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><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 11.4</b></p> <p>Test procedures or instructions provide for the following:</p> <ul style="list-style-type: none"> <li>A. The requirements and acceptance limits are contained in applicable documents, including precision and accuracy.</li> <li>B. Instructions for performing the test.</li> <li>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.</li> <li>D. Mandatory inspection hold points (as required).</li> <li>E. Acceptance and rejection criteria, including required levels of precision and accuracy.</li> <li>F. Methods of data analysis.</li> <li>G. Methods of documenting or recording test data and results.</li> <li>H. Provisions for assuring test prerequisites have been met.</li> </ul>	<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>

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

Requirement	BWIP Project Implementation
<p data-bbox="111 327 674 356">REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p data-bbox="111 389 984 452">Test results shall be documented and evaluated to assure that test requirements have been satisfied.</p> <p data-bbox="111 579 552 609">NRC REVIEW PLAN SECTION 11.5</p> <p data-bbox="111 645 968 768">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 data-bbox="1052 389 1797 419">This requirement shall be implemented as stated.</p> <p data-bbox="1052 452 1913 541">For site characterization, the NRC has provided additional guidance for this requirement in Section 11.5 of the NRC Review Plan.</p> <p data-bbox="1052 640 1944 763">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 data-bbox="1052 799 1944 921">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 data-bbox="1052 958 1965 1047">In addition, document requirements for experiment and research for geologic repository projects are specified in OGR/B-3, Supplement 5, Section 5.0.</p>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 12.1</b></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><b>NRC REVIEW PLAN SECTION 12.2</b></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>

BQARD

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 data-bbox="163 310 604 340"><b>NRC REVIEW PLAN SECTION 12.6</b></p> <p data-bbox="163 373 1010 500">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 data-bbox="1104 373 1938 464">This requirement shall be implemented as stated. In addition, Supplement 12S-1, Section 3.1 of NQA-1-1986 shall be implemented.</p> <p data-bbox="1104 500 1980 687">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 data-bbox="163 723 604 753"><b>NRC REVIEW PLAN SECTION 12.7</b></p> <p data-bbox="163 786 1041 946">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 data-bbox="1104 786 1938 877">This requirement shall be implemented as stated. In addition, Supplement 12S-1, Section 3.2 of NQA-1-1986 shall be implemented.</p> <p data-bbox="1104 913 1923 976">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;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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 data-bbox="149 327 716 360"><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="149 393 1024 517">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 data-bbox="149 550 590 583"><b>NRC REVIEW PLAN SECTION 13.1</b></p> <p data-bbox="149 616 1045 740">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 data-bbox="1085 393 1839 426">This requirement shall be implemented as stated.</p> <p data-bbox="1085 459 1955 517">For site characterization, additional guidance has been provided in Section 13.1 of the NRC Review Plan.</p> <p data-bbox="1085 616 2001 740">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>

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

Requirement	BWIP Project Implementation
<p data-bbox="129 327 708 360"><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="129 389 1034 517">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 data-bbox="129 546 587 579"><b>NRC REVIEW PLAN SECTION 13.2</b></p> <p data-bbox="129 609 1023 769">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 data-bbox="1070 384 1836 417">This requirement shall be implemented as stated.</p> <p data-bbox="1070 447 1953 513">For site characterization, additional guidance has been provided in Section 13.2 of the NRC Review Plan.</p> <p data-bbox="1070 604 1906 703">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>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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	BWIP 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>

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

Requirement	BWIP Project Implementation
<p data-bbox="172 332 737 365"><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="172 394 1016 525">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 data-bbox="1108 394 1898 459">This requirement is addressed in NQA-1-1986, Basic Requirement 14.</p>

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

Requirement	BWIP Project Implementation
<p data-bbox="178 332 743 365"><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="178 393 1037 551">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 data-bbox="1119 393 1902 452">This requirement is addressed in NQA-1-1986, Basic Requirement 14.</p>

**BQARD**  
**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;"><b>Potentially Licenseable Construction</b></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 data-bbox="128 327 695 360"><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="128 389 1020 513">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 data-bbox="128 546 569 579"><b>NRC REVIEW PLAN SECTION 15.1</b></p> <p data-bbox="128 612 999 769">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 data-bbox="1064 389 1818 422">This requirement shall be implemented as stated.</p> <p data-bbox="1064 455 1934 513">For site characterization, additional guidance has been provided in Section 15.1 of the NRC Review Plan.</p> <p data-bbox="1064 612 1965 670">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><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</b></p> <p>These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.</p> <p><b>NRC REVIEW PLAN SECTION 15.2</b></p> <p>QA responsibilities related to nonconformance control are described.</p> <p><b>NRC REVIEW PLAN SECTION 15.3</b></p> <p>Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.</p> <p><b>NRC REVIEW PLAN SECTION 15.4</b></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 data-bbox="119 332 683 360"><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="119 393 917 488">Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.</p>	<p data-bbox="1057 393 1881 488">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>

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

Requirement	BWIP Project Implementation
	<p style="text-align: center;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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 data-bbox="157 322 735 355"><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="157 388 1029 545">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 data-bbox="157 578 609 611"><b>NRC REVIEW PLAN SECTION 16.1</b></p> <p data-bbox="157 644 1029 768">Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.</p> <p data-bbox="157 801 609 834"><b>NRC REVIEW PLAN SECTION 16.2</b></p> <p data-bbox="157 867 1060 1024">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 data-bbox="157 1057 609 1090"><b>NRC REVIEW PLAN SECTION 16.3</b></p> <p data-bbox="157 1123 1050 1214">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 data-bbox="1094 379 1858 421">This requirement shall be implemented as stated.</p> <p data-bbox="1094 446 1974 545">For site characterization, additional guidance has been provided in Sections 16.1, 16.2, and 16.3 of the NRC Review Plan.</p> <p data-bbox="1094 636 1879 735">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1094 859 1879 958">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1094 1115 1879 1214">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</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><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 16.4</b></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;"><b>Site Characterization</b></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;"><b>Potentially Licenseable Construction</b></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 3 of 7)**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 17.1</b></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 data-bbox="149 327 716 356"><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="149 389 1024 484">The records shall also include closely related data such as qualifications of personnel, procedures, and equipment.</p>	<p data-bbox="1087 389 1871 513">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>

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

Requirement	BWIP Project Implementation
<p data-bbox="149 332 716 365"><b>REQUIREMENT 4: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="149 394 1010 522">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 data-bbox="149 551 590 584"><b>NRC REVIEW PLAN SECTION 17.3</b></p> <p data-bbox="149 614 1010 680">Inspection and test records contain the following where applicable:</p> <ul data-bbox="149 710 1010 1060" style="list-style-type: none"><li>a. A description of the type of observation.</li><li>b. The date and results of the inspection or test.</li><li>c. Information related to conditions adverse to quality.</li><li>d. Inspector or data recorder identification.</li><li>e. Evidence as to the acceptability of the results.</li><li>f. Action taken to resolve any discrepancies noted.</li></ul>	<p data-bbox="1087 389 1839 422">This requirement shall be implemented as stated.</p> <p data-bbox="1087 452 1955 518">For site characterization, additional guidance has been provided in Section 17.3 of the NRC Review Plan.</p> <p data-bbox="1087 614 1860 713">This requirement is not specifically addressed in NQA-1-1986. Therefore, this requirement shall be implemented as stated.</p> <p data-bbox="1087 743 1986 868">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	BWIP Project Implementation
<p data-bbox="170 327 735 360"><b>REQUIREMENT 5: 10 CFR 50 APPENDIX B</b></p> <p data-bbox="170 389 884 422">Records shall be identifiable and retrievable.</p>	<p data-bbox="1104 389 1871 513">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  
REVISION 3 (sheet 7 of 7)

**DRAFT**

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 6: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 17.4</b></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>

**BOARD**  
**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;"><b>Potentially Licenseable Construction</b></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><b>REQUIREMENT 1: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 18.1</b></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><b>NRC REVIEW PLAN SECTION 18.2</b></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"> <li>(a) Previous audits and corrective actions</li> <li>(b) Nonconformance reports</li> <li>(c) Independent information (e.g., from other sources such as generic experience of the nuclear industry, ASME, peer organizations, regulating bodies).</li> </ul>

**BOARD**  
**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"> <li>(a) To determine the capability of a Supplier's quality assurance program prior to awarding a contract or purchase order</li> <li>(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</li> <li>(c) When significant changes are made in functional areas of the quality assurance program (e.g., significant reorganization or procedure revisions)</li> <li>(d) When it is suspected that the quality of an item is in jeopardy due to deficiencies in the quality assurance program</li> <li>(d) When a systematic, independent assessment of program effectiveness is considered desirable</li> <li>(f) When it is necessary to verify implementation of required corrective action.</li> </ul> <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>

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

Requirement	BWIP Project Implementation
<p><b>NRC REVIEW PLAN SECTION 18.6</b></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><b>NRC REVIEW PLAN SECTION 18.7</b></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><b>NRC REVIEW PLAN SECTION 18.8</b></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-RL).</p>

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

Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 2: 10 CFR 50 APPENDIX B</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><b>NRC REVIEW PLAN SECTION 18.5</b></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>

BOARD

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

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Requirement	BWIP Project Implementation
<p><b>REQUIREMENT 3: 10 CFR 50 APPENDIX B</b></p> <p>Audit results shall be documented and reviewed by management having responsibility in the area audited.</p> <p><b>NRC REVIEW PLAN SECTION 18.4</b></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
<p>REQUIREMENT 4: 10 CFR 50 APPENDIX B</p> <p>Follow-up action, including reaudit of deficient areas, shall be taken where indicated.</p>	<p>This requirement shall be met by implementing Supplement 18S-1, Sections 6 and 7 of NQA-1-1986.</p> <p>Audit records shall comply with Supplement 18S-1, Section 8 of NQA-1-1986.</p>