

Revision 1
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BASALT WASTE ISOLATION
PROJECT
QUALITY ASSURANCE PLAN

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U. S. Department of Energy
Richland Operations Office
Basalt Waste Isolation Division

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BASALT WASTE ISOLATION PROJECT
QUALITY ASSURANCE PLAN
(Revision 1)

TABLE OF CONTENTS

SUMMARY

1.0 ORGANIZATION

1.1 OVERALL ORGANIZATION

1.2 BASALT WASTE ISOLATION PROJECT ORGANIZATION RESPONSIBILITIES

- 1.2.1 DOE-RL Basalt Waste Isolation Division
- 1.2.2 Project
- 1.2.3 Integrating Contractor
- 1.2.4 Architect/Engineer, Construction Manager, and Other
Participants under Direct Contract to DOE for Project Work
- 1.2.5 Project Participants on Subcontract
- 1.2.6 Stop Work Authority
- 1.2.7 Resolution of Disputes Involving Quality

1.3 DOE-RL INTERNAL ORGANIZATION FOR BWI PROJECT QUALITY ASSURANCE

- 1.3.1 BWI Division
- 1.3.2 BWI Division Quality Systems Branch

1.4 QA INTERFACE WITH DOE HEADQUARTERS

1.5 INTERDIVISION INTERFACES WITHIN DOE-RL

2.0 QUALITY ASSURANCE PROGRAM

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES

2.2 BWI PROJECT QA PROGRAM STRUCTURE AND EXECUTION

- 2.2.1 QA Program Controls
- 2.2.2 Project QA Program Documentation
- 2.2.3 Graded Quality Assurance
 - 2.2.3.1 QL-1
 - 2.2.3.2 QL-2
 - 2.2.3.3 QL-3

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2.3 INDOCTRINATION, TRAINING AND QUALIFICATION

- 2.3.1 Indoctrination
- 2.3.2 Training
- 2.3.3 Qualification
- 2.3.4 Documentation and Records

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

3.0 DESIGN CONTROL

3.1 POLICY

3.2 COMPUTER SOFTWARE

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION

- 3.3.1 Design Control versus Test Control
- 3.3.2 Existing Data
- 3.3.3 Current Data
- 3.3.4 Published Studies

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

- 3.4.1 Design Verification by Formal Design Review
- 3.4.2 Design Verification by Testing
- 3.4.3 Design Verification by Alternate Calculations
- 3.4.4 Design Verification by Similarity

3.5 PEER REVIEW

3.6 DESIGN CHANGES

3.7 DESIGN INTERFACES

3.8 REVIEW PLAN

3.9 BWI DIVISION COGNIZANCE

- 3.9.1 DOE-RL BWI Division Technical Surveillance
- 3.9.2 DOE-RL BWI Division Participation in Peer Reviews
- 3.9.3 Document Review
- 3.9.4 Documented Review Meetings
- 3.9.5 BWI Division QS Audit and Surveillance of Design Controls
- 3.9.6 Readiness Reviews

4.0 PROCUREMENT DOCUMENT CONTROLS

4.1 PROJECT PARTICIPANTS

4.2 INTEGRATING CONTRACTOR ROLE

4.3 BWI DIVISION EVALUATION ROLE

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 ADMINISTRATIVE PROCEDURES

5.2 TECHNICAL PROCEDURES

5.3 INSTRUCTIONS

5.4 DRAWINGS

5.5 ACCEPTANCE CRITERIA

5.6 USE AND AVAILABILITY

6.0 DOCUMENT CONTROL

6.1 CONTROL ELEMENTS

6.2 BWI DIVISION DOCUMENT CONTROL

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL

6.3.1 BWI Division QA Documents

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

6.3.3 Other Participants' Documents

6.3.4 Technical Documents

6.4 REVIEW AND APPROVAL PROCESS

6.5 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 SUPPLIER QA PROGRAMS

7.2 SUPPLIER SELECTION AND EVALUATION

7.3 VERIFICATION

7.3.1 Verification of Work in Progress

7.3.2 Acceptance

7.4 SUPPLIER-FURNISHED DOCUMENTATION

7.5 BWI DIVISION CONTROL OF PURCHASED ITEMS AND SERVICES

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SPECIAL PROCESS - DEFINITION

9.2 IDENTIFICATION AND QUALIFICATION

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES

9.4 STANDARD "SPECIAL PROCESSES"

10.0 INSPECTION

10.1 INSPECTION ACTIVITIES

10.2 INSPECTOR QUALIFICATION

10.3 RESPONSIBILITIES

10.4 INSPECTION PROCEDURES

10.5 INSPECTION RESULTS

10.6 DOCUMENTATION AND RECORDS

11.0 TEST CONTROL

11.1 TEST ACTIVITIES

11.2 TEST PLANS AND PROCEDURES REVIEW

11.3 UNCERTAINTIES AND ERROR

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION

11.5 PERSONNEL QUALIFICATION

11.6 TEST PROCEDURE CONTENT

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE

11.8 DOE-RL BWI DIVISION RESPONSIBILITIES

- 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)
 - 12.1 CALIBRATION PROGRAM
 - 12.2 QA INVOLVEMENT
 - 12.3 DOE BWI DIVISION OVERVIEW
- 13.0 HANDLING, STORAGE AND SHIPPING OF ITEMS, MATERIALS AND SAMPLES
- 14.0 INSPECTION, TEST AND OPERATING STATUS
- 15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES
 - 15.1 IDENTIFICATION AND CONTROL
 - 15.2 EVALUATION AND DISPOSITION
 - 15.3 ACCOMPLISHMENT OF DISPOSITIONS
 - 15.4 TRENDS
- 16.0 CORRECTIVE ACTION
 - 16.1 CORRECTIVE ACTION PROGRAM
- 17.0 RECORDS MANAGEMENT
 - 17.1 RECORDS MANAGEMENT SYSTEM
 - 17.2 DOE-RL BWI DIVISION RECORDS
 - 17.3 ARCHIVAL FACILITY
- 18.0 AUDIT AND SURVEILLANCE
 - 18.1 AUDIT - GENERAL
 - 18.2 AUDIT PROGRAM CONTENT
 - 18.3 AUDIT SCHEDULING
 - 18.4 AUDITOR QUALIFICATION
 - 18.5 AUDIT PREPARATION
 - 18.6 AUDIT PERFORMANCE
 - 18.7 AUDIT REPORTS
 - 18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS
 - 18.9 SURVEILLANCE - GENERAL
 - 18.10 QUALIFICATION FOR SURVEILLANCE
 - 18.11 BWI DIVISION SURVEILLANCE
 - 18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS
 - 18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES
 - 18.13.1 By Audited or Surveilled Activity
 - 18.13.2 By Auditing or Surveilling Organization

Fig. 1-1 U.S. Department of Energy - Geologic Repository Projects

Fig. 1-2 DOE-RL Basalt Waste Isolation Division Organization

Fig. 1-3 BWI Project QA Program Management Responsibilities

Table 2-1 DOE-RL BWI Division QS Administrative Procedures

Table 2-2 Matrix: NRC Review Plan vs QAP

Appendix A Exceptions and Clarifications to Requirements Documents

POLICY STATEMENT

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

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

BASALT WASTE ISOLATION PROJECT
QUALITY ASSURANCE PLAN

1.0 ORGANIZATION

1.1 OVERALL ORGANIZATION

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

1.2 BASALT WASTE ISOLATION PROJECT ORGANIZATION RESPONSIBILITIES

1.2.1 DOE-RL Basalt Waste Isolation Division

The Manager, DOE-Richland Operations, has established the BWI Division as the DOE field project office for the BWI Project. The BWI Division establishes Project policy within the constraints of requirements and guidelines set forth in licensing regulations and overall DOE policy (see Section 2.1, QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES).

1.2.2 Project

The BWI Project is organized for quality assurance as shown in Figure 1-3. The BWI Division establishes QA policy, defines the overall Project QA program, approves the QA program descriptions and QA administrative procedures prepared by the Integrating Contractor the Construction Management Contractor and the Architect Engineer, and verifies effective program implementation. Roles of the other participants are described below.

1.2.3 Integrating Contractor

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

The Integrating Contractor's Project Management role includes responsibility for ensuring that BWI Division QS policy and direction is implemented effectively and consistently across the Project.

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

- a. Reviews and recommends DOE approval of QA program descriptions and QA administrative procedures prepared by the Construction Management Contractor and the Architect/Engineer,
- b. Approves the QA program descriptions and QA administrative procedures prepared by (1) Project participants under direct contract to DOE for their Project work, other than the Architect/Engineer and the Construction Manager, and (2) all Project participants under direct contract to the Integrating Contractor for their Project work,
- c. Establishes Project-wide systems and/or methods for implementing QA program elements for which such uniformity produces important cost and/or control benefits,
- d. Verifies effective implementation of the QA program by means of audit, surveillance, trending and management assessment of QA activities of (1) the Architect/Engineer, (2) the Construction Manager, (3) the other Project participants under direct contract to DOE for their Project work, and (4) all Project participants under direct contract to the Integrating Contractor for their Project work, and
- e. Ensures that applicable elements of his (the Integrating Contractor's) QA program are effectively implemented for direct work performed in-house.

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

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

- a. Developing and implementing a QA program that (1) meets all applicable requirements identified in the Basalt Quality Assurance Requirements Document (BQARD), (2) is consistent with the Project QA program described in this QAP, and (3) reflects any Project-wide QA systems or methods specified by the Integrating Contractor,

- b. Approving the QA Plans and QA administrative procedures of participants doing Project work under contract to him, and
- c. Verifying effective implementation his own QA program and of the QA programs of participants doing Project work under direct contract to him.

1.2.5 Project Participants on Subcontract

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

1.2.6 Stop Work Authority

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

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

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

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

The Director, DOE-RL BWI Division is to be notified immediately of any STOP WORK on the Project. Notification is expected to include the intended criteria for resumption of work. The Director, BWI Division, reserves the authority to require that work be resumed only upon his approval.

Similarly, the next higher authority in the Project management hierarchy is to be notified of any STOP WORK issued by, or upon, a lower tier Project participant, and has the authority to require that work be resumed only with his approval.

1.2.7 Resolution of Disputes Involving Quality

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

1.3 DOE-RL INTERNAL ORGANIZATION FOR BWI PROJECT QUALITY ASSURANCE

1.3.1 BWI Division

The Director, BWI Division, reporting to the Manager, DOE-RL, through the Assistant Manager, Office of Commercial Nuclear Waste, is responsible for:

- a. Approving the Project QA Plan and procedures necessary to its implementation,
- b. Effective implementation of the QA Plan,
- c. Issuing formal program direction to Project participants,
- d. Approving the QA program descriptions and QA administrative procedures prepared by the Integrating Contractor, the Construction Management Contractor and the Architect/Engineer.
- e. Evaluating technical effectiveness of QA program controls by participants prior to initiation of work.

1.3.2 BWI Quality Systems (QS) Branch

The Chief, BWI Division QS Branch, is at the same authority level in the Project as the Chiefs of the BWI Division's technical branches, who exercise the highest direct line authority in the Project, reporting to the Director of the Division. The Chief, BWI Division QS, has no other responsibilities that prevent his devoting his full attention to QA matters. He is responsible for:

- a. Preparing and maintaining the Project QA Plan and the BWI Division procedures necessary to its implementation,
- b. Establishing the requirements/for BWI participants' QA programs,
- c. Reviewing and recommending BWI Division Director approval of the QA Plan and implementing QA administrative procedures prepared by the Integrating Contractor,
- d. Evaluating the Integrating Contractor's recommendations for approval of the QA program descriptions and QA administrative procedures prepared by the Construction Management Contractor and the Architect/Engineer, and recommending BWI Division Director approval,
- e. Exercising Project oversight of overall QA program implementation,
- f. Verifying effective implementation of the Project QA Plan by BWI Division technical branches, and
- g. Providing direct QA support within the Division.

1.4 QA INTERFACE WITH DOE HEADQUARTERS

Quality assurance direction and policy guidance from DOE-HQ reaches DOE-RL through the Office of Geologic Repositories (OGR), as specified in the OGR QA Plan, the requirements documents it cites, and directives issued from that office.

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

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

1.5 INTERDIVISION INTERFACES WITHIN DOE-RL

The primary interfaces between BWI Division and other DOE-RL organizations in establishment and implementation of the Project QA program involve BWI Division QS, the Procurement Division, the Personnel Division, and the Quality Assurance Branch of the ES&H Division, as follows:

a. Procurement Division (PRO)

All direct procurement for the DOE BWI Division is accomplished by PRO. The BWI Division and PRO interface at the following points in the procurement process:

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

The BWI Division Branch that initiated the procurement and BWI Division QS interface with PRO on technical and quality assurance matters, respectively (refer to Sections 4.0 and 7.0 of this QAP for details).

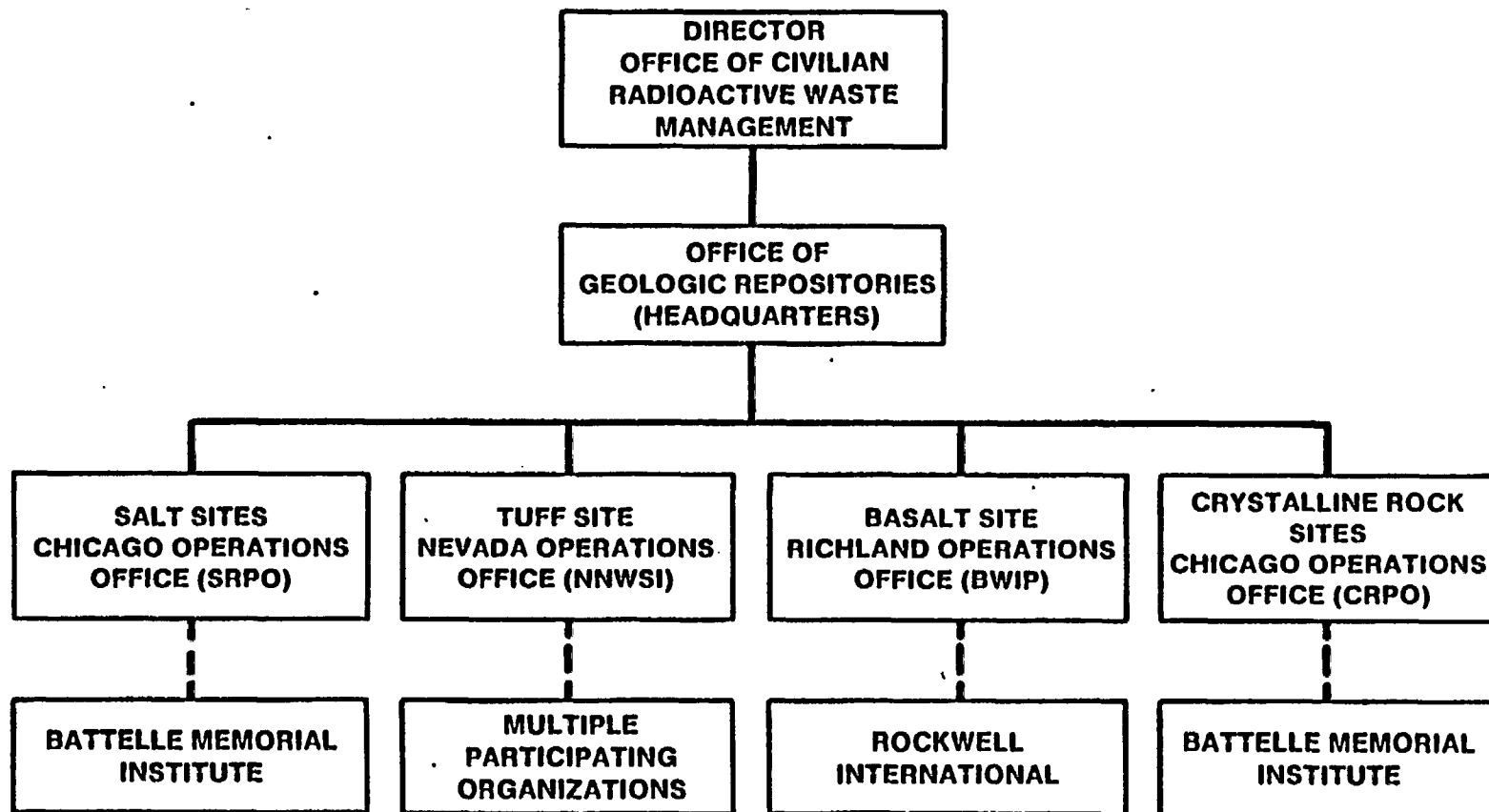
b. Quality Assurance Branch, ES&H Division

The QA Branch of ES&H provides or arranges for independent verification of the effectiveness of QA functions performed by BWI Division QS.

c. Personnel Division

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

FIGURE 1-1: GEOLOGIC REPOSITORY PROGRAM



LEGEND:

———— PROGRAM/PROJECT MANAGEMENT
RESPONSIBILITY

- - - - - MAJOR CONTRACTOR SUPPORT

FIGURE 1-2: BWI DIVISION ORGANIZATION

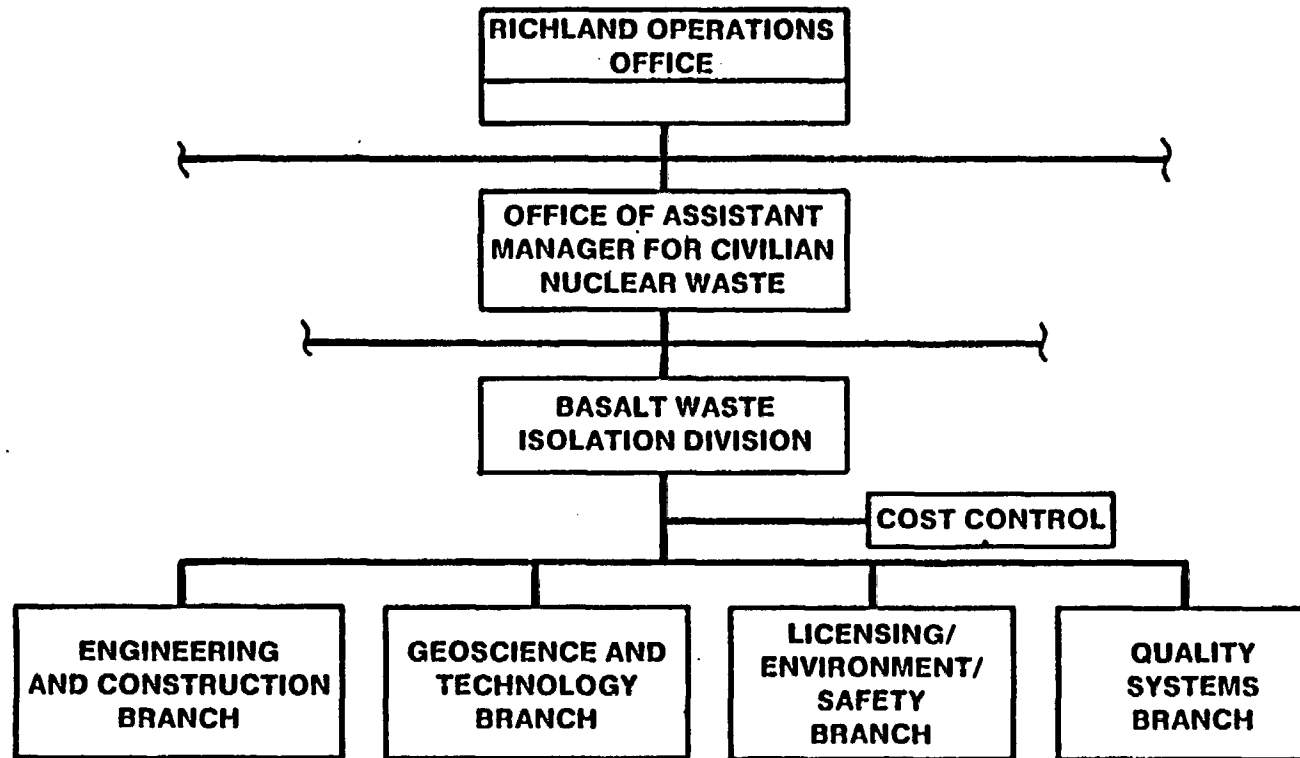
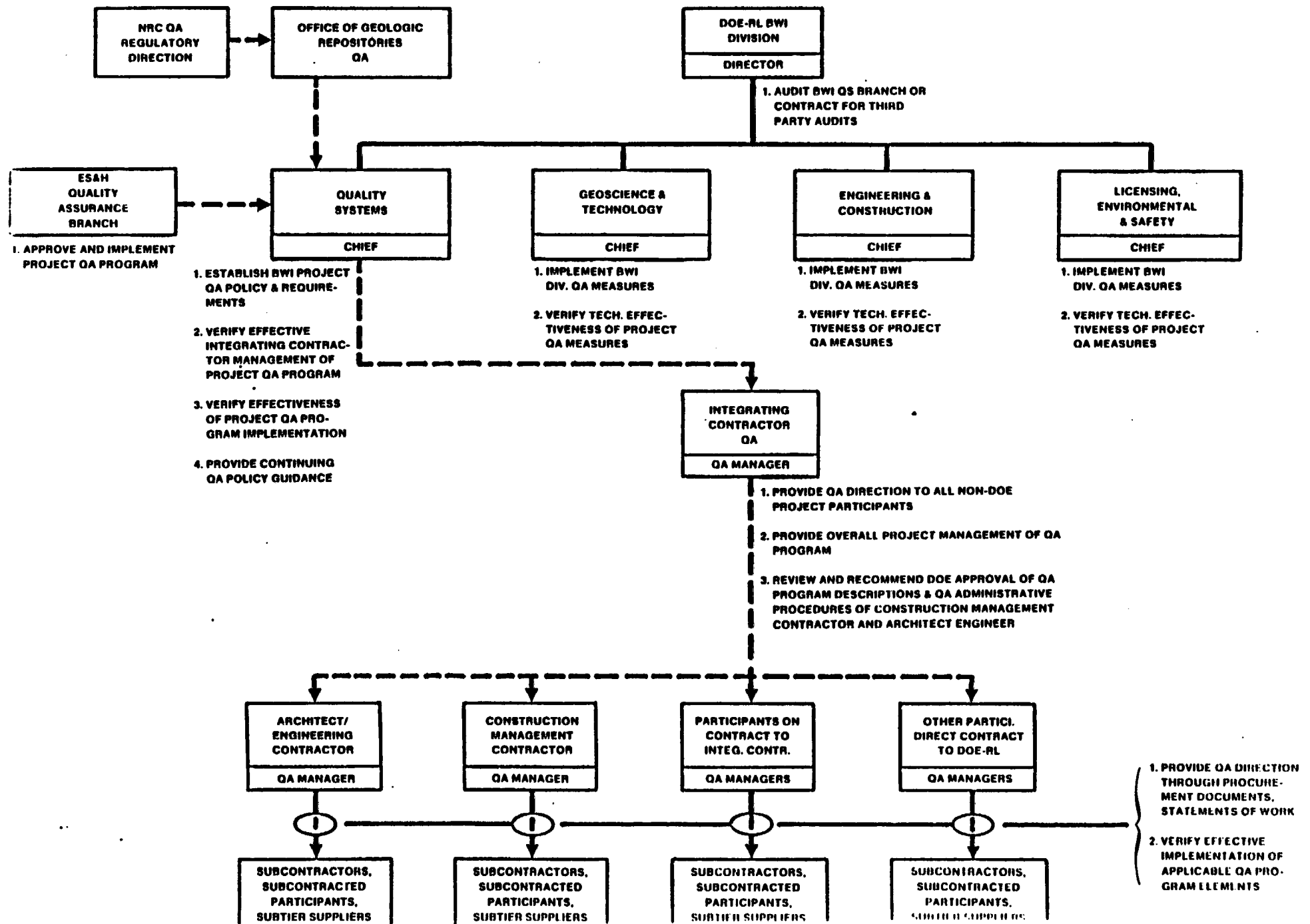


FIGURE 1-3: BWI PROJECT QA PROGRAM MANAGEMENT RESPONSIBILITIES



2.0 QUALITY ASSURANCE PROGRAM

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

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

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES

- a. DOE Order 5700.6A, Quality Assurance
- b. DOE/RW-0032, Quality Assurance Management Policies and Requirements
- c. 10CFR60, Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures
- d. 10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- e. NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories, June 1984
- f. OGR/B-3, Quality Assurance Plan for Siting and site characterization of High-Level Radioactive Waste Repositories, and supplements
- g. ANSI/ASME NQA-1-1983, Quality Assurance Program Requirements for Nuclear Facilities, and supplements
- h. Basalt Waste Isolation Quality Assurance Requirements Document, January 1986

The Project QA Program described in this QA Plan is intended to comply with applicable provisions of these documents with the exceptions/clarifications noted in Appendix A to this QAP.

2.2 BWI PROJECT QA PROGRAM STRUCTURE AND EXECUTION

2.2.1 QA Program Controls

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

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

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

2.2.2 Project QA Program Documentation

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

The DOE BWI Division, as project office, has issued a set of Project-wide Management Guides (PMGs) that specify how certain management activities are to be conducted throughout the Project and a set of QA administrative procedures, Division Procedures (DP's), providing direction and guidance for in-house management and quality related activities. Table 2-1 lists the BWI Division's QA administrative procedures. Note that the table includes two PMGs, because they provide direction for activities within the scope of the Project QA program.

Each participant on the Project is required to prepare a top-level description of his internal QA program and the necessary implementing procedures for his Project-related activities. Each Project participant's QA program description is expected to include a list of his implementing QA administrative procedures. Section 8.6 of the Site Characterization Plan will identify all technical procedures applied to Project activities within the scope of the Project QA program. Responsibility for approval of QA program descriptions and QA administrative procedures prepared by the Integrating Contractor, Construction Manager and Architect/Engineer is addressed in Sections 1.2.4 and 1.3. The Integrating Contractor, Construction Manager and Architect/Engineer are responsible for review and approval of QA program descriptions and QA administrative procedures prepared by their subcontractors. The Integrating Contractor is also responsible for review and approval of the QA program descriptions and QA administrative procedures prepared by direct-DOE-funded participants other than the Construction Management Contractor and the Architect/Engineer.

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

2.2.3 Graded Quality Assurance

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

Quality Level 1 (QL-1) will be based on the 18 basic requirements of NQA-1, all NQA-1 supplements (where NQA-1 does not relax or conflict with applicable regulatory requirements), nonmandatory Appendix 2A-1, the 18 criteria of Appendix B to 10CFR50, and the NRC Review Plan.

Quality Level 2 (QL-2) will be based on the 18 basic requirements of NQA-1 and NQA-1 supplements S-1, 2S-3, 3S-1, 7S-1, 10S-1, 17S-1 and 18S-1. The other supplements to NQA-1 were judged to be unnecessary for Quality Level 2 because they contain additional detail that is unneeded for the level of quality desired (however, see individual sections of this QAP for portions of other NQA-1 supplements that may be applied to QL-2 for the BWI Project, in order to avoid hazards inherent in operating under two different systems).

Quality Level 3 (QL-3) will require the use of good work practice and will meet appropriate quality program requirements as determined by the projects on a case by case basis.

Deviations from requirements specified for QL-2 are permitted where written justification is provided and approved by the individual or organization that makes the initial determination of quality level. Deviations include deletion of a requirement, addition of a requirement, or any modification to a requirement.

2.2.3.1 QL-1

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

All Q-List Items/Activities.

All items/activities that have a reasonable potential of later needing to be added to the Q-List. (Note: Although QA measures applied to QL-1 items that are not on the Q-List are equivalent to those applied to Q-listed items, upgrading would also require determination that applicable design requirements had been or could retroactively be met.)

Any items/activities that are considered by the project to have a potential programmatic impact of \$1000K or a 6 month schedule delay.

Activities that are important to waste retrieval.

Worker safety features whose failure or malfunction could result in a fatality or whole body exposure to radiation in excess of 0.5 REM.

2.2.3.2 QL-2

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

Worker safety (Radiological and Industrial).

Cost impacts of more than \$500K but less than \$1000K or schedular delays of more than 3 months but less than 6 months.

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

2.2.3.3 QL-3

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

2.3 INDOCTRINATION, TRAINING AND QUALIFICATION

2.3.1 Indoctrination

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

2.3.2 Training

Within DOE's BWI Division, cognizant Branch Chiefs are responsible for determining training needs of their personnel. The DOE BWI Division Training Coordinator prepares and maintains a BWI Division training plan to meet those needs in a timely manner. The BWI Division QS Chief identifies QA-oriented training needed by non-QA personnel for performance of surveillance activities involving evaluation of contractor control effectiveness. BWI Division training and qualification are addressed by Division procedures DP 2.5 PERSONNEL TRAINING, and DP 2.6, PERSONNEL QUALIFICATION AND CERTIFICATION.

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

2.3.3 Qualification

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

Qualification in the "designated skills" indicated above is established by education and/or training, evaluation of credentials, and demonstration of the specific capabilities in question. Such special skills qualification is certified by specifically authorized individuals, and certifications become part of the record that substantiates work performed by those personnel.

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

2.3.4 Documentation and Records

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

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

At intervals determined by the Director, BWI Division, but not exceeding one year, a management team assesses effectiveness of the overall Project QA program. The structure of the assessment team and mechanics of the assessment process are addressed by an approved procedure. (Ref. BWI Division procedure DP 2.1, QUALITY ASSURANCE PROGRAM ASSESSMENT AND REPORTS.)

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

TABLE 2-1

DOE-RL BWI DIVISION QS ADMINISTRATIVE PROCEDURES

DP	1.1	ORGANIZATION
DP	1.7	COMMITMENT CONTROL
DP	1.8	CORRESPONDENCE CONTROL
DP	1.11	STOP WORK
DP	2.1	QA PROGRAM ASSESSMENT AND REPORTS
DP	2.2	WORK PROGRESS AND DESIGN REVIEWS
DP	2.5	PERSONNEL TRAINING
DP	2.6	PERSONNEL QUALIFICATION
DP	2.7	APPEALS ON QUALITY CONCERNS
DP	2.8	CONTROL OF LICENSING DOCUMENTS
DP	2.10	REPORTING OF SIGNIFICANT DEFICIENCIES
DP	3.1	PROJECT REVIEWS
DP	3.3	PEER REVIEW
DP	3.4	READINESS REVIEWS
DP	4.1	PREPARATION AND CONTROL OF PROCUREMENT DOCUMENTS
DP	4.2	CONTRACTOR INITIATED PROCUREMENTS
DP	5.1	RL-BWI PROCEDURE DEVELOPMENT
DP	6.1	PREPARATION AND RELEASE OF BWID DOCUMENTS
DP	6.2	CONTROLLED DOCUMENTS ISSUED TO THE BWI DIVISION AND STAFF
DP	6.3	REVIEW OF DOCUMENTS GENERATED EXTERNAL TO BWI
DP	7.1	SUPPLIER EVALUATION, SELECTION AND VERIFICATION
DP	7.2	SUPPLIER FURNISHED RECORDS
DP	15.1	PROCESSING SUPPLIER NCRS AND UNUSUAL OCCURRENCES
DP	15.2	TREND ANALYSIS
DP	16.1	CORRECTIVE ACTION REPORTING SYSTEM
DP	17.1	QUALITY RECORDS
DP	18.1	AUDIT AND SURVEILLANCE PLANNING
DP	18.2	INTERNAL AUDITS
DP	18.3	EXTERNAL AUDITS
DP	18.4	AUDITOR QUALIFICATION
DP	18.5	SURVEILLANCE OF PROJECT ACTIVITIES
PMG	19.10	ACQUISITION/PROCUREMENT PROCESS OVERVIEW
PMG	19.13	CONTROL OF PROPRIETARY INFORMATION

TABLE 2-2
REQUIREMENTS MATRIX

<u>NQA-1-1983</u>	<u>NRC Review Plan</u>	<u>QAP</u>
1 Basic		1.0
1S-1, Sect. 2.1, 2.2		1.2.2
1S-1, Sect. 2.3		1.2.6
	1.1, Sent. 1	1.3, 1.3.2, 1.3.3, Append A
	1.1, Sent. 2	1.3.1, 1.3.2, 2.2.1, Fig. 1-1, 1-2, 1-3
	1.2	1.2
1S-1, Sect. 3.1	1.3	1.2, 1.3.1, 1.3.2
1S-1, Sect. 3.2		1.2
	1.4, Sent. 1, 2	1.2.2, 1.3.2, 18.1
	1.4, Sent. 3	2.2.1, 18.0
	1.5	1.3.1, 3.6.3
	1.6	1.2, Fig. 1-3
	1.8	1.2.4, 1.2.5, 2.2.1
	1.9	1.2
	1.10	1.2.3.1, 1.3, 1.3.2, Append A
	1.11	1.2.3, 1.2.4, 10.2, 10.3
	1.12a, b, c	1.3.2
	1.12d	1.2.6
	1.13	1.2.7
	1.14	QAP Policy Statement
	1.15	1.3.1, 1.3.2
2 Basic		2.0

<u>NQA-1-1983</u>	<u>NRC Review Plan</u>	<u>QAP</u>
	2.1	2.0
	2.2	3.2
	2.3	2.2.2
	2.4	5.2
	2.5	2.0
	2.6	2.2.2
	2.7	2.5
	2.8a	2.3.1
	2.8b	2.3.3
	2.8c	2.3.4
	2.8d	2.3.2
	2.8e	2.3.4
2S-1, 2S-2		2.3.3, 10.2
2S-3		2.3.3, 18.4
3 Basic		3.0
3S-1, Sect. 2		3.2, 3.3, 3.4, 3.5
3S-1, Sect. 3		3.2, 3.3, 3.4
	3.1	3.1
	3.2	Site Characterization Plan, Sect. 8.6)
	3.3	3.3, 3.4
	3.4	3.1
3S-1, Sect. 6	3.5	3.7
	3.6	3.41
3S-1, Sect. 4	3.7	3.4
	3.8	3.5
	3.9	3.3.2, 3.4, 3.5

<u>NQA-1-1983</u>	<u>NRC Review Plan</u>	<u>QAP</u>
3S-1, Sect. 5	3.10	3.6
3S-1, Sect. 7		17.1
4 Basic		4.0
4S-1, Sect. 2		4.1
4S-1, Sect. 3	4.1	4.1e
	4.2	4.1
5 Basic		5.0
	5.1	5.1, 5.2
	5.2	5.5
6 Basic		6.0
6S-1		6.1
	6.1	6.1
	6.2	6.1, 6.4
	6.3	5.6, 6.1e
	6.4	6.1g
	6.5	6.1i
	6.6	6.1j
7 Basic		7.0
	7.1	7.0
7S-1, Sect. 2		7.1
7S-1, Sect. 3	7.2	7.2, 7.3.1, 7.3.2
7S-1, Sect. 4		7.0
7S-1, Sect 5		7.2
7S-1, Sect. 6, 7, 9	7.3	7.4
7S-1, Sect. 8	7.4	7.3.2
	7.5	11.4

<u>NQA-1-1983</u>	<u>NRC Review Plan</u>	<u>OAP</u>
7S-1, Sect. 10		2.2.3
8 Basic		8.0
	8.1	8.0
	8.2	8.0
	8.3	8.0
8S-1		8.0
	8.4	8.0
9 Basic		9.0
9S-1, Sect. 2, 3	9.1	9.1, 9.2
	9.2	9.2
	9.3	9.2
	9.4	9.3
	9.5	9.3
10 Basic		10.0
	10.1	10.1
10S-1, Sect. 2	10.2	10.2, 10.3
	10.3	10.2
10S-1, Sect. 3, 4	10.4	10.4
10S-1, Sect. 5	10.5	10.4
	10.6	10.5, 10.6
10S-1, Sect. 6		10.1, 10.5
11 Basic		11.0
11S-1, Sect. 2		11.2
	11.1, Sent. 1	11.1
	11.1, Sent. 2	11.2, 11.5
	11.1, Sent. 3	11.5

<u>NQA-1-1983</u>	<u>NRC Review Plan</u>	<u>QAP</u>
	11.2	11.2
	11.3	11.3
11S-1, Sect. 3	11.4	11.6
11S-1, Sect. 4, 5	11.5	11.7
12 Basic		12.0
	12.1	12.1
	12.2	12.2
12S-1		12.1
	12.3	12.1, 12.2
	12.4	12.1
	12.5	12.1
	12.6	12.1
	12.7	12.1
13 Basic, 13S-1		13.0
	13.1	13.0
	13.2	13.0
14 Basic		14.0
	14.1	14.0
15 Basic		15.0
	15.1	15.1, 15.2, 15.3
15S-1, Sect. 2, 3	15.2	15.1, 15.2, 15.3
15S-1, Sect 4	15.3	15.1, 15.2, 15.3
	15.4	15.4
16. Basic		16.0
	16.1	16.1
	16.2	16.1, Append. A

<u>NQA-1-1983</u>	<u>NRC Review Plan</u>	<u>QAP</u>
	16.3	16.1
	16.4	16.1
17 Basic		17.0
17S-1, Sect. 2, 3, 5		17.1
17S-1, Sect. 4		17.3
	17.1	17.1
	17.2	17.1
	17.3	10.6, 11.7
18 Basic		18.0
	18.1	18.1
18S-1, Sect. 2	18.2	18.3
18S-1, Sect. 3	18.3	18.2, 18.5
18S-1, Sect. 5	18.4	18.6, 18.7
18S-1, Sect. 4	18.5	18.4, 18.5, 18.6
18S-1, Sect. 6, 7	18.6	18.3, 18.13
18S-1, Sect. 7	18.7	18.13
	18.8	18.13

3.0 DESIGN CONTROL

3.1 POLICY

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

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

3.2 COMPUTER SOFTWARE

Computer software for technical computer codes important to safety or waste isolation is to be controlled by participants' procedures consistent with guidelines established in NUREG 0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management and Supplement 6, Computer Software, to the OGR QA plan as modified by exceptions and clarifications that will be included in Appendix A to this plan when approved. These controls will be applied throughout all phases of the project.

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION

3.3.1 Design Control versus Test Control

The processes of identifying data needs, planning data acquisition work and sequence, and experiment design (i.e., preparation of the necessary "test procedures") for the basalt waste isolation project are associated with (a) establishing how much of the "as built design" of the site must be determined, (b) how and in what sequence the "as-built" characterization is to be done, and (c) what processes of data acquisition best assure the validity of such exploration and measurement. Therefore, the activities of data acquisition (test) planning and data acquisition (text) procedure generation require the same generic controls that more conventional downstream design activities require.

While preparation, review and approval of data acquisition planning and procedure generation are controlled under the design control provisions of the QA program, actual performance of the experiments, measurement, collection, etc., for acquiring data is controlled under applicable provisions of Section 11.0, TEST CONTROL.

3.3.2 Existing Data

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

Criteria for determining data qualification levels will be developed by the Project, with due regard to relevant NRC and/or OGR guidance.

3.3.3 Current Data

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

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

3.3.4 Published Studies

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

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

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

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

3.4.1 Design Verification by Formal Design Review

Formal design review consists of critical appraisal of the design by independent, competent personnel having expertise in the disciplines or practices upon which the design is based and/or in those related fields that may affect ability of the design to perform its intended function. Individuals participating in design verification are expected to verify that the design adequately addresses limitations and effects associated with factors related to their fields of expertise.

3.4.2 Design Verification by Testing

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

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

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

3.4.3 Design Verification by Alternate Calculations

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

3.4.4 Design Verification by Similarity

Where all or portions of a design is/are verified by similarity to prior designs, verification shall establish that (1) conditions under which the prior design operated were the same as, or more severe than, relevant conditions in which the present design will operate, (2) the prior design operated or was tested under the most adverse combination of design conditions applicable to the present design, and (3) the designer has determined and appropriately accounted for any deficiencies discovered during operation of the prior design.

3.5 PEER REVIEW

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

3.6 DESIGN CHANGES

Design changes require technical controls commensurate with controls exercised on the original design, including review by the design organization who was responsible for the original design (unless otherwise specified by DOE). In addition, design changes that might entail significant impact to Project concept, cost, schedules or safety apportionments must be submitted for Project Change Control Board approval.

3.7 DESIGN INTERFACES

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

3.8 REVIEW PLAN

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

3.9 BWI DIVISION COGNIZANCE

3.9.1 DOE-RL BWI Division Technical Surveillance

BWI Division personnel exercise regular and frequent surveillance within their areas of expertise over technical work being performed by Project participants (ref. BWI Division procedure DP 18.5, SURVEILLANCE OF PROJECT ACTIVITIES). Technical surveillance includes:

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

3.9.2 DOE-RL BWI Division Participation in Peer Reviews

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

3.9.3 Document Review

BWI Division technical personnel review technical documents (such as test reports, analyses, reports of study results, etc.) for appropriateness of approach, reasonableness of conclusions, clarity and evidence of necessary supporting inputs (ref. BWI Division procedure DP 6.3, REVIEW AND APPROVAL OF DOCUMENTS GENERATED EXTERNAL TO BWI). Such reviews and subsequent approval are to be accomplished prior to initiation of affected follow-on work unless provisional go-ahead is authorized explicitly on an exception basis.

3.9.4 Documented Review Meetings

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

3.9.5 BWI Division QS Audit and Surveillance of Design Controls

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

3.9.6 Readiness Reviews

Project readiness reviews are conducted in accordance with program management guide PMG 19.11, READINESS REVIEW.

4.0 PROCUREMENT DOCUMENT CONTROLS

4.1 PROJECT PARTICIPANTS

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

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

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

4.2 INTEGRATING CONTRACTOR ROLE

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

4.3 BWI DIVISION EVALUATION ROLE

BWI Division QS will review selected procurement document packages prepared by Project participants, including those prepared by the Integrating Contractor, during QA audits and surveillances of Project activities.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Project activities are prescribed by, and performed in accordance with, written instructions, procedures and/or drawings appropriate to the work. Such procedures, instructions and drawings are to be reviewed for accuracy and adequacy by personnel who are competent in the subject matter addressed and who meet the independence criteria specified in Section 3.4 of this QAP.

5.1 ADMINISTRATIVE PROCEDURES

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

Each participating entity (i.e., government agency, public institution or civilian contractor) in the Project is responsible for QA administrative procedures necessary to implement its approved QA Plan (QA program description).

5.2 TECHNICAL PROCEDURES

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

5.3 INSTRUCTIONS

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

5.4 DRAWINGS

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

5.5 ACCEPTANCE CRITERIA

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

5.6 USE AND AVAILABILITY

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

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

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

6.0 DOCUMENT CONTROL

6.1 CONTROL ELEMENTS

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

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

6.2 BWI DIVISION DOCUMENT CONTROL

Document control within the BWI Division is exercised in accordance with Division Procedures DP 6.1, PREPARATION AND RELEASE OF BWID DOCUMENTS, and DP 6.2, CONTROLLED DOCUMENTS ISSUED TO BWI DIVISION AND STAFF.

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL

6.3.1 BWI Division QA Documents

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

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

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

6.3.3 Other Participants' Documents

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

6.3.4 Technical Documents

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

6.4 REVIEW AND APPROVAL PROCESS

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

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

6.5 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS

Controlled documents reaching the BWI Division, or sent out of the Division, are controlled in accordance with Division Procedures DP 1.8, CORRESPONDENCE CONTROL, DP 6.1, PREPARATION AND RELEASE OF BWI DIVISION DOCUMENTS, and DP 6.2, CONTROLLED DOCUMENTS ISSUED TO BWI DIVISION AND STAFF. Controls include logging, updating of distribution lists and document indices, and a formal receipt acknowledgment system.

Project participants are required to establish and implement similar administrative procedures to control the movement of documents between themselves and other participants.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

BWI Project participants are required to institute measures to ensure that purchased items and services conform to the requirements specified in applicable procurement documents. Controls include evaluation and selection of suppliers with a demonstrated capability of providing the required item(s) or service(s), verification that applicable controls are exercised during item processing or performance of the contracted services, and verification that completed items or services conform to procurement acceptance criteria. The cognizant QA organization is required to ensure that these controls are adequate and appropriate to the procurement.

For precautions during procurement of instrumentation or equipment that is to be used for data collection, where failure or malfunction would not be readily detectable either during data collection or evaluation, see Section 11.4.

7.1 SUPPLIER QA PROGRAMS

Project participants are required to determine with the help or leadership of the cognizant QA organization, which elements of the project QA program are necessary to ensure that purchased materials, items or services will meet technical needs and that they are supported by credible documentation. Suppliers may be required to implement QA programs embodying those control elements, or the participant responsible for the procurement may elect to provide the QA or procure it separately. Suppliers may be required to prepare formal QA program descriptions for approval by the purchaser, or the purchaser may provide a questionnaire covering the required controls, so that an acceptable, certified response to the questionnaire will constitute the necessary program description.

7.2 SUPPLIER SELECTION AND EVALUATION

It is recognized that some of the research and analysis required for site characterization requires the services of specialists, or of institutions or agencies whose work does not ordinarily involve formal QA activities. In these instances, selection is based on technical capability, and establishment of QA measures appropriate to the services to be performed is required at the outset of their work.

Except where technical requirements dictate selection on the basis of unique capabilities, as indicated above, procurement of BWI Project items or services within the scope of the Project QA program will be made from suppliers who are pre-approved by the responsible QA organization in the Project.

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

Where DOE-RL BWI Division contracts directly (via DOE-RL Procurement Division) for items or services within the scope of the BWI Project QA program, supplier selection and evaluation is accomplished in accordance with BWI Division procedure DP-7.1, SUPPLIER EVALUATION; SELECTION AND VERIFICATION.

7.3 VERIFICATION

7.3.1 Verification of Work in Progress

The extent and nature of verification activities to be accomplished for procured items or services within the scope of the BWI Project QA program will be planned at the outset. Such verification is expected to include mandatory hold points for inspection or witnessing, where appropriate, and surveillance and/or audit. In-progress inspection, witnessing and surveillance is expected to include review of the status of required documentation.

7.3.2 Acceptance

Acceptance of completed items or services is accomplished as follows:

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

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

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

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

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

7.4 SUPPLIER-FURNISHED DOCUMENTATION

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

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

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

7.5 BWI DIVISION CONTROL OF PURCHASED ITEMS AND SERVICES

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

DOE-RL's BWI Division is responsible for administering that entire procurement network, for specifying the necessary QA program, and for ensuring that delivered items, materials and services comply with applicable quality assurance requirements. Compliance with applicable provisions of the QA program described in this QA Plan is a condition of all BWI Project procurement contracts. Direct procurements within the scope of the BWI Project QA program initiated by the BWI Division are managed by BWI Division under Division procedures DP 4.1, PREPARATION AND CONTROL OF PROCUREMENT DOCUMENTS DP 7.1, SUPPLIER EVALUATION, SELECTION AND VERIFICATION, and DP 7.2, SUPPLIER FURNISHED RECORDS. Nonconforming items or services the Integrating Contractor proposes to disposition "accept as is" or "repair" (or to disposition in a way that fits the definition of either of those two dispositions) are reviewed and approved or disapproved by BWI Division personnel in accordance with Division procedure DP 15.1, PROCESSING CONTRACTOR NCRs AND UNUSUAL OCCURRENCES.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES

Items, materials and samples are identified and controlled on the BWI Project in order to ensure (a) that the history of items and materials is fully known from the time of receipt to the point of use, and (b) that samples are traceable from the sampling point to the point of consumption or long-term storage. (Note: Continued traceability of samples in storage is a part of records management.)

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

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SPECIAL PROCESS - DEFINITION

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

9.2 IDENTIFICATION AND QUALIFICATION

Special processes used on the BWI Project are explicitly identified in appropriate QA program documents (QAP or QA-related administrative procedures), and it is expected that each participant will develop and maintain a list of those processes that are considered to fall within the scope defined by Section 9.1, above, for incorporation in the Site Characterization Plan. The procedures that specify how individual special processes are to be performed are qualified by demonstration that, when performed as specified, the process yields required results. Special process personnel are qualified by training (where appropriate) and demonstration that they can perform the process(es) with the desired results. Where equipment affects the outcome of a special process, the equipment is similarly qualified. The responsible participant's QA Plan describes the role the QA organization plays in qualification of special process procedures, personnel and/or equipment.

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES

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

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

9.4 STANDARD "SPECIAL PROCESSES"

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

10.0 INSPECTION

10.1 INSPECTION ACTIVITIES

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

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

Acceptance of results of technical studies, design activities, etc., is not an "inspection" activity as discussed here. See Section 7 for acceptance of such procured services.

10.2 INSPECTOR QUALIFICATION

Formal inspection is performed either by inspectors reporting to a participant's QA organization or, where appropriate, by personnel possessing particular expertise. QA personnel performing inspection functions will be qualified in accordance with ANSI/ASME NQA-1-1983, Appendix 2A-1, NONMANDATORY GUIDANCE ON THE QUALIFICATIONS OF INSPECTION AND TEST PERSONNEL. Where inspection requires special expertise, the expert(s) will be selected on the basis of the required expertise, without regard to formal inspector qualification. In these cases, the participant's QA inspection function will ensure that the specialist is properly oriented in the use of the necessary inspection equipment, forms, accept/reject practices and reporting method.

10.3 RESPONSIBILITIES

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

DOE BWI Division verifies that project inspection activities are achieving intended results through audit and surveillance.

10.4 INSPECTION PROCEDURES

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

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

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

10.5 INSPECTION RESULTS

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

10.6 DOCUMENTATION AND RECORDS

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

11.0 TEST CONTROL

11.1 TEST ACTIVITIES

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

11.2 TEST PLANS AND PROCEDURES REVIEW

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

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

11.3 UNCERTAINTIES AND ERROR

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

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION

For instrumentation and/or equipment used in data collection, Project participants 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 will be selected specifically to minimize the likelihood of undetectable anomalies, and (b) test planning and procedures will include any special provisions for equipment/instrumentation configuration, installation and use that can further reduce risk of undetectable failure or malfunction.

11.5 PERSONNEL QUALIFICATION

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

11.6 TEST PROCEDURE CONTENT

Test procedures are expected to include the following elements:

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

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

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE

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

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

11.8 DOE-RL BWI DIVISION RESPONSIBILITIES

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

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

12.1 CALIBRATION PROGRAM

The Integrating Contractor is responsible for ensuring that adequate calibration control systems are implemented for M&TE to be used on the project. These systems are expected to provide for use of calibration standards traceable to nationally recognized standards; selection of M&TE on the basis of application requirements; tagging or other appropriate and effective means of knowing calibration status of individual items of M&TE; calibration intervals based on M&TE characteristics and usage; repair or replacement of M&TE found to be damaged or consistently outside allowable calibration limits; and reevaluation of results obtained by use of M&TE subsequently determined to be out of calibration.

When a nationally recognized standard does not exist, the basis for calibration is expected to be documented, and the need for peer review of the method and basis evaluated.

12.2 QA INVOLVEMENT

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

12.3 DOE BWI DIVISION OVERVIEW

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

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

Each Project participant whose tasks include receipt, processing or storage of items, materials or samples within the scope of the BWI Project QA program is required to establish and implement controls that protect them from loss, damage or deterioration. These procedures are expected to require that specific handling, storage, preservation, packaging and shipping instructions be prepared by knowledgeable, responsible individuals, and that such activities be performed in accordance with approved instructions by suitably trained personnel. Where appropriate, qualification of special lifting equipment, slings and hoists is to be addressed explicitly.

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

14.0 INSPECTION, TEST AND OPERATING STATUS

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

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

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

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES

15.1 IDENTIFICATION AND CONTROL

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

Any nonconformance is required to be documented upon discovery and reported promptly for evaluation and disposition. Project participants are expected to establish and implement systems for tracking nonconforming items until disposition has been accomplished, and for preventing inadvertent use of such items.

15.2 EVALUATION AND DISPOSITION

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

Decisions to use the nonconforming item, material or sample as is, or to restore it to usable condition without returning it to fully conforming condition, require technical review and approval at the next higher level of project participation (e.g., disposition decisions of "use-as-is" or "repair" made by the Integrating Contractor require DOE BWI Division review and approval).

15.3 ACCOMPLISHMENT OF DISPOSITIONS

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

15.4 TRENDS

The Project will establish a system for monitoring and analyzing nonconformance trends on a Project-wide basis and initiating appropriate action where the need is indicated. BWI Division review of nonconformance reports submitted by the Integrating contractor is accomplished in accordance with procedure DP-15.1, PROCESSING CONTRACTOR NCRS AND UNUSUAL OCCURRENCES, and trends are determined and monitored in accordance with Division procedure DP-15.2, TREND ANALYSIS.

16.0 CORRECTIVE ACTION

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

16.1 CORRECTIVE ACTION PROGRAM

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

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

DOE BWI Division conducts corrective action in accordance with procedure DP-16.1, CORRECTIVE ACTION.

17.0 RECORDS MANAGEMENT

17.1 RECORDS MANAGEMENT SYSTEM

The Integrating Contractor is responsible for definition and operation of the BWI Project records management system. The system is described in controlled document SD-BWI-AP-001, BASALT WASTE ISOLATION PROJECT RECORDS MANAGEMENT PLAN, which "...provides direction to all BWIP end functions and other affected end-functions regarding collection, administration, storage and retrieval of BWIP records/documents and one-of-a-kind items after their preparation for the BWIP." (Quoted from the abstract of the plan.) Documents and items (such as core samples, etc.) that are to become part of the formal record are transmitted directly to the Integrating Contractor for the necessary processing and storage. (See Appendix A, Exceptions and Clarification, for exceptions to standard requirements with regard to (a) classification of records by retention times, and (b) disposition planning.) Organizational responsibilities for elements of the overall records management system are specified in appropriate participant procedures.

17.2 DOE-RL BWI DIVISION RECORDS

DOE BWI Division generated material is submitted to the record in accordance with BWI Division procedure DP-17.1, QUALITY RECORDS.

17.3 ARCHIVAL FACILITY

Project records in long-term storage are expected to be kept in a facility that meets all applicable requirements relative to record protection from deterioration and disaster. The required facility will be established when and if the basalt waste isolation site is officially designated for site characterization.

18.0 AUDIT AND SURVEILLANCE

18.1 AUDIT - GENERAL

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

BWI Division audits Project activities indicated below:

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

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

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

18.2 AUDIT PROGRAM CONTENT

QA audit within the BWI Project addresses the following questions:

- a. Is the audited participant carrying out his approved QA program?
- b. Are the controls and/or control systems defined in the audited participant's QA program working effectively?
- c. Does the record provide convincing objective evidence that the controls and/or control systems have been, and are being, rigorously applied (i.e., that a rigorous forensic record is being compiled)?
- d. Does the audited participant exhibit an acceptable degree of procedural discipline?

18.3 AUDIT SCHEDULING

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

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

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

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

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

18.4 AUDITOR QUALIFICATION

The use of a certified lead auditor as team leader for every QA audit is a formal Project requirement. Lead auditor qualification complies with the requirements of NQA-1-1983.

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

18.5 AUDIT PREPARATION

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

18.6 AUDIT PERFORMANCE

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

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

18.7 AUDIT REPORTS

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

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

18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS

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

Typical situations justifying this approach include the following:

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

18.9 SURVEILLANCE - GENERAL

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

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

- a. Actual observation of the physical performance of work,
- b. Observation of the work place for presence of suitable conditions and adequate housekeeping and safety measures,
- c. Observation of related access control, fire prevention provisions, etc.,
- d. Review or spot checks of documents in preparation,
- e. Review or spot checks of procedures or instructions governing the work,
- f. Evaluation or verification of the presence and effectiveness of applicable controls, and
- g. Discussion with personnel performing or supervising the work.

18.10 QUALIFICATION FOR SURVEILLANCE

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

18.11 BWI DIVISION SURVEILLANCE

Surveillance performed by BWI Division personnel is controlled by BWI Division procedure DP 18.5, SURVEILLANCE OF PROJECT ACTIVITIES. Technical personnel perform surveillance of work within their areas of expertise and evaluate technical effectiveness of applicable controls. BWI Division QS personnel perform surveillances of ongoing control activities.

18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS

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

18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES

18.13.1 By Audited or Surveilled Activity

Project participant activities are expected to address deficiencies identified by audit or surveillance with prompt, vigorous corrective action. Adverse findings identified as significant are to be investigated to determine the root cause of the deficiency and to define action that will prevent recurrence.

18.13.2 By Auditing or Surveilling Organization

The auditing or surveilling organization is expected to:

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

Project participants are expected to maintain tracking and trending systems that will provide long term visibility of significant problems so that any recurrence will immediately be recognized.

Appendix A: Exceptions/Clarifications to the NRC Review Plan

PREAMBLE

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

The attached exceptions/clarifications to the NRC Review Plan reflect the following perception of responsibilities:

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

EXCEPTIONS/CLARIFICATIONS TO NRC REVIEW PLAN

1. NRC Review Plan Section 1.1

"The responsibility for the overall program is retained and exercised by the DOE at a level that is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls."

Clarification

Responsibility for overall QA program policy and direction is exercised by DOE Headquarters and the Office of Geologic Repositories. Within the Basalt Waste Isolation project field office, project management is exercised through DOE Basalt Waste Isolation Division technical staff monitoring (surveillance) and review. Surveillance includes evaluation of contractor technical performance and of the effectiveness of controls under which the work is performed. BWI Division technical staff is normally not involved in direct project work, but exercises technically oriented management functions. Thus, verification of proper performance of work is not limited to the DOE "QA organization". However, QA program controls are exercised by line functions.

2. NRC Review Plan, Section 1.5

"Qualified individual(s) or organizational element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities."

Clarification

Qualified individual(s) or organizational element(s) will be identified within DOE's organization, prior to initiation of activities, as responsible for assuring that delegated work meets established quality standards.

3. NRC Review Plan, Section, 1.10

"DOE and its prime contractor identify a management organization that retains overall authority for the QA program..."

Clarification

DOE and its prime contractors will identify a management organization that retains overall responsibility for performing the "QA functions". DOE will identify a DOE management position that retains responsibility for: (1) performing QA functions, (2) quality affecting activities within DOE, (2) verifying quality-related controls applicable to quality assurance by DOE personnel, and (3) verifying proper performance within contractor QA programs.

DAM OPINION

WORDY BUT WORTHWHILE
IT POINTS OUT THE
FACT THAT ALL NONCONFORMANCES
NEED NOT BE FOLLOWED
BY C.A.

④ NRC Review Plan, Section 1.11

"Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization..."

DAM OPINION

Clarification

DOE verification of conformance to established both by DOE project technical surveillance activities, and by personnel. Contractor verification of conformance be performed by personnel or organization the work or directly supervise its performance belong to the contractor's QA organization basis of technical expertise, depending the work whose conformance is being verified.

THIS CLARIFICATION IS UNNECESSARY - IT ONLY REITERATES THE POLICY OF THE SRP. I.E. TECH OR SPECIAL "VERIFIERS" CAN BE OUTSIDE THE QA ORG AS LONG AS THEY ARE "INDEPENDENT"

5. NRC Review Plan, Section 1.15

"The persons responsible for directing and managing the overall QA program are identified ...This [sic] individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented."

Clarification

The director of the DOE project office responsible for the selected repository program will be responsible for directing and managing line function implementation of the overall QA program. A DOE management level individual in the selected DOE field office will be assigned responsibility for directing and managing QA functions with respect to quality affecting activities performed by DOE personnel and for tracking effective performance of contractor QA functions. This will be a dedicated QA assignment.

Assessment and verification of effectiveness of project QA program controls will be addressed as integral to DOE assessment and verification of contractor technical performance.

Individuals responsible for directing and managing quality assurance functions will be free from non-QA duties and will thus be able to give their full attention to assuring that the QA program is being effectively implemented.

⑥ NRC Review Plan, Section 3.6

DAM OPINION

THIS IS A REASONABLE CLARIFICATION - I.E. LIMITING THE "RANGE" TO THE CONTRACTOR'S QA ORG. HIGHER LEVEL QA ORGS CAN GET INTO THE ACT (AFTER THE FACT) THRU AUDITS, SURVEILLANCES, ETC.

drawings, specifications, criteria, and organization to assure that the documents are in accordance with documented requirements."

is will require that design drawings, etc. be reviewed by the contractor QA documents are prepared, reviewed, and tested procedures and quality assurance

7. NRC Review Plan, Section 9.1

"The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided."

Clarification

DOE will identify special processes as those processes for which end results cannot be fully characterized by nondestructive means. Contractors will be required to identify and list applicable processes. Geological data acquisition "testing" is not considered to belong to the "special process" category for purposes of process demonstration.

8. NRC Review Plan, Section 11.3

"The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled..., are identified."

Clarification

Contractors will be required to perform documented evaluations of uncertainties associated with testing and data acquisition. Potential sources of uncertainties will be identified and quantified to the greatest extent practicable.

9. NRC Review Plan, Section 13.1

"Sampling, handling, preservation..."

Clarification

This requirement is taken to address "Sample handling, preservation..." rather than "Sampling, handling, preservation..."

10. NRC Review Plan, Section 14.1

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

Exception

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

⑪. NRC Review Plan, Section 16.2

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

Exception

Nonconformances that do not meet the criteria for significance (see Review Plan Section 16.4) will be evaluated to determine whether or not action to preclude recurrence would serve the best interests of the project. Evaluation will involve consideration of such factors as cost of remedial action for repetitive occurrence, nuisance value of repetitions, potential impact of repeated occurrences on more significant aspects of the work, potential for repeated occurrences to produce a negative perception of overall control effectiveness and cost to isolate cause(s) and implement preventive action(s).

12. NRC Review Plan, Section 16.4

"Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper of management for review and assessment."

Clarification

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

⑬ NRC Review Plan, Section 17.1

"The scope of the records program is described. QA records include geotechnical samples and data;..."

Exception

The scope of the records programs is described. QA records include geotechnical data;..." "Geotechnical samples will be afforded archival controls and protection for the period during which additional examination or analysis by DOE or the NRC may be needed, or during which natural time-dependent deterioration processes inherent to the sample materials have not destroyed or substantially changed sample properties."

DAM OPINION

NOT REALLY AN EXCEPTION
SEEMS TO RETAIN "SAMPLES"
AS A RECORD - BUT
LIMIT RETENTION TO THEIR
USEFUL LIFE.