ENCLOSURE 2

HQO.880205.0027

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN

REVISION 3

EFFECTIVE DATE:_____

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

RECOMMENDED FOR APPROVAL R. P. Saget 1/11/88
R. P. Saget, Director
Quality Systems Division

APPROVED 1/12/88
J. J. Anttonen, Assistant Manager
for Commercial Nuclear Waste

APPROVED _____
Associate Director
Office of Geologic Repositories

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN, REV. 3

TABLE OF CONTENTS

POLICY STATEMENT viii

1.0 ORGANIZATION 1

1.1 OVERALL ORGANIZATION 1

1.2 BASALT WASTE ISOLATION PROJECT ORGANIZATION RESPONSIBILITIES . . 1

1.2.1 DOE-RL Office of Assistant Manager for Commercial Nuclear Waste 1
1.2.2 Project 1
1.2.3 Integrating Contractor. 2
1.2.4 Architect/Engineer, Construction Manager, and Other Participants under Direct Contract to DOE for Project Work Including The Laboratory Support Contractor. 3
1.2.5 Project Participants on Subcontract 4
1.2.6 Stop Work Authority 4
1.2.7 Resolution of Disputes Involving Quality. 5

1.3 DOE-RL INTERNAL ORGANIZATION FOR AMC PROJECT QUALITY ASSURANCE . 5

1.3.1 AMC BWIP Organization 5
1.3.2 AMC BWI Division. 6
1.3.3 AMC Quality Systems Division. 7

1.4 QA INTERFACE WITH DOE HEADQUARTERS 8

1.5 INTERDIVISION INTERFACES WITHIN DOE-RL 8

2.0 QUALITY ASSURANCE PROGRAM 14

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES. 14

2.2 BWI PROJECT QA PROGRAM STRUCTURE AND EXECUTION 15

2.2.1 QA Program Controls 15
2.2.2 Project QA Program Documentation. 16
2.2.3 Graded Quality Assurance. 17

2.2.3.1 QL-1 18
2.2.3.2 QL-2 18
2.2.3.3 QL-3 18

TABLE OF CONTENTS

2.2.4 AMC Evaluation Role 19

2.3 INDOCTRINATION, TRAINING AND QUALIFICATION 19

2.3.1 Indoctrination. 19
2.3.2 Training. 19
2.3.3 Qualification 20
2.3.4 Documentation and Records 20

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS. 21

2.5 PROJECT QUALITY ASSURANCE STATUS REPORTING 21

2.5.1 Report Content. 21
2.5.2 Submittal Requirements. 22

2.6 REVIEW PLAN. 22

2.6.1 Readiness Reviews 22

3.0 DESIGN CONTROL. 33

3.1 POLICY 33

3.2 COMPUTER SOFTWARE. 33

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION 33

3.3.1 Design Control versus Test Control. 33
3.3.2 Existing Data 34
3.3.3 Current Data. 34
3.3.4 Published Studies 35

3.4 DESIGN CONTROLS FOR SITE CHARACTERIZATION STUDIES AND DESIGN OF EQUIPMENT, FACILITY, WASTE FORM AND WASTE PACKAGING 35

3.4.1 Design Verification by Formal Design Review 36
3.4.2 Design Verification by Testing. 36
3.4.3 Design Verification by Alternate Calculations 36
3.4.4 Design Verification by Similarity 36

3.5 PEER REVIEW. 37

3.6 DESIGN CHANGES 38

3.7 DESIGN INTERFACES. 38

3.8 AMC COGNIZANCE 38

3.8.1 DOE-RL AMC Technical Surveillance 38
3.8.2 DOE-RL AMC Participation in Peer Reviews. 39

TABLE OF CONTENTS

3.8.3 Document Review 39
3.8.4 Documented Review Meetings 39
3.8.5 AMC QS Division Audit and Surveillance of Design Controls 39

4.0 PROCUREMENT DOCUMENT CONTROLS 40

4.1 PROJECT PARTICIPANTS 40

4.2 INTEGRATING CONTRACTOR ROLE. 40

4.3 AMC EVALUATION ROLE. 41

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS 42

5.1 ADMINISTRATIVE PROCEDURES. 42

5.2 TECHNICAL PROCEDURES 42

5.3 INSTRUCTIONS 42

5.4 DRAWINGS 43

5.5 ACCEPTANCE CRITERIA. 43

5.6 USE AND AVAILABILITY 43

5.7 AMC PREPARATION OF BASALT PROCEDURES (BPs) 44

5.8 PROJECT OVERVIEW 44

6.0 DOCUMENT CONTROL. 45

6.1 CONTROL ELEMENTS 45

6.2 AMC DOCUMENT CONTROL 45

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL 46

6.3.1 AMC QA Documents. 46
6.3.2 Integrating Contractor, Construction Management Contractor and Architect/Engineer Documents 46
6.3.3 Other Participants' Documents 46
6.3.4 Technical Documents 46

6.4 REVIEW AND APPROVAL PROCESS. 46

6.5 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS. 47

6.6 CONFIGURATION MANAGEMENT 47

TABLE OF CONTENTS

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES 48

7.1 SUPPLIER QA PROGRAMS 48

7.2 SUPPLIER SELECTION AND EVALUATION. 48

7.3 VERIFICATION 49

7.3.1 Verification of Work in Progress. 49
7.3.2 Acceptance. 49

7.4 SUPPLIER-FURNISHED DOCUMENTATION 50

7.5 AMC CONTROL OF PURCHASED ITEMS AND SERVICES. 50

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES. 51

9.0 CONTROL OF SPECIAL PROCESSES. 52

9.1 SPECIAL PROCESS - DEFINITION 52

9.2 IDENTIFICATION AND QUALIFICATION 52

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES. 52

9.4 STANDARD PROCESSES 52

9.5 RESPONSIBILITY 53

10.0 INSPECTION. 54

10.1 INSPECTION ACTIVITIES. 54

10.2 INSPECTOR QUALIFICATION. 54

10.3 RESPONSIBILITIES 54

10.4 INSPECTION PROCEDURES. 55

10.5 INSPECTION RESULTS 55

10.6 DOCUMENTATION AND RECORDS. 56

11.0 TEST CONTROL. 57

11.1 TEST ACTIVITIES. 57

11.2 TEST PLANS AND PROCEDURES REVIEW 57

11.3 UNCERTAINTIES AND ERROR. 57

TABLE OF CONTENTS

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION. 58

11.5 PERSONNEL QUALIFICATION. 58

11.6 TEST PROCEDURE CONTENT 58

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE 59

11.8 DOE-RL AMC TEST CONTROL RESPONSIBILITIES 59

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE). 60

12.1 CALIBRATION PROGRAM. 60

12.2 QA INVOLVEMENT 60

12.3 DOE AMC OVERVIEW 61

13.0 HANDLING, STORAGE AND SHIPPING OF ITEMS, MATERIALS AND SAMPLES. 62

13.1 PROJECT IMPLEMENTATION 62

13.2 PROJECT OVERVIEW 62

14.0 INSPECTION, TEST AND OPERATING STATUS 63

14.1 PROJECT CONTROLS 63

14.2 PROJECT OVERVIEW 63

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES 64

15.1 IDENTIFICATION AND CONTROL 64

15.2 EVALUATION AND DISPOSITION 64

15.3 ACCOMPLISHMENT OF DISPOSITIONS 65

15.4 DOE-RL AMC OVERVIEW 65

16.0 CORRECTIVE ACTION 66

16.1 CORRECTIVE ACTION PROGRAM. 66

16.2 TRENDS 66

17.0 RECORDS MANAGEMENT. 67

17.1 RECORDS MANAGEMENT SYSTEM. 67

17.2 REPOSITORY RECORDS DEFINITIONS 67

TABLE OF CONTENTS

17.2.1 Record Types 67

17.2.2 Quality Assurance Record Definition 68

17.3 RESPONSIBILITIES 68

17.4 DOE-RL AMC RECORDS 69

17.5 ARCHIVAL FACILITY 69

17.6 RECORDS PROGRAM OVERVIEW 69

18.0 AUDIT AND SURVEILLANCE 70

18.1 AUDIT - GENERAL 70

18.2 AUDIT PROGRAM CONTENT 70

18.3 AUDIT SCHEDULING 71

18.4 AUDITOR QUALIFICATION 72

18.5 AUDIT PREPARATION 72

18.6 AUDIT PERFORMANCE 72

18.7 AUDIT REPORTS 73

18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS 73

18.9 SURVEILLANCE - GENERAL 73

18.10 QUALIFICATION FOR SURVEILLANCE 74

18.11 AMC QS DIVISION SURVEILLANCE 74

18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS 74

18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES 74

18.13.1 By Audited or Surveilled Activity 74

18.13.2 By Auditing or Surveilling Organization 75

TABLE OF CONTENTS

LIST OF FIGURES

FIGURE 1-1	Geologic Repository Program Organization	10
FIGURE 1-2	Office of Assistant Manager for Commercial Nuclear Waste BWI Project Organization	11
FIGURE 1-3	BWI Project QA Program Management Responsibilities . . .	12
FIGURE 1-4	BWI Project Organization with Support Services Contractor	13

LIST OF TABLES

TABLE 2-1	DOE-RL AMC BWI Project QA Administrative Procedures . . .	24
TABLE 2-2	Matrix: NRC Review Plan vs QAP	25
TABLE 2-3	Matrix: BWIP QA Program Responsibility Matrix	32

APPENDIX

APPENDIX A	Clarifications to NRC Review Plan	76

TABLE OF CONTENTS

POLICY STATEMENT

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

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

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

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN, REV. 3

1.0 ORGANIZATION

1.1 OVERALL ORGANIZATION

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

1.2 BASALT WASTE ISOLATION PROJECT ORGANIZATION RESPONSIBILITIES

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

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

1.2.2 Project

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

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

1.2.3 Integrating Contractor

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

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

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

a. Reviews and recommends DOE approval of QA program descriptions and QA administrative procedures prepared by the Construction Management Contractor and the Architect/Engineer,

b. Approves the QA program descriptions and QA administrative procedures prepared by (1) Project participants under direct contract to DOE for their Project work, other than the Architect/Engineer and the Construction Manager, and (2) all Project participants under direct contract to the Integrating Contractor for their Project work,

c. Establishes Project-wide systems and/or methods for implementing QA program elements for which such uniformity produces important cost and/or control benefits by issuing controlled documents such as project directives,

d. Verifies effective implementation of the QA program by means of audit, surveillance, trending and management assessment of QA activities of (1) the Architect/Engineer, (2) the Construction Manager, (3) the other Project participants under direct contract to DOE for their Project work, and (4) all Project participants under direct contract to the Integrating Contractor for their Project work, and

e. Ensures that applicable elements of his (the Integrating Contractor's) QA program are effectively implemented for direct work performed in-house.

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

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

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

b. Submitting to the Integrating Contractor for review QA program descriptions and QA administrative procedures and revisions where DOE approval is required.

NOTE: AMC approves the Laboratory Support Contractor's QA Plan and administrative procedures for environmental and socioeconomic studies when they are outside the scope of the Integrating Contractor's project management functions.

c. Approving the QA Plans and QA administrative procedures of participants doing Project work under contract to him (as shown in Figure 1-3), and

d. Verifying effective implementation of his own QA program and of the QA programs of participants doing Project work under direct contract to him, as shown in Figure 1-3. The architect/engineer and his QA organization are not located onsite. The Construction Manager's Home Office provides functional management responsibilities in project management, QA management and corporate safety.

1.2.5 Project Participants on Subcontract

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

1.2.6 Stop Work Authority

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

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

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

a. Corrective action for substantive quality problems has not been accomplished, and the responsible organization(s) has/have not established an acceptable plan of corrective action or the approved corrective action plan is not being implemented in a timely manner, or

b. One or more elements of the established QA program is determined to be out of control, so that the usability of work performed under existing conditions is in serious question.

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

The Assistant Manager, AMC, the Project Manager for BWIP is to be notified immediately of any STOP WORK on the Project. Notification is expected to include the intended criteria for resumption of work (not always is the criteria for restart available when the stop work is issued). The Project Manager

reserves the authority to require that work be resumed only upon his approval.

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

1.2.7 Resolution of Disputes Involving Quality

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

1.3 DOE-RL INTERNAL ORGANIZATION FOR AMC PROJECT QUALITY ASSURANCE

1.3.1 AMC BWIP Organization

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

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

In recognizing that individuals involved in the BWIP may observe or detect potential problems or concerns which have not been resolved by normal means to the satisfaction of the individual, the Assistant Manager for Commercial Nuclear Waste has established a Quality Concern Hotline Program (reference BP 2.3, Quality Concern Hotline). Individuals may report their concern in confidence, and these concerns are then logged, tracked and investigated. The individual is notified of the results of the investigation and any remedial actions taken. Notices and signs are posted throughout the BWIP project areas to advise interested individuals that this program has been established in DOE-RL-AMC.

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

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

a. Approving the BWIP Quality Assurance Plan and the procedures necessary for its implementation.

b. Approving project plans, as necessary, to permit the AMC Divisions to fulfill their technical and quality assurance program requirements.

c. Assuring adequate funding for technical and quality assurance activities.

d. Appointing the AMC Training Coordinator and approves the QA Training Plan for AMC personnel.

e. Effectively implementing the quality assurance program.

f. Approving formal quality and technical program direction issued by the BWI Division and Quality Systems Division to BWI project participants.

g. Ensuring and evaluating the effectiveness of implementation of the quality assurance program.

h. Evaluating the quality of delegated work as reported by the BWI and Quality Systems Divisions.

i. Evaluating management assessment reports of quality assurance program implementation.

j. Fulfilling other management responsibilities, as assigned by the DOE-RL Manager.

1.3.2 AMC BWI Division

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

a. Effectively implementing the quality assurance plan in the engineering, geoscience, and licensing areas.

b. Evaluating technical effectiveness of quality assurance program control by participants prior to and during ongoing work.

c. Serving on and providing support for the DOE-RL Readiness Review Board.

d. Preparing and issuing management plans and instructions as required.

1.3.3 AMC Quality Systems Division

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

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

b. Preparing and maintaining the QA Training Plan for AMC personnel.

c. Establishing requirements for BWI Division participants' QA programs.

d. Review and approval of the quality assurance plan and implementing quality assurance administrative procedures prepared by the integrating contractor.

e. Evaluating the integrating contractor's recommendations for approval of the quality assurance program descriptions and quality assurance administrative procedures prepared by the construction management contractor and architect-engineer.

f. Approval of the quality assurance program and administrative procedures of the construction management contractor and the architect-engineer for use on the BWIP.

g. Exercising BWIP oversight of overall quality assurance program implementation.

h. Verifying effective implementation of the BWIP Quality Assurance Plan and procedures by the BWI Division and AMC administration.

i. Reviewing and (or) specifying quality assurance requirements in procurement documents.

j. Approving contractor and subcontractor quality assurance programs when their work is not subject to cognizance by the integrating contractor.

k. Approving government agency quality programs when the scope of work is covered by a Memorandum of Understanding.

l. Providing direct quality assurance support to the BWI Division. X

m. Serving on and providing support for the DOE-RL Readiness Review Board and Readiness Review Teams.

n. Verifying the effectiveness of the Integrating Contractor QA organization in providing management and QA program guidance to project participants.

1.4 QA INTERFACE WITH DOE HEADQUARTERS

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

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

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

1.5 INTERDIVISION INTERFACES WITHIN DOE-RL

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

a. Procurement Division (PRO)

All direct procurement for the DOE AMC Division is accomplished by PRO. The PRO interfaces with the AMC Division/Branch that

initiated the procurement regarding technical matters, and with the QS Division on quality assurance matters. (Refer to Sections 4.0 and 7.0 of this QAP for details.) The AMC Divisions and PRO interface at the following points in the procurement process:

(1) When requirements for the item or service(s) are delivered to PRO in the procurement initiation stage,

(2) When PRO is determining which bids are responsive to the specified requirements,

(3) When PRO is determining which responsive bidders are qualified to provide the required items or services,

(4) During contract performance, as determined by verification planning, and

(5) At the time of shipment (or delivery) of the purchased item or service during the acceptance action (PRO contracts with project participants to perform inspections of items and materials).

b. Personnel Division

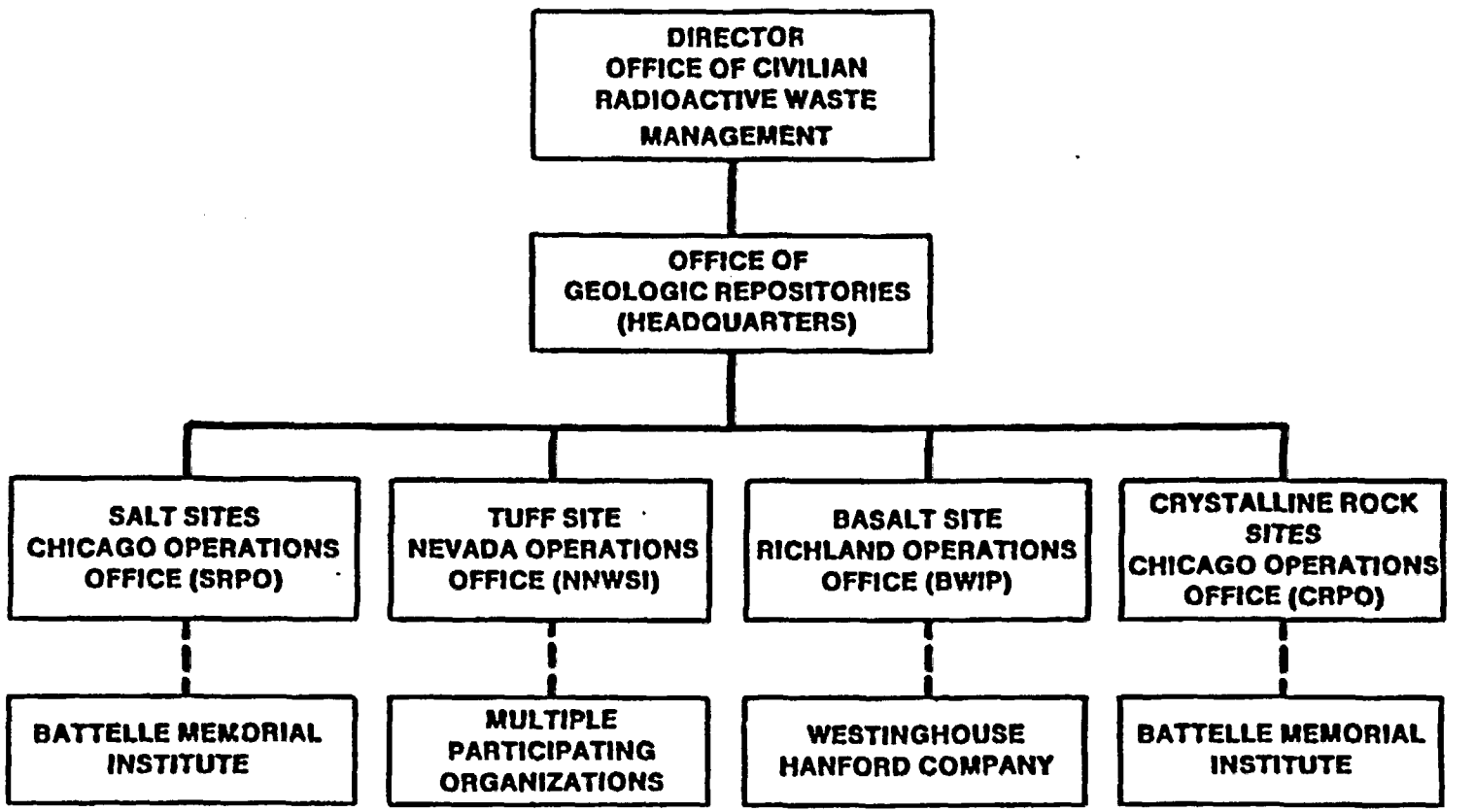
AMC relies on the Director, Personnel Division, to provide personnel for AMC positions and to verify that such personnel meet applicable position qualification requirements defined by the AMC Divisions.

c. EQA Division

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

FIGURE 1-1

GEOLOGIC REPOSITORY PROGRAM



LEGEND:

——— PROGRAM/PROJECT MANAGEMENT RESPONSIBILITY

— — — MAJOR CONTRACTOR SUPPORT

FIGURE 1-1 GEOLOGIC REPOSITORY PROGRAM ORGANIZATION

FIGURE 1-2

BWI PROJECT ORGANIZATION

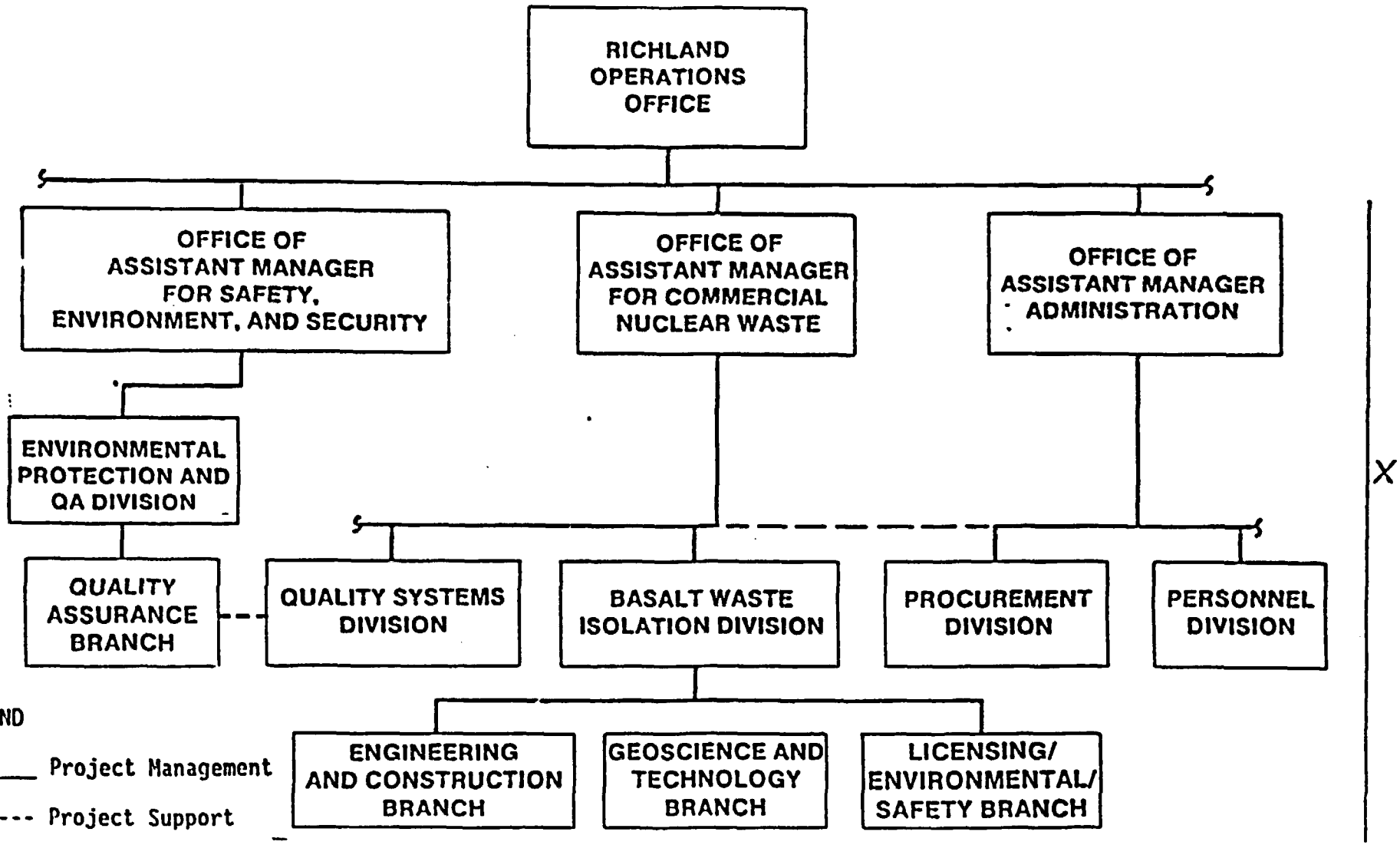


FIGURE 1-3
BWI PROJECT QA
PROGRAM MANAGEMENT RESPONSIBILITIES

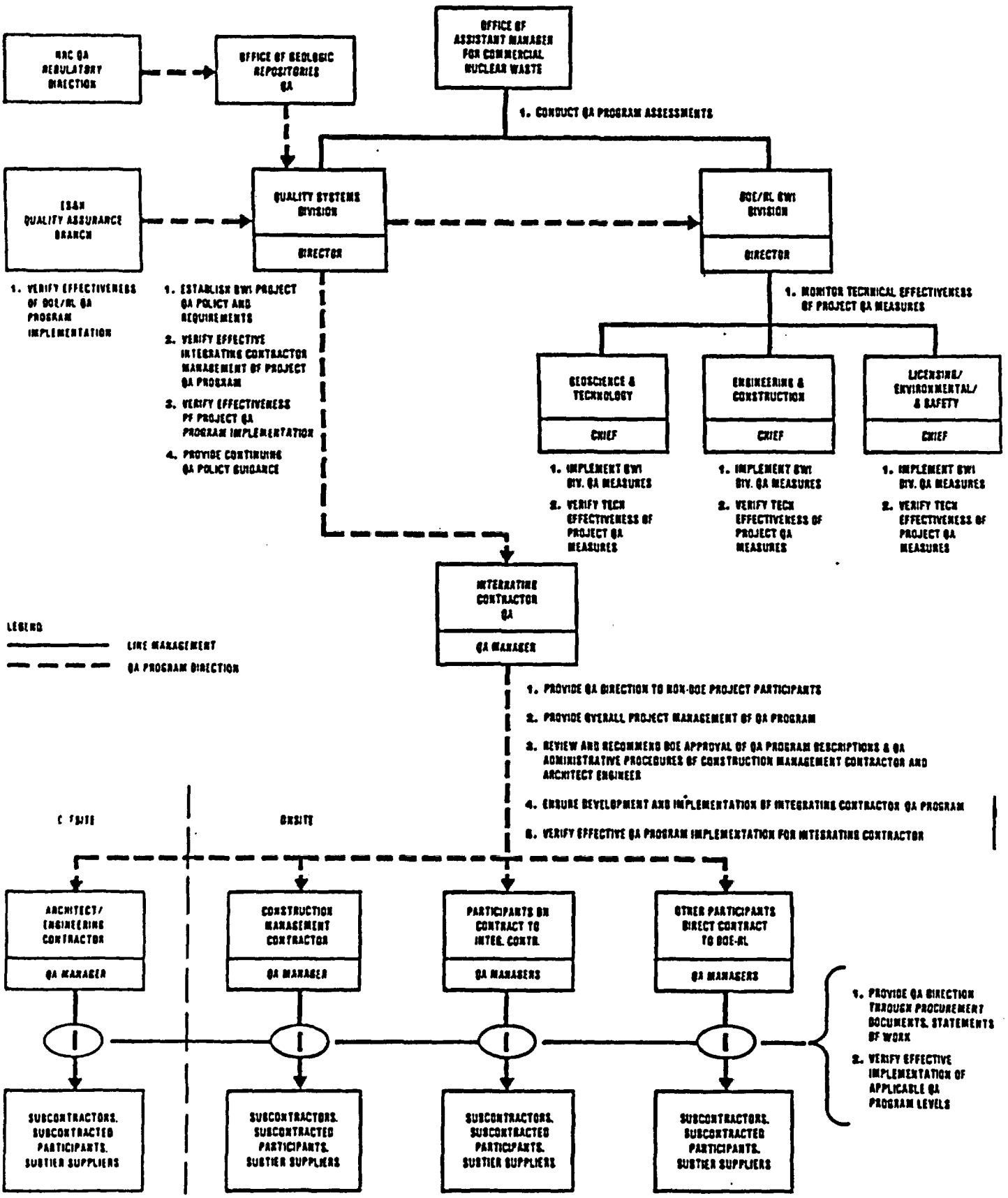
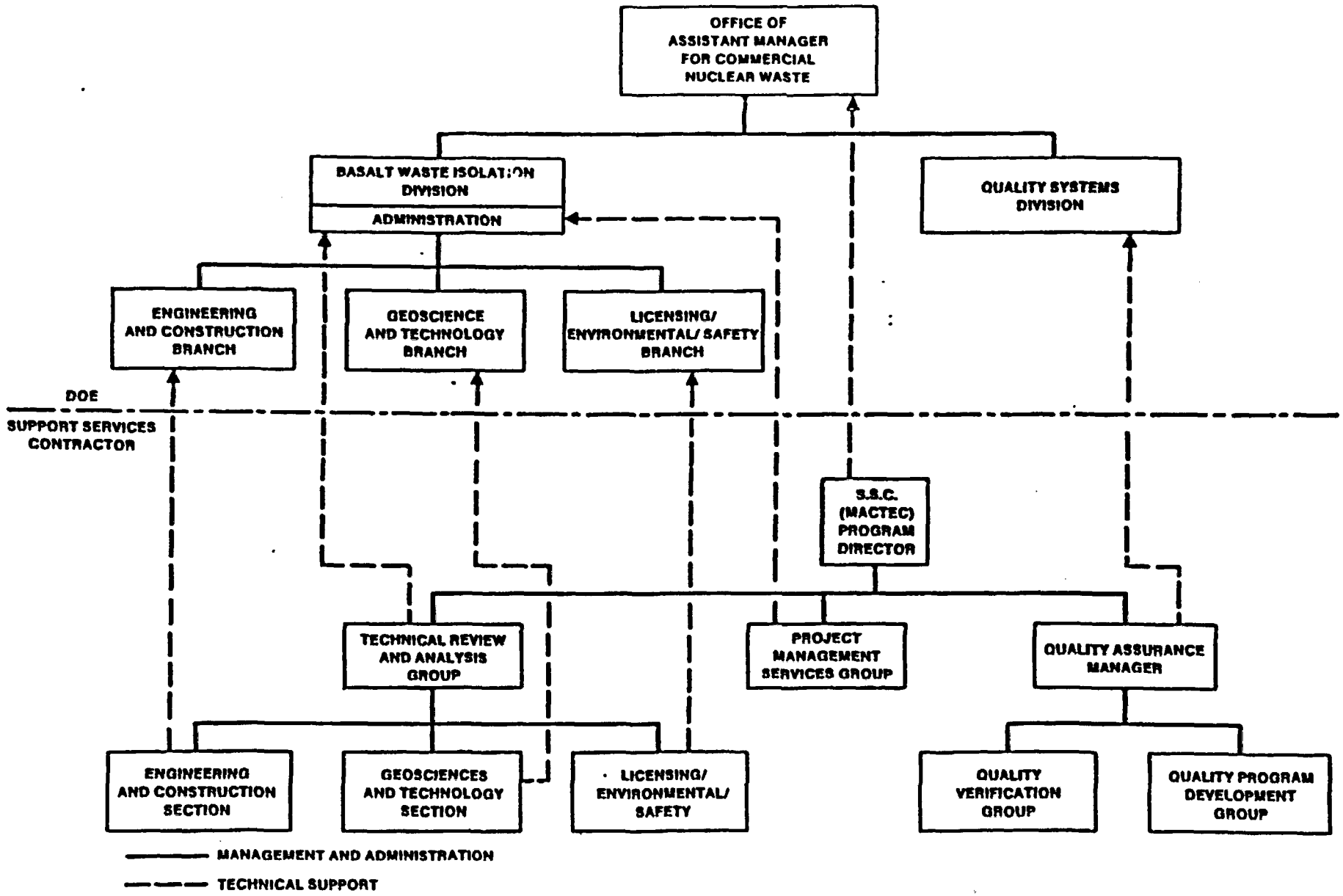


FIGURE 1-4

BWI PROJECT ORGANIZATION WITH SUPPORT SERVICES CONTRACTOR



2.0 QUALITY ASSURANCE PROGRAM

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

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

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES

a. DOE Order 5700.6B, Quality Assurance

b. DOE/RL Order 5700.1A, Quality Assurance

c. DOE/RW-0032, Quality Assurance Management Policies and Requirements

d. 10CFR60, Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures

e. 10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

f. NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories, June 1984

g. OGR/B-3, Quality Assurance Plan for High-Level Radioactive Waste Repositories, and Supplements

h. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities, Supplements and Appendices as specified.

i. Basalt Quality Assurance Requirements Document, (DOE/RL 86-1)

j. DOE Order 4700.1, Project Management System.

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

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

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

2.2 BWI PROJECT QA PROGRAM STRUCTURE AND EXECUTION

2.2.1 QA Program Controls

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

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

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

2.2.2 Project QA Program Documentation

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

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

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

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

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

2.2.3 Graded Quality Assurance

Quality assurance measures for Project activities are applied on the basis of the Graded QA Approach adopted for DOE's geologic repository program. The Graded QA Approach is the method wherein QA program requirements and procedural controls are applied selectively and judiciously to technical items and activities within a designated Quality Level consistent with intended application. The scope of work in completing an item or activity may be further divided into sub-elements where Quality Levels and QA program requirements may vary from the initial determination. The graded approach establishes three quality levels, as follows:

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

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

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

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

2.2.3.1 QL-1

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

All Q-List Items/Activities.

This will include items/activities important to public safety, waste isolation and activities important to waste placement or retrieval and items/activities designated by OGR-HQ.

2.2.3.2 QL-2

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

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

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

It may apply to items involving assessment of a number of Field and Laboratory investigations and/or complex manufacturing assembly and construction processes. X

2.2.3.3 QL-3

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

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

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

2.2.4 AMC Evaluation Role

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

2.3 INDOCTRINATION, TRAINING AND QUALIFICATION

2.3.1 Indoctrination

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

2.3.2 Training

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

To ensure that all BWIP participant personnel performing activities affecting quality achieve and maintain suitable proficiency, a BWIP-wide program to provide appropriate training and indoctrination is required. The AMC Project Manager has delegated to the Integrating Contractor the responsibility for determining appropriate scope and content of the training program commensurate with the current project

phase and for forecasting and planning training needs for future work. The IC is to ensure training requirements are implemented by project participant organizations and to perform verifications of the effectiveness of each training program.

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

2.3.3 Qualification

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

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

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

2.3.4 Documentation and Records

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

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

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

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

2.5 PROJECT QUALITY ASSURANCE STATUS REPORTING

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

2.5.1 Report Content

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

- Results of verifications, surveillances, and audits (including positive results)
- Significant quality accomplishments, issues, problems and nonconformances
- The status of open corrective actions
- A listing of corrective action items closed since the previous status reports
- Staffing levels
- Status of action items for QA program implementation
- Training program status

- o Results and/or issues raised based upon interactions with major contractors, the regulatory agencies, etc.

- o Results of any management assessment activity.

2.5.2 Submittal Requirements

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

2.6 REVIEW PLAN

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

2.6.1 Readiness Reviews

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

The AMC establishes Readiness Review Program requirements, including applicable QA requirements as a minimum, in the Readiness Review Program Plan. The AMC coordinates Readiness Review activities among the HQ-OGR, the Integrating Contractor (IC), the NRC, States and Indian Tribes, as necessary. The AMC approves internal and IC Readiness Review documents, and concurs with Hold Points established in the Project Schedule by the IC. AMC internal activities associated with Readiness Reviews are conducted in accordance with BP 2.12, Readiness Review.

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

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

TABLE 2-1

DOE-RL AMC BWI PROJECT QA ADMINISTRATIVE PROCEDURES

BP	1.1	ORGANIZATION
BP	1.11	STOP WORK
BP	2.1	QA PROGRAM ASSESSMENT
BP	2.2	WORK PROGRESS AND DESIGN REVIEWS
BP	2.3	QUALITY CONCERNS HOTLINE
BP	2.5	PERSONNEL TRAINING
BP	2.7	APPEALS ON QUALITY CONCERNS
BP	2.8	CONTROL OF AND RELEASE OF LICENSING DOCUMENTS
BP	2.10	REPORTING OF SIGNIFICANT DEFICIENCIES
BP	2.12	READINESS REVIEW
BP	3.1	PROJECT REVIEWS
BP	3.3	PEER REVIEW
BP	3.4	GRADED QUALITY ASSURANCE
BP	3.5	DATA QUALIFICATION ACTIVITIES FOR BWIP
BP	4.1	PREPARATION AND CONTROL OF PROCUREMENT DOCUMENTS
BP	4.2	CONTRACTOR INITIATED PROCUREMENTS
BP	5.1	PROCEDURE DEVELOPMENT
BP	6.1	PREPARATION AND RELEASE OF AMC DOCUMENTS
BP	6.2	CONTROLLED DOCUMENTS ISSUED TO THE AMC DIVISION AND STAFF
BP	6.3	REVIEW OF AND APPROVAL OF EXTERNAL DOCUMENTS
BP	7.1	SUPPLIER EVALUATION, SELECTION AND VERIFICATION
BP	7.2	SUPPLIER FURNISHED RECORDS
BP	15.1	PROCESSING CONTRACTOR NCRS AND UNUSUAL OCCURRENCES
BP	15.2	TREND ANALYSIS
BP	16.1	CORRECTIVE ACTION
BP	16.2	REQUEST FOR INFORMATION/ACTION
BP	17.1	QUALITY RECORDS
BP	18.1	AUDIT AND SURVEILLANCE PLANNING
BP	18.4	AUDITOR QUALIFICATIONS
BP	18.5	SURVEILLANCE OF PROJECT ACTIVITIES
BP	18.6	QUALITY ASSURANCE AUDITS

AMC directs technical, quality and management on the Basalt Waste Isolation Project. The direct controls on delegated work is prescribed in approved participants QA Plans and Procedures.

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

NQA-1-1986	NRC REVIEW PLAN	QAP
	3.1	3.1, 2.2.3
	3.2	Site Characterization Plan, Sect. 8.6
	3.3	3.3, 3.4
	3.4	3.1
3S-1, Sect. 6	3.5	3.7
	3.6	3.4i
3S-1, Sect. 4	3.7	3.4
	3.8	3.5
	3.9	3.3.2, 3.4, 3.5
3S-1, Sect. 5	3.10	3.6
3S-1, Sect. 7		17.1
4 Basic		4.0
4S-1, Sect. 2		4.1
4S-1, Sect. 3	4.1	4.1c, e
	4.2	4.1
5 Basic		5.0
	5.1	5.1, 5.2, 3.4, 3.4.1
	5.2	5.5
6 Basic		6.0
6S-1		6.1
	6.1	6.1
	6.2	6.1, 6.4
	6.3	5.6, 6.1e

TABLE 2-2

REQUIREMENTS MATRIX

NQA-1-1986	NRC REVIEW PLAN	QAP
	6.4	6.1g
	6.5	6.1i
	6.6	6.1j
7 Basic		7.0
	7.1	7.0
7S-1, Sect. 2		7.1
7S-1, Sect. 3	7.2	7.2, 7.3.1, 7.3.2
7S-1, Sect. 4		7.0
7S-1, Sect 5		7.2
7S-1, Sect. 6, 7, 9	7.3	7.4
7S-1, Sect. 8	7.4	7.3.2
	7.5	11.4
7S-1, Sect. 10		2.2.3
8 Basic		8.0
	8.1	8.0
	8.2	8.0
	8.3	8.0
8S-1		8.0
	8.4	8.0
9 Basic		9.0
9S-1, Sect. 2, 3	9.1	9.1, 9.2
	9.2	9.2
	9.3	9.2

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

NQA-1-1986	NRC REVIEW PLAN	QAP
	12.3	12.1, 12.2
	12.4	12.1
	12.5	12.1
	12.6	12.1
	12.7	12.1
13 Basic, 13S-1		13.0
	13.1	13.0
	13.2	13.0
14 Basic		14.0
	14.1	14.0
15 Basic		15.0
	15.1	15.1, 15.2, 15.3
15S-1, Sect. 2, 3	15.2	15.1, 15.2, 15.3
15S-1, Sect 4	15.3	15.1, 15.2, 15.3
	15.4	15.4
16. Basic		16.0
	16.1	16.1
	16.2	16.1, 15.4 Append. A
	16.3	16.1
	16.4	16.0
17 Basic		17.0
17S-1, Sect. 2, 3, 5		17.1
17S-1, Sect. 4		17.3

TABLE 2-2

REQUIREMENTS MATRIX

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

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

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

Responsible organizations:

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

Responsibility:

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

3.0 DESIGN CONTROL

3.1 POLICY

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

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

3.2 COMPUTER SOFTWARE

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

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION

3.3.1 Design Control versus Test Control

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

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

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

3.3.2 Existing Data

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

The use of such data in the site characterization process which will be used to support the licensing process will require qualification. There are four alternative methods or combination of methods that may be used as follows: (a) Peer Review as described in Section 3.5; (b) Use of corroborating data; (c) Use of confirmatory testing; and (d) Demonstrating that appropriate QA program controls equivalent to 10CFR60 Subpart G had been used. Methods (b), (c) and (d) should include a documented technical review to determine the acceptability of the data (additional confidence/credibility could be achieved by using a combination of methods). Note: The definition of existing data does not include information which is accepted by the scientific and engineering communities as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.), and requires no qualification for use. (AMC technical and quality personnel will monitor this activity as prescribed in AMC Procedure BP 3.5, Data Qualification Activities for BWIP). X

3.3.3 Current Data

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

a. Documentation of assumptions, calculations, computer codes used, and intermediate results, as applicable,

b. Independent review of the reduced data or completed analysis, to include consideration of appropriateness of assumptions and approaches, if applicable, and a check on reasonableness of calculation results (using simplified alternate calculations if necessary),

c. Peer review if the reduction or analysis of the approach or technique is untried or goes beyond the existing state-of-the-art,

d. Clear identification of results or conclusions requiring subsequent confirmation by additional exploration or research, or completion of on-going work, and

e. Verification of effective implementation of applicable controls (by audit, surveillance, etc.).

3.3.4 Published Studies

Exploration or research results reported in the literature may be used as background, evidence of consensus, or explicit support for site characterization conclusions. When used in direct support of conclusions, such application shall be controlled by participant procedures that provide criteria for such use as prescribed in Section 3.3.2.

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

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

a. Traceable documentation of design inputs, Design Bases, Regulatory Requirements, and the rationale for design decisions,

b. Documentation of design assumptions, including rationale,

c. Approved and correct computer software and controls,

d. Competent checking including numerical accuracy of computations and correct data input to computer codes,

e. Approval by designated authority,

f. Documented design verification,

g. Control of design interfaces,

h. Control of design changes equivalent to the controls applied to original design, and

i. Review of design drawings, specification, criteria, and analyses by personnel of the cognizant QA organization to ensure compliance with governing procedures and QA program requirements.

3.4.1 Design Verification by Formal Design Review

Formal design review consists of documented traceable review performed by qualified personnel who are independent of those who performed the work or the checking, but who have technical expertise at least equivalent to that required to have performed the original work and shall comply with ANSI/ASME NQA-1, Supplement 3S-1. Technical reviews are in-depth, critical reviews, analyses and evaluations of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness and conformance to predetermined requirements. |x

3.4.2 Design Verification by Testing

Verification by testing is used to establish the ability of some or all features of the design to perform the required 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 required to reinforce each other if they were to occur simultaneously (such as seismic events and outbreak of fire). |x

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

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

3.4.3 Design Verification by Alternate Calculations

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

3.4.4 Design Verification by Similarity

Where all or portions of a design is/are verified by similarity to prior designs, verification shall establish that (1) conditions under which the prior design operated were the same as, or more severe than, relevant conditions in which the present design will operate, (2) the prior design operated

or was tested under the most adverse combination of design conditions applicable to the present design, (3) the designer has determined and appropriately accounted for any deficiencies discovered during operation of the prior design, and (4) the design characteristic features or attributes that are not identical are verified by one or more of the methods described above.

3.5 PEER REVIEW

"Peer Reviews" are documented, in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions or when conclusions, material or data contained in a report go beyond the existing state of the art. Project participants shall establish a peer review process to be applied when design or design activities involve use of untried or beyond state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed. A peer review should be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and/or waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

Procedures implementing Peer Review shall define the peer group selection process and describe the conduct and documentation of peer reviews. The peer reviewers shall consider the validity of conclusions and adequacy of requirements and criteria.

Peer reviewers shall be individuals who have qualifications at least equivalent to those required for performance of the original work nd who are independent of performing or supervising the work being reviewed. The peer reviewer's qualifications shall be documented and verified by the organization requesting the peer review.

Documentation of peer review will include a record of issues addressed during the review, resolution of relevant questions and comments including minority opinions not resolved, and their relationship between reviewers' qualifications and the subject of the review.

The cognizant QA organization shall conduct surveillance and audits of peer review activities. AMC monitors and performs Peer Reviews in accordance with BP 3.3 "Peer Review".

3.6 DESIGN CHANGES

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

3.7 DESIGN INTERFACES

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

3.8 AMC COGNIZANCE

3.8.1 DOE-RL AMC Technical Surveillance

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

a. Confirmation that approaches conform to recognized practice within the discipline, or to practice evaluated and endorsed via the peer review process,

b. Confirmation that in-process results reasonably proceed from the assumptions and approaches being used, and

c. Evaluation of technical effectiveness of controls applied to collection, reduction and analysis of supporting data or studies.

3.8.2 DOE-RL AMC Participation in Peer Reviews

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

3.8.3 Document Review

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

3.8.4 Documented Review Meetings

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

3.8.5 AMC QS Division Audit and Surveillance of Design Controls

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

4.0 PROCUREMENT DOCUMENT CONTROLS

4.1 PROJECT PARTICIPANTS

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

a. Procurement planning,

b. Preparation, review, approval and control of procurement documents,

c. Review of procurement documents by the participant's QA personnel to determine that applicable regulatory requirements, design bases (where applicable), and other requirements are referenced or included in the procurement documents; that adequate accept/reject criteria and plans for acceptance are included where appropriate; that an appropriate supplier QA program has been specified; and that the procurement documents have been prepared in accordance with the applicable procedure(s).

d. Bid evaluation, with participation by the initiator and/or QA (as applicable) for bids that restate or interpret technical and/or quality assurance requirements,

e. Review of, and concurrence with, the supplier QA program prior to initiation of supplier work subject to program requirements.

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

4.2 INTEGRATING CONTRACTOR ROLE

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

4.3 AMC EVALUATION ROLE

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

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

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

5.1 ADMINISTRATIVE PROCEDURES

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

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

5.2 TECHNICAL PROCEDURES

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

5.3 INSTRUCTIONS

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

5.4 DRAWINGS

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

5.5 ACCEPTANCE CRITERIA

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

5.6 USE AND AVAILABILITY

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

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

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

5.7 AMC PREPARATION OF BASALT PROCEDURES (BPs)

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

5.8 PROJECT OVERVIEW **

AMC Quality Systems Division verifies effectiveness of the participants' controls by surveillance and audit. x

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, such as updated controlled and maintained Tables of Contents, published Master Document Lists, Controlled files, etc., with access through computer terminals and/or telephones, and

j. Explicit identification and control of documents that are released prior to required verification, and of any Project data resulting from the use of such unverified documents prior to their verification.

6.2 AMC DOCUMENT CONTROL

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

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL

6.3.1 AMC QA Documents

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

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

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

6.3.3 Other Participants' Documents

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

6.3.4 Technical Documents

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

6.4 REVIEW AND APPROVAL PROCESS

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

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

6.5 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS

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

6.6 CONFIGURATION MANAGEMENT

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

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

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

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

7.3 VERIFICATION

7.3.1 Verification of Work in Progress

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

7.3.2 Acceptance

Acceptance of completed items or services is accomplished as follows:

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

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

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

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

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

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

7.4 SUPPLIER-FURNISHED DOCUMENTATION

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

a. Documentation that identifies the purchased service and the specific procurement requirements met (e.g., codes, standards and specifications),

b. Documentation identifying any procurement requirements that have not been met, and

c. A description of any nonconformances from the procurement requirements that have been dispositioned "accept as is" or "repair".

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

7.5 AMC CONTROL OF PURCHASED ITEMS AND SERVICES

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

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

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES

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

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

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

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SPECIAL PROCESS - DEFINITION

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

9.2 IDENTIFICATION AND QUALIFICATION

Special processes used on the BWI Project are explicitly identified in appropriate QA program documents (QAP or QA-related administrative procedures), and each participant shall develop and maintain a list of those processes that are considered to fall within the scope defined by Section 9.1, above for engineered items. Special processes are required to be in compliance with applicable codes, standards, specifications, and QA procedures. Special processes include welding, heat treating, and nondestructive examinations (NDE). The procedures that specify how individual special processes are to be performed are qualified by demonstration that, when performed as specified, the process yields required results. Special process personnel are qualified by training (where appropriate) and demonstration that they can perform the process(es) with the desired results. Where equipment affects the outcome of a special process, the equipment is similarly qualified. The responsible participant's QA Plan shall describe the role the QA organization plays in qualification of special process procedures, personnel and/or equipment.

9.3 DOCUMENTATION OF PERFORMANCE OF 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 PROCESSES

It is recognized that site characterization involves scientific investigations and process controls which will involve laboratory and field processes (chemical analyses, and ASTM methods for example) for which standard techniques have been developed within the scientific community and whose reliability has been demonstrated by

broad usage in data acquisition activities. Such processes do not require formal qualification within the Project. Independent verification that such 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. These controls shall ensure that process parameters are controlled and that specified environmental conditions are maintained.

9.5 RESPONSIBILITY

The responsibility for identification of special processes and their qualification has been delegated to the Integrating Contractor, the Construction Management Contractor, the Architect/Engineer, the Laboratory Support Contractor and other participants who have identified special processes they will perform.

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

10.0 INSPECTION

10.1 INSPECTION ACTIVITIES

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

a. Source inspection during designated procurements,

b. Receipt inspection for procured items and materials,

c. In-process and acceptance inspections of engineered items during and after fabrication, construction, installation, test or modification work performed by Project participants, and

d. Inspection of samples.

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

10.2 INSPECTOR QUALIFICATION

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

10.3 RESPONSIBILITIES

DOE-RL AMC has delegated inspection responsibility which is assigned to those participants performing activities identified in Section 10.1. The Integrating Contractor requires project-wide standardization of certain inspection practices and formats to

facilitate processing and later use of results and is responsible for ensuring the effectiveness of Project inspection activities. Participating contractors who perform inspections shall perform audits and surveillances of inspection activities.
AMC QS Division verifies that Project inspection activities are achieving intended results through audit and surveillance.

10.4 INSPECTION PROCEDURES

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

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

a. Identification of the characteristics and/or activities to be inspected,

b. The method(s) or inspection to be used,

c. Identification of the individual(s) or groups(s) responsible for performing the inspection,

d. Identification of required prerequisites (including required procedures, drawings, and specifications and revisions) and working conditions for the work to be inspected,

e. A means for recording inspector or data recorder identity and the results of the inspection operation,

f. Specification of measuring and test equipment required to perform the inspection, as well as accuracy requirements, and

g. Acceptance and rejection criteria or reference to the requirements document(s) (such as drawings) that specify these criteria, and

h. Date of inspection.

10.5 INSPECTION RESULTS

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

10.6 DOCUMENTATION AND RECORDS

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

11.0 TEST CONTROL

11.1 TEST ACTIVITIES

In addition to testing accomplished in traditional projects, BWI Project activities conducted for the purpose of acquiring physical data for site characterization (such as sample collection, sample analysis, tests of rock behavior or hydrologic dynamics, etc.) are considered site characterization test activities. Such data acquisition activities will be performed with controls applied to traditional testing, such as procedures, controlled selection and use of measuring and test equipment, verification that specified prerequisites (when applicable) are met, etc. Where the course of action has to be determined as data acquisition proceeds, based on ongoing results, the test planning organizations must identify this need during test procedure preparation, and make provision for field decisions or other appropriate actions to preclude invalidation of test results. The intent is to ensure that there is the necessary flexibility to deal with needed field changes within the controlled test planning.

11.2 TEST PLANS AND PROCEDURES REVIEW

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

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

11.3 UNCERTAINTIES AND ERROR

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

and to assure adequate control of the test, are to be addressed explicitly in test procedures.

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION

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

11.5 PERSONNEL QUALIFICATION

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

11.6 TEST PROCEDURE CONTENT

Test procedures shall include as appropriate the following elements:

a. Requirements and acceptance limits, including precision and accuracy, contained in applicable documents.

b. Test prerequisites such as calibrated instrumentation, presence of specified test equipment and instrumentation, completeness and/or acceptability of item or condition to be tested, specified environmental conditions, and provision for data collection and storage. For tests of long duration, it is expected that specific provisions will be made for instrumentation whose calibration interval is shorter than expected test duration. Such provisions are to be designed to ensure validity of data throughout the test.

c. Instructions for performing the test.

d. Mandatory verification and/or witness points (as required).

e. Acceptance and/or rejection criteria, including required levels of precision and accuracy. (Note: "Accept/reject criteria" means that those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output which, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)

f. Methods of data analysis (which may, however, appear in data analysis procedures other than the procedures used for performing the testing).

g. Methods of documenting or otherwise recording test data and results.

h. Provisions for assuring and documenting the fact that test prerequisites were met.

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE

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

a. A description of the type of observation,

b. The date and results of the test,

c. Information related to conditions adverse to quality,

d. Data recorder identity,

e. Evidence as to acceptability of results, and

f. Action taken to resolve any discrepancies noted.

11.8 DOE-RL AMC TEST CONTROL RESPONSIBILITIES

DOE-RL AMC has delegated the management and implementation of test control to the Integrating Contractor and project participants. AMC will verify by technical surveillance, QA surveillance and QA audit that the Integrating Contractor's direction and management is producing effective test controls throughout the project.

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

12.1 CALIBRATION PROGRAM

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

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

12.2 QA INVOLVEMENT

Cognizant QA organizations within the Project are responsible for verifying that the calibration controls established and implemented by their parent organizations are adequate, effective and implement the calibration program provisions of Section 12.1. QA involvement includes a documented review of, and concurrence with, calibration program procedures, as well as audit and surveillance of calibration activities.

12.3 DOE AMC OVERVIEW

DOE-RL AMC has delegated the responsibility for control of M&TE to the Integrating Contractor and participating contractors whose work includes the use of M&TE. AMC QS Division verifies effectiveness of the Integrating Contractor's management of the calibration control system by surveillance and audit.

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

13.1 PROJECT IMPLEMENTATION

Each Project participant whose tasks include receipt, processing or storage of items, materials or samples within the scope of the BWI Project QA program is required to establish and implement controls that protect them from loss, damage or deterioration. Participants' QA organizations shall monitor their programs to assure controls are in place. (DOE-RL AMC has delegated these responsibilities to the Integrating Contractor and Participants.)

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

13.2 PROJECT OVERVIEW

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

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 PROJECT CONTROLS

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. (DOE-RL AMC has delegated responsibility for project controls to the Integrating Contrator and other participants who perform inspections and tests.)

14.2 PROJECT OVERVIEW

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

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES

15.1 IDENTIFICATION AND CONTROL

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

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

15.2 EVALUATION AND DISPOSITION

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

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

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

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

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

15.3 ACCOMPLISHMENT OF DISPOSITIONS

Each participant's procedure(s) for control of nonconforming items, materials or samples is/are required to contain provisions for documented verification that disposition of such items, materials or samples is carried out in accordance with instructions and meets the specified accept/reject criteria. AMC review of nonconformance reports submitted by the Integrating Contractor is accomplished in accordance with AMC Procedure BP 15.1, Processing Contractor NCRs and Unusual Occurrences.

15.4 DOE-RL AMC OVERVIEW

DOE-RL personnel do not initiate nonconformance reports (NCRs) as this has been delegated to the project participants, who will be required to initiate NCRs if discovered by DOE AMC during surveillances and audits. DOE-RL AMC QSD will evaluate nonconformance control effectiveness by audits and surveillance of project participants.

16.0 CORRECTIVE ACTION

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

16.1 CORRECTIVE ACTION PROGRAM

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

a. Evaluation of participant reported problems to determine significance, including potential implications to previously completed Project work,

b. Investigation to determine the root cause of problems determined to be significant,

c. Action to eliminate or compensate for the identified root cause,

d. QA verification that defined preventive action is accomplished, and

e. QA verification that the preventive action actually prevents recurrence.

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

16.2 TRENDS

The participants shall establish systems for monitoring and analyzing deficiency documents (e.g., nonconformance reports, audit findings, etc.), for trends to help to determine root cause and to initiate appropriate corrective action where the need is indicated. Deficiency reporting documents initiated by AMC are trended in accordance with AMC Procedure BP 15.2, Trend Analysis. The AMC QS Division Director evaluates trend reports and notifies the BWIP Project Manager of significant trend information.

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 which shall comply with ANSI/ASME NQA-1 and Supplement 17S-1. Quality Assurance requirements governing generation and control of records are incorporated into the Integrating Contractor's implementing procedures, which apply to all project participants. Documents and items (such as core samples, etc.) that are to become part of the formal record are transmitted directly to the Integrating Contractor for the necessary processing and storage.

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

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

17.2 REPOSITORY RECORDS DEFINITIONS

17.2.1 Record Types

For a geologic repository, records may be of two types:

a. Documents - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results, some of which may be one-of-a-kind.

b. Items - Physical samples, magnetic media, and other materials that retain or support data, and other one-of-a-kind items that cannot be reproduced.

A document or item is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below. The term "records", used throughout this QA Plan is to be interpreted as Quality Assurance Records, both documents and items.

17.2.2 Quality Assurance Record Definition

A Quality Assurance Record is an individual document that has been executed, completed, and approved and that evidence of the quality and completeness of data (including raw data), items, and activities affecting quality; documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); procurement documents; other documents such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; and items such as magnetic media, physical samples (such as rock, core, and water); and other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document or item (and documentation) which will receive no more entries, whose revisions would normally consist of a reissue of the document (or documentation) or corrections, and that is signed and dated by the originator and, as applicable, by approval personnel (an item would generally not require any additional testing or evaluation).

17.3 RECORDS MANAGEMENT

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

17.4 DOE-RL AMC RECORDS

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

17.5 ARCHIVAL FACILITY

Project records other than geotechnical samples in long-term storage shall be kept in a facility that meets all applicable requirements relative to record protection from deterioration and disaster as specified in ANSI/ASME NQA-1.

17.6 RECORDS PROGRAM OVERVIEW

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

18.0 AUDIT AND SURVEILLANCE

18.1 AUDIT - GENERAL

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

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

AMC QS Division audits Project activities indicated below:

a. Activities within the scope of this QA program performed by the BWI Division,

b. Implementation of the Project QA program as established and managed by the Integrating Contractor, and

c. Selected activities throughout the Project, with emphasis on performance of major contractors in their implementation of the Project QA program as it applies to them and on effectiveness of contractor audit programs.

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

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

18.2 AUDIT PROGRAM CONTENT

QA audit within the BWI Project addresses the following questions:

a. Is the audited participant carrying out his approved QA program?

b. Are the controls and/or control systems defined in the audited participant's QA program working effectively?

c. Does the record provide convincing objective evidence that the controls and/or control systems have been, and are being, rigorously applied (i.e., that a rigorous forensic record is being compiled)?

d. Does the audited participant exhibit an acceptable degree of procedural discipline?

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

18.3 AUDIT SCHEDULING

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

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

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

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

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

18.4 AUDITOR QUALIFICATION

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

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

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

18.5 AUDIT PREPARATION

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

18.6 AUDIT PERFORMANCE

Audits are performed to check lists or procedures prepared or identified during audit preparation and will include compliance and product oriented auditing. Conditions observed during performance of a part of the audit may open additional areas of interest or may warrant a change of emphasis. However, if such conditions are outside the scope of the audit, 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 shall not interfere with proper accomplishment of the objectives of the audit in work.

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

18.7 AUDIT REPORTS

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

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

18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS

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

Typical situations justifying this approach include the following:

a. Academic institutions

b. Government agencies participating under memoranda of understanding

c. Small specialized organizations or individual contributors (such that no uninvolved staff is available for auditing)

18.9 SURVEILLANCE - GENERAL

Each Project participant who is required to conduct a QA audit program shall also develop and implement an approved surveillance plan, which shall 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 should bear a clear relationship to the field under surveillance. QA personnel performing surveillance of controls applied to technical activities are not required to be qualified in the technical discipline(s) involved.

18.11 AMC QS DIVISION SURVEILLANCE

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

18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS

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

18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES

18.13.1 By Audited or Surveilled Activity

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

18.13.2 By Auditing or Surveilling Organization

The auditing or surveilling QA organization shall:

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

b. Confirm timely implementation of approved corrective action(s).

c. Verify that the corrective action was effective in preventing recurrence.

d. Results of QA evaluations are provided to responsible management as described in Section 18.7.

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

APPENDIX A: CLARIFICATIONS TO THE NRC REVIEW PLAN

PREAMBLE

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

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

1. Almost all controls that make up the quality assurance program are exercised by line organizations of the participant contractors. Nothing in the working of regulatory requirements or DOE QA program descriptions should give the appearance of relieving the highest line official of responsibility for effective implementation of those controls.

2. The highest ranking DOE QA official on the project should be held accountable for QA functions, as defined in Criterion I of 10 CFR 50 Appendix B. That official should be at a level in the organization that provides sufficient authority so that he or she can deal directly and effectively with the top line official and so that communication concerning status and effectiveness of the QA program produces timely, appropriate line action.

CLARIFICATIONS TO NRC REVIEW PLAN

1. NRC REVIEW PLAN SECTION 1.1

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

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/RL AMC Basalt Waste Isolation Division technical staff monitoring (surveillance) and review. Surveillance includes evaluation of contractor technical performance and of the effectiveness of controls under which the work is performed. The BWI Division technical staff is not normally involved in direct project work, but exercises technically oriented management functions with line organizations performing quality affecting activities. Thus, verification of proper performance of work is not limited to the DOE-RL AMC QS Division as the BWI Division also does verification of technical adequacy in their technical management role.

The BWIP Project organization is described in section 1.0 of the QA Plan. The Integrating Contractor as described in section 1.23 is the Westinghouse Hanford Company (WHC) in a joint venture consolidated with Boeing Computer Services Richland manages for DOE-RL AMC the BWIP. In addition they perform direct work in the Science, Engineering, Licensing, computer service, configuration management, information & records management, and direct and perform site characterization activities including the near surface test facilities and geotechnical research and testing. Pacific Northwest Laboratories, the Laboratory Support Contractor described in Section 1.2.4, performs research and test activities related to the site characterization, waste package and waste package container development. The architect/engineer is a joint venture company Kaiser Engineers, Inc./Parsons Brinckerhoff, Quade & Douglas, Inc. (KE/PB) who performs engineering studies and design services for the repository, explora-tory shaft, waste package, and repository surface facilities. The Construction Management Contractor is Morrison Knudsen Company, Inc. who is responsible for the planning and construction of the design work performed by KE/PB when construction is scheduled. In addition to the field and laboratory testing performed for the Integrating Contractor, the Laboratory Support Contractor performs the environmental and socio-economic studies for the Basalt Waste Isolation Project.

2. NRC REVIEW PLAN, SECTION 3.6

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

Clarification

Contractor design control procedures will require that design drawings, specifications, criteria, and analyses be reviewed by the contractor QA organization to assure that the documents are prepared, reviewed, and

approved in accordance with documented procedures and quality assurance requirements.

3. NRC REVIEW PLAN, SECTION 14.1

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

Clarification

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

4. NRC REVIEW PLAN, SECTION 16.2

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

Clarification

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

5. NRC REVIEW PLAN, SECTION 16.4

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

Clarification

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