

Revision 0

06/10/86

**SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS**

**SUPPLEMENT No. 9**  
**RELIABILITY OF DATA**

June 10, 1986

**U.S. Department of Energy**  
**Office of Civilian Radioactive Waste Management**  
**Office of Geologic Repositories**

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**SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS**

**Reliability of Data**

**1.0 GENERAL**

This Supplement provides amplified requirements for the control of the reliability of data. It supplements the OGR QA Plan and ANSI/ASME NQA-1-1983 (Basic Requirement 3 and Supplement 3S-1). The requirements in this Supplement are to be used in conjunction with the requirements embodied or referenced in the governing QA plans and procedures.

**2.0 PURPOSE**

The purpose of this Supplement is to specify requirements for the control of the reliability of data for geologic repository projects.

**3.0 SCOPE**

The requirements of this Supplement are applicable to all data and data interpretations that are (1) related to quality levels 1 or 2 items or activities and (2) that were not generated under the controls of project QA plans or contractor QA programs that meet the requirements of Appendix B of 10 CFR 50 and NQA-1.

These requirements apply to the following categories of data or data interpretations that will be used to support site characterization and licensing of the repository.

- (a) Primary data or data interpretations and reports that were generated by the OGR Project Offices, predecessor organizations or their contractors involved in siting activities prior to the implementation date of a QA Plan complying with the requirements of 10 CFR 50, Appendix B.
- (b) Primary data from reports, books and theses from non-OGR Project participants.
- (c) Primary data or data interpretations from technical journals.

**4.0 DEFINITIONS**

(None)

## 5.0 REQUIREMENTS

### 5.1 Project Office Procedures

Each Project Office is to establish (or require to be established) detailed written procedures for the review, evaluation, acceptance and approval of data or data interpretations described in 3(a), (b) and (c) above. The procedures are to describe the scope, applicability, definitions, responsibility and methods to be used to comply with this supplemental requirement and are to be submitted to HQ for approval. The Project Office procedures shall also establish requirements for disposition of accepted and rejected data and data interpretations.

### 5.2 Acceptability of Non-Journal Data

The acceptability of non-journal data or data interpretations as defined in 3(a) or (b) above, shall be based on independent reviews of available documentation by at least two (2) appropriately qualified technical reviewers and one (1) quality assurance specialist.

#### 5.2.1 Available Documentation (Non-Journal)

Available documentation that is collected and assembled for data or data interpretation acceptability reviews should include the following to the maximum extent possible:

- (a) Statement of work and QA Program used, if any.
- (b) Log books or other documents containing data or data interpretations.
- (c) Technical procedures
- (d) Documented reviews.
- (e) Calibration records.
- (f) Samples
- (g) Other available pertinent documented information.

#### 5.2.2 Acceptability Reviews (Non-Journal)

Acceptability reviews of non-journal data or data interpretations shall be performed in accordance with a written checklist containing attributes similar to those noted in Attachment 1. Review results shall be documented in a written report, as a minimum, which includes the following information:

- (a) Identification of original investigator or organization.
- (b) Detailed description of data and its relationship to the current activity or item for which it will be used.
- (c) Technical justification explaining why the subject data should be used and why the process cannot or should not be (i.e., it is demonstrably unnecessary to repeat it) repeated in accordance with applicable Project Office QA Plan requirements.
- (d) Description of the QA methods that may have been used during generation of data including methods of data collection and equipment and computer programs used.

### 5.3 Acceptability of Journal Data

The acceptability of journal data or data interpretations as defined in 3(c) above shall be based on independent reviews of available documentation by at least two (2) appropriately qualified technical reviewers.

#### 5.3.1 Available Documentation (Journal)

Available documentation that is collected and assembled for data and data interpretation acceptability reviews should include to the maximum extent possible:

- (a) Additional data from published technical journals that support the information under review.
- (b) Additional data from published technical journals rebutting the information under review.
- (c) Any documentation of an independent verification.

#### 5.3.2 Acceptability Reviews (Journal)

Acceptability reviews of journal data or data interpretations shall be performed in accordance with a written checklist containing attributes similar to those noted in Attachment 2 and documented in a written report that includes, as a minimum, the following information:

- (a) Complete reference of the subject technical journal.
- (b) Concise description of the information in the article and its relationship to the current activity or item for which it will be used.

- (c) Technical justification explaining why the subject technical journal information should be used and why the process cannot or should not be (i.e., it is demonstrably unnecessary to repeat it) repeated in accordance with applicable OGR Project QA Plan requirements.

#### 5.4 Technical Reviewers

Technical reviewers shall at least be qualified to perform the activities that originated the data being reviewed. They shall also be independent of the work that originated the data being reviewed.

#### 5.5 RECORDS

- 5.5.1 All references, reports and other attachments to the completed and approved review document package shall be retained as lifetime QA records.

DATA/INTERPRETATION ACCEPTANCE

REVIEW ATTRIBUTES

1. Were experiments and tests associated with the data conducted in accordance with documented plans, procedures, etc., and was the documentation of such sufficient? TQ
2. Were the methods, practices, techniques, and experiments used to obtain and treat the data technically sound, objective, and properly selected? T
3. Are data calculations (including statistical analysis) correct? T
4. Were measuring and testing equipment calibrated to known standards? TQ
5. Did conclusions take into account deviations (sensitivity) in the measuring and testing equipment? T
6. Were samples, specimens, and data adequately identified and controlled for use within the test or equipment? TQ
7. Are original samples or specimens available for further tests or experiments? TQ

8. Was the operating procedure stated in sufficient detail so that the test or experiment can be reconstructed? TQ
9. Is the raw data sufficiently recorded and retrievable? Q
10. Was the data input sufficient to make a reasonable interpretation, supported by documented analysis, when compared to the input data? T
11. Were the results of the data or interpretation presented in an understandable format consistent with obtaining the desired results? T
12. Were assumptions used in the data or interpretation adequately identified and reasonable, and were all possible assumptions taken into account? T
13. Based on your review, do you concur with the use of the subject information for its intended purpose? (Explain) TQ

T = Technical Reviewer Attributes

Q = QA Reviewer Attributes

TECHNICAL JOURNAL

DATA/INTERPRETATION ACCEPTANCE

REVIEW ATTRIBUTES

1. Are you aware of additional published technical journal articles (other than those provided) supporting the technical conclusions of the work undergoing the acceptance review? (Provide a complete reference)
2. Are you aware of additional published technical journal articles (other than those provided) rebutting the work undergoing acceptance review? (Provide a complete reference)
3. Address any significant agreement or disagreement between the information being reviewed and published rebuttals.
4. In your opinion do you technically concur with the use of the information in this technical publication for its intended purposes? (Explain)

**SUPPLEMENTAL QA REQUIREMENTS**

**HQ-OGR Oversight of QA Activities  
for Defense Wastes**

**1.0 GENERAL**

This Supplement provides the requirements for the oversight of QA activities of West Valley (WV) and the Defense Waste Processing Facility (DWPF). The technical activities of these two producers of high-level radioactive wastes (HLW) will be subject to OGR oversight to assure that their QA Programs are established and implemented in compliance with the OGR QA Plan.

**2.0 PURPOSE**

The purpose of this Supplement is to specify the QA requirements to be imposed on WV and DWPF and the oversight methods to verify compliance.

**3.0 SCOPE**

The requirements of this Supplement are applicable to WV and DWPF activities that relate to the processing of HLW preparatory to final storage at OGR geologic repositories.

**4.0 DEFINITIONS**

None

**5.0 REQUIREMENTS**

**5.1 QA Plans and Implementing Procedures**

5.1.1 WV and the DWPF shall each establish a Quality Assurance Program that will encompass all items and activities that are necessary for the processing and preparation of HLW in such form and content that will meet the requirements for safety and waste isolation (as defined in 10 CFR 60.2).

5.1.2 The QA Program shall meet the applicable QA requirements of the following documents:

- a. Appendix B to 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities".
- b. ANSI/ASME NQA-1, 1983, "Quality Assurance Program Requirements for Nuclear Facilities".

- c. NRC Review Plan, 1984, "Quality Assurance Programs for Site Characterization of High-Level Waste Repositories".
- d. OCRWM Quality Assurance Management Policies and Requirements, DOE/RW-0032.
- e. OGR Quality Assurance Plan for High-Level Radioactive Waste Repositories, Revision 1, OGR/B-3.

5.1.3 The QA Program of each organization shall be documented in a QA Plan and Administrative Procedures which are to be submitted to the Associate Director - OGR and the Project Office Managers for comment.

## 5.2 HQ-OGR Oversight

HQ-OGR shall verify the adequacy and implementation of the WV and DWPF QA Programs by performing the following oversight functions:

- a. Review and comment on WV and DWPF QA Plans and Implementing Procedures.
  - 1. Review shall be in accordance with QIP 2.0, "Headquarters Review of Project QA Plans and Procedures"
- b. QA Audits of activities applicable to the QA Program.
  - 1. Audits shall be conducted by HQ-OGR and DOE-Nuclear Energy for WV and by HQ-OGR and DOE-Defense Programs for DWPF.
  - 2. Audits shall be performed in accordance with QIP 18.0, "External Audits".
- c. HQ-OGR may participate in selected QA audits conducted by WV and DWPF on the technical activities of their major contractors.
  - 1. Participation shall be in accordance with QIP 18.1, "HQ Participation in Project QA Audits of Contractors".
- d. Reports of QA Audits performed by WV and DWPF of their contractors shall be reviewed by HQ-OGR in accordance with QIP 18.2, "Review of Project Submitted Audit Reports".
- e. Verifying the performance and adequacy of WV and DWPF design, technical and peer reviews on identified critical items and activities. These reviews by WV and DWPF shall be in compliance with appropriate HQ-OGR procedures.

### 5.3 Project Office Participation

5.3.1 The Project Offices may participate in the following oversight functions:

- a. Review and comment on WV and DWPF QA Plans and Implementing Procedures.
- b. Participate in QA audits of WV and DWPF and of their contractors.
- c. Review of QA Audit Reports of WV and DWPF on their contractors.
- d. Review of results of design, peer and technical reviews on applicable activities performed by WV and DWPF.

5.3.2 The Project Offices shall develop appropriate procedures for the performance of oversight functions.

### 5.4 NRC Involvement

HQ-OGR shall advise the NRC concerning the adequacy and implementation of the QA Programs at WV and DWPF. After review of the QA Programs, HQ-OGR shall summarize the results in a report to the NRC. The report shall contain the following information:

- a. An assessment of the QA Program;
- b. The basis used for the assessment;
- c. Results of QA Audits of WV and DWPF and their contractors;
- d. Planned oversight activities (review of changes, audits, etc.) to assure continued compliance with requirements.

# memorandum

DATE: JUL - 7 1986

REPLY TO: RW-24  
ATTN OF:

SUBJECT: HQ Review of Basalt Waste Isolation Division (BWID) QA Plan

TO: Lee Olson, BWID

We have completed our review of the Basalt Waste Isolation Division (BWID) QA Plan, Revision 1, which was transmitted to us by your letter of April 15, 1986. We find your plan acceptable with the exceptions indicated below and approve it for use.

We do not fully agree with the "Clarifications/Exceptions to the NRC Review Plan" set forth in Appendix A to the BWID QA Plan. We feel you have in some instances misunderstood the Review Plan requirements and that the clarification/exceptions are unneeded; in other cases we disagree with the exceptions you proposed to take. Our comments on Appendix A to you QA Plan are attached and these should be incorporated at the time of your next revision. In the interim we will be asking for NRC's comments on these issues.

We commend you for the thoroughness and organization of this QA Plan, particularly the Requirements Matrix in Table 2-2. This was very helpful to our review. One missing element, which I ask that you develop and issue as soon as possible, is a matrix clearly delineating the duties and responsibilities of the Project Office, Integrating contractor, and other project participants.

  
William J. Purcell  
Associate Director for  
Geologic Repositories

Attachment

Attachment

HQ Comments on Appendix A to BWID QA Plan

Item 4

The NRC Review Plan clearly requires an independent verification of conformance to established requirements and clearly requires that the QA organization be responsible for this independent verification. We concur with the NRC position. Thus the BWID proposed clarification (item 4 of Appendix A), as written, is rejected. We feel it is permissible to use DOE project technical staff and independent contractor staff to aid in the independent verification, as suggested by BWID, but that such personnel must do so under the purview and control of the QA organization. The QA organization's responsibility for the independent verification cannot be "shared" with other organizational elements.

Item 6

The BWID proposed clarification is acceptable only if all design activities are delegated to the contractor.

Item 11

We concur with the NRC position that corrective action to prevent recurrence of nonconformances always be taken and documented. The BWID proposal to evaluate some nonconformances is rejected.

Item 13

It is unclear what BWID is proposing. We feel it is essential that geotechnical samples be considered geotechnical records as specified in the NRC Review Plan.

Quality Assurance Manual Evaluation

Check List

Project Name BWIP  
 Manual Title BWIP QA Plan  
 Review Date 5/20/86

Revision No. 1  
 Revision Date 4/15/86

To be acceptable, the program must meet the applicable portions of ANSI/ASME, the NRC Review Plan, June 1984 and HQ-OGR QA Plan OGR/B-3.

Organization

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

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

1.1 E1  
 1.3 E  
 1.2  
 1.2 E1.5  
 1.1 E1  
 1.2.5  
 1.2.5  
 1.3 E  
 1.3  
 1.2

Organization (Continued)

7. Do organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines or responsibility?
8. Is the QA organization involved in the aspects of the high level waste repository program that affect safety and waste isolation? Are the extent of QA controls determined by QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2?
9. Has DOE described the QA responsibilities of each of the organizational elements noted on the organization charts?
10. Does the DOE identify a management position within its organization that retains overall authority and responsibility for the QA program? This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:
  - a) Is it at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule?
  - b) Has effective communication channels with other senior management positions been established?
  - c) Has responsibility for approval of QA Manual(s), changes thereto, and interpretations there of been established?
  - d) Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters?
11. Is verification of conformance to established requirements accomplished by individuals or groups within the QA organization? Certain exceptions for: design, item 3.7; inspections, item 10.2; and test data evaluation, item 11.3 are outlined in these sections
12. Do persons and organizations performing QA functions have direct access to management levels which will assure the ability to:
  - a) Identify quality problems?

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

Figure 1.3  
1.3.2  
2.2.1  
1.2  
1.3.2  
1.4  
1.3.2  
1.3.2  
1.2.3  
10.2  
1.2.7

Organization (Continued)

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

Yes	No	N/A
X		1.3.2
X		1.3.2
X		1.2.6
X		15.4
X		1.2.7
X		Policy Station
X		1.3.2
X		Figures 1.3
X		1.3.2
X		1.3.2 1.4

QA Program

1. Does the QA program include all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2? Are the items and activities covered by the QA program identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2? Are these terms defined as numerical performance objectives and standards? Does the rationale include systems analyses that are used to determine what specific items and activities are covered?
2. Does the QA program include a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program? Is guidance for the content of documentation of computer codes provided by NUREG-0856, "Final Technical Position on Documentation of Computer codes for High-Level Waste Management?"
3. Have provisions been established to assure that technical and quality assurance procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official?
4. Does the QA organization review and document concurrence with the quality-related procedures relative to QA requirements?
5. Does the QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls that are to be applied to specified items and activities? Does this effort involve applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR Part 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B?
6. Are existing or proposed QA procedures and detailed technical procedures identified and documented, reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met?

Yes	No	N/A
X		2.0
X		2.0
X		2.0
X		2.0 & 2.2.3
X		3.2
X		3.2
X		2.2.2 B1E Station
X		1.3.2 & 5.2
X		2.2.1
X		2.2.1: 2.2.3
X		2.2.3
X		2.2.2: Table 2

QA Program (Continued)

7. Is a description provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B?
- Do these measures include:
- a) Frequent contact with program status through reports, meetings, and/or audits?
- b) Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked?
8. Have indoctrination, training and qualification programs been established such that:
- a) Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures?
- b) Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed?
- c) For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance?
- d) Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement?  
Does a system of annual appraisal and evaluation satisfy this criterion?
- e) Are qualified personnel certified in accordance with applicable codes and standards?
9. Does the Plan describe the project office QA program and identify applicable lower tier documents, such as QA Administrative Procedures which, with the QA plan, comprise the project office overall QA program?
10. Does the Plan describe the process for the project office review and approval of the QA programs of their contractors?

Yes	No	N/A	
X			2.4 DP-2.1 Not Issue
X			2.4
X			2.4
X			2.3.2 DP-2.5 Issue QA Issue 2.3.2
X			2.3.4
X			2.3.2
X			2.3.2
X			2.3.3
X			2.2.2 Table 2
X			1.3

QA Program (Continued)

- 11. Does the Plan identify those elements of the overall field project office QA program that have been delegated to the contractors and describe the controls that are implemented by the project office to monitor the performance of the contractor in these delegated elements?
- 12. Does the Plan describe the program being implemented for the indoctrination and training of the project office personnel who perform activities affecting quality?  
Does the Plan identify the areas of inspection and testing that will require training, qualification and certification, and describe the method for accomplishing this?

Yes	No	N/A
X		
X		
X		

1.2

2.3

2.3

DP2.6  
Not  
Issues



Design Control (Continued)

- a) The supervisor is the only technically qualified individual?
- b) The need is individually documented and approved in advance with concurrence of the quality assurance manager?
- 10. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, is a peer review conducted? Do the procedures define the selection process for a peer group, and the process by which the peer group conducts its review? Is a peer review a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work? Have outside consultants been retained for needed expertise, where required?
- 11. Have the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation been identified in the procedures?
- 12. Are design changes, including field changes, subjected to the same design controls that were applicable to the original design? Is a configuration control system in place at the earliest practicable time? Are these changes analyzed to assure that change is required? Have associated changes to procedures and training been considered, and are changes communicated to all affected groups or individuals?
- 13. Does the plan describe the project office process for monitoring contractors' design controls and the extent of participation of the project office in design reviews?

Yes	No	N/A	
		X	Not Addressed
		X	Not Addressed
X			3.5
X			3.6
X			3.6
X			3.6
X			3.7
X			3.9

Procurement Document Control

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

Yes	No	N/A
X		4.1.c
X		4.1.c
X		4.1.c
X		4.1
		4.1.a
X		4.1
X		4.1
X		4.1.d
X		4.1.e
X		4.1, 4.2 4.3
X		4.2
X		4.1, 4.2 4.3

Instructions, Procedures and Drawings

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

Yes	No	N/A
X		5.1
X		5.1 & 5.2
X		5.5
X		3.2
X		6.0
X		6.0

Document Control

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

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

6.1 e  
6.2  
6.4  
6.4  
6.f  
6.1.e  
6.1.g  
6.1.i  
6.1.j  
6.2 e  
6.3

Control of Purchased Material, Equipment, and Services

1. Have organizational responsibilities been described for the control of purchased material, equipment, and services?
2. Do procedures governing procurement of items or services include appropriate QA organization participation?  
Do these procedures provide for:
  - a) Evaluation and selection of suppliers?
  - b) Verification of supplier's activities?
  - c) Receiving inspections?
3. Do the procedures governing procurement require that the organization providing materials, equipment, or services furnish the following records to the purchaser:
  - a) Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met?
  - b) Documentation identifying any procurement requirements that have not been met?
  - c) A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair"?
4. Is the procedure for review and acceptance of these documents described in the purchaser's QA program?
5. Are supplier's certificates of conformance periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented?
6. When developing quality assurance requirements for data collection, test equipment and other equipment, is consideration given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected)? Where no specific QA controls are found to be necessary, are special quality/performance verification requirements established and described in procedures governing the use of the equipment?

Yes	No	N/A
X		7.0
X		7.2
X		7.2
X		7.3.1
X		7.3.2
X		7.4
X		7.3.2
X		11.4

Identification and Control of Items

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

Yes	No	N/A	
X			8.0
X			7.0
X			8.0
X			8.0
X			8.0
X			18.0

Control of Special Processes

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

Yes	No	N/A
X		9.1
X		9.2
X		9.3
X		9.3

Inspection

1. Does the scope of the inspection program describe an effective inspection program and has it been implemented? Do program procedures provide criteria for determining when inspections are required or define how and when inspections are performed? Does the QA organization participate in these functions?
2. Are the organizational responsibilities for inspection described? Are individuals performing inspections part of the QA organization? For inspections requiring special expertise are other individuals used providing the independence of the inspection function is maintained?
3. Has a qualification program for inspectors been established and documented, and the qualifications and certifications of inspectors kept current?
4. Do inspection procedures, instructions, or checklists provide for the following:
  - a) Identification of characteristics and activities to be inspected?
  - b) A description of the method of inspection?
  - c) Identification of the individuals or groups responsible for performing the inspection operation?
  - d) Acceptance and rejection criteria?
  - e) Identification of required procedures, drawings, and specifications and revisions?
  - f) Recording inspector or data recorder and the results of the inspection operation?
  - g) Specifying necessary measuring and test equipment including accuracy requirements?
5. Do procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector?
6. Are inspection results documented and evaluated, and their acceptability determined by a responsible individual?

Yes	No	N/A
X		10.1
X		10.4
X		10.2
X		10.4
X		10.5
X		10.6

Test Control

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

Does the program's procedures provide criteria for:

  - a) Determining when a test is required or how and when testing activities are performed?
  - b) Requiring that the test program is conducted by trained or appropriately qualified personnel?
  - c) The QA organization to audit these functions?
2. Are test plans and procedures reviewed in accordance with the verification requirements in Design Control?
3. Are the potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well controlled, identified?
4. Do test procedures or instructions provide for the following:
  - a) That the requirements and acceptance limits are contained in applicable documents, including precision and accuracy?
  - b) Instructions for performing the test?
  - c) Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage?
  - d) Mandatory inspection hold points (as required)?
  - e) Acceptance and rejection criteria, including required levels of precision and accuracy?
  - f) Methods of data analysis?
  - g) Methods of documenting or recording test data and results?
  - h) Provisions for assuring test prerequisites have been met?
5. Are test results documented, evaluated, and their acceptability determined by a responsible individual or group as described in Design Control?

Yes	No	N/A
X		11.1
X		11.2
X		11.5
X		11.8
X		11.2
X		11.3
X		11.6.a
X		11.6.c
X		11.6.e
X		11.6
X		11.6.e
X		11.6.f
X		11.6.g
X		11.6.h.
X		11.7

Control of Measuring and Test Equipment

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

Yes	No	N/A
X		12.1
X		12.2
X		12.2
X		12.1

Handling Storage and Shipping

1. Are sampling, handling, preservation, storage packaging, and shipping requirements established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions?
2. Have procedures been established that describe sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity?

Yes	No	N/A
X		
X		

13.0

13.0

Inspection, Test and Operating Status

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

Yes	No	N/A
λ		
λ		

14.0

14.0

Nonconformances

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

Yes	No	N/A	
X			15.1
X			15.2
X			15.2
X			15.2
X			15.4 (DP 15.2)
X			15.4 (DP 2.12 N/T Issue)
X			15.4 (DP 15.1 DP 15.2)
X			15.4 (DP 15.2)
X			15.4 (DP 15.2)

Corrective Action

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

Yes	No	N/A
X		
X		
X		
X		
X		

16.0  
(DP-13)

16.0

16.1

16.1

16.0  
Approved  
A

Quality Assurance Records

1. Is the scope of the records program described in a written procedure? Do QA records include geotechnical samples and data; results of reviews; inspections; tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings; specifications, procurement documents, calibration procedures and reports; design review reports; peer review reports; nonconformance reports; and corrective action reports?
2. Are QA and other organizations identified and their responsibilities described for the definition and implementation of activities related to QA records?
3. Do inspection and test records contain the following (where applicable):
  - a) A description of the type of observation?
  - b) The date and results of the inspection or test?
  - c) Information related to conditions adverse to quality?
  - d) Inspector or data recorder identification?
  - e) Evidence as to the acceptability of the results?
  - f) Action taken to resolve any discrepancies noted?
4. Are records classified as Lifetime or Nonpermanent in accordance with written instructions?
5. Does the record and/or record indexing system provide sufficient information to permit identification between the record and the item or activity to which it applies?
6. Does the record indexing system include as a minimum:
  - a) Record retention time?
  - b) Location of the record in the system?
7. Does the record procedure include, as a minimum, the following:
  - a) A description of the storage facility?
  - b) The filing system to be used?

Yes	No	N/A
X		17.1
X		17.1
X		17.1
X		10.4, 11.7 11.7
		17.1 (DP 17.1)
X		17.1 (DP 17.1)
X		17.1 DP 17.1
X		17.1 & 17.3

Quality Assurance Records (Continued)

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

Yes	No	N/A
X		17.1 17.3
X		17.1

Audits

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

Yes	No	N/A	
X			18.1
X			18.1
X			18.3
X			18.3
X			18.2 17.5
X			18.7
X			18.6
X			18.13
X			18.13
X			18.13
X			18.4
X			18.4
X			18.4 DP18.2



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APR 2 1985 D.J. BROWN

*Subj File # 9.2*

APR 10 1985

William J. Purcell  
Associate Director  
for Geologic Repositories  
Office of Civilian Radioactive  
Waste Management, HQ

**BASALT WASTE ISOLATION DIVISION QUALITY ASSURANCE PLAN**

Revision 0 of the subject plan was submitted to DOE-OGR on March 28, 1985, and approved by your memorandum of May 15, 1985.

Transmitted for your review and approval is Revision 1 of the Quality Assurance Plan for the Basalt Waste Isolation Division. This revision incorporates the requirements of the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories" with the exceptions as noted in Appendix A of this Quality Assurance Plan.

If there are any questions, please call R. P. Saget of my staff, FTS 444-7250.

**ORIGINAL SIGNED BY**  
**O. L. OLSON**

O. L. Olson, Director  
Basalt Waste Isolation Division

MAC:JBS

Enclosure

cc: J. Morris, RW-22, w/o encl.  
D. C. Newton, RW-23, w/encl.  
E. Sulek, Weston, w/encl.