See Docket 1 for end. 101.7

PDR-1
LPDR
WM-10 (2)
E3 WM-11 (2)
WM-16 (2)

RL F 1325.6 (5-87)

United States Government | Department of Energy

memorandum

Richland Operations Office

DATE: JUL 21 1987

87-QSD-198

REPLY TO ATTN OF: QSD:RPS

SUBJECT: RESPONSE TO THE NRC'S REQUEST FOR INFORMATION AND REV. 3 OF OUR QUALITY ASSURANCE PLAN

TO: J. P. Knight, Director, Siting, Licensing and Quality Assurance, HQ

In accordance with your memorandums of June 1 and 15, 1987, we have reviewed the NRC's comments on Rev. 1 of our QA Plan (DOE/RL 86-6).

Enclosed is our response to the NRC's Request for additional information and Rev. 3, of our QA Plan. The document entitled "Response to NRC" provides our response to each of the NRC's comments. The questions are in bold type. These responses were discussed with Mr. Carl Newton of your staff on June 3, 1987. Rev. 3, of our BWIP QA Plan, incorporates the necessary changes to resolve the NRC's comments.

We have enclosed two copies of each of the documents, one for your review and approval, the other to be forwarded to the NRC. Your assistance in obtaining the NRC's acceptance of the methods, in which we have resolved their comments, will be appreciated.

If you have any questions, please contact myself or Mr. C. K. Kasch of my staff.

8709290303 870721
PDR WASTE
WM-10 PDR

R. P. Saget

R. P. Saget, Director
Quality Systems Division

Enclosures

cc: J. A. Dawson, WHC/Licensing

WM DOCKET CONTROL CENTER
'87 AUG -3 A10:18

WM Record File 101.7

WM Project 10
Docket No.
PDR ✓
LPDR ✓

Distribution:
Kennedy
Riddle
(Return to WM, 623-SS)
Dellingatti
RDM
Donnelly
Linehan

87236902
WM Project: WM-10
PDR w/encl
(Return to WM, 623-SS)

WM Record File: 101.7
LPDR w/encl

1456

2580

encl. to 7/21/87 Memorandum to JP Knight - Response to NRC's request for Info and Rev. 3 of the QA Plan 101.7

RESPONSE TO NRC

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

1. The BWI Project Quality Assurance Plan was written prior to the following NRC June 1986 draft generic technical positions (GTPs):

   a. Peer review.

   b. Qualification of existing data.

   c. Items and activities subject to QA requirements.

   An evaluation should be made against the draft guidance of these GTPs, and differences between the plan and the draft GTPs should be addressed.

RESPONSE (1)

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

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

RESPONSE (3)

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

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

RESPONSE (2) (3)

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

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

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

RESPONSE (3)

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

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

RESPONSE (3)

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

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

RESPONSE (2)

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

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

RESPONSE (2,3)

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

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

RESPONSE (2)

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

9. Identify a management position within DOE-RL, the Integrating Contractor, Architect/Engineer, and Construction Manager organizations that retains overall authority and responsibility for the applicable QA program. Describe the management, QA, and technical experience and knowledge requirements for these positions. Verify that each of these positions has the following characteristics:

   a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

   b. Has effective communication channels with other senior management positions.

   c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.

   d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10)

RESPONSE (2)

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

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

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

10. Describe measures which ensure that persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

    a. Identify quality problems.

    b. Initiate, recommend, or provide solutions through designated channels.

    c. Verify implementation of solutions.

    Describe how these actions are accomplished. (1.12)

RESPONSE (3)

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

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

RESPONSE (3)

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

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

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

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

RESPONSE (3)

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

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

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

RESPONSE (2)

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

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

RESPONSE (3)

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

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

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

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

RESPONSE (3)

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

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

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

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

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

RESPONSE (2)

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

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

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

RESPONSE (3)

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

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

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

RESPONSE (3)

Section 3.4 in Revision 3 has been changed to read:

> "f. Documented independent design verification."

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

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

RESPONSE (3)

Section 3.6 in Revision 3 has been revised as follows:

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

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

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

RESPONSE (3)

Section 5.0 has been revised and clarified.

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

RESPONSE (3)

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

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

RESPONSE (2)

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

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

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

RESPONSE (3)

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

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

RESPONSE (3)

Section 7.3.1 of the QA Plan has been revised.

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

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

RESPONSE (3)

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

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

RESPONSE (3)

Section 9.2 has been revised.

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

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

RESPONSE (3)

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

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

RESPONSE (2)

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

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

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

RESPONSE (2)

Section 10.2 has been revised and clarified.

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

RESPONSE (2)

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

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

RESPONSE (3)

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

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

RESPONSE (2,3)

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

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

RESPONSE (2)

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

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

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

RESPONSE (2)

Section 15.2 has been revised.

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

RESPONSE (2)

This is covered in Section 15.2.

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

RESPONSE (3)

Section 15.4 in Revision 3 has been clarified as follows:

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

38. Describe measures which ensure that the significance of each

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

RESPONSE (2)

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

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

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

RESPONSE (3)

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

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

RESPONSE (3)

Sections 17.1 and 17.4 in Revision 3 requires the following:

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

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

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

RESPONSE (3)

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

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

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

RESPONSE (3)

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

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

RESPONSE (3)

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

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

RESPONSE (3)

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

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

RESPONSE (2)

Section 18.0 has been revised.

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

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

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

RESPONSE (3)

This clarification has been revised.

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

RESPONSE (2)

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

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

RESPONSE (2)

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

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

RESPONSE (2)

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

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

Response (2)

Clarification has been deleted. Section 9.2 addresses this subject.

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

Response (2)

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

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN

REVISION 3

EFFECTIVE DATE:_____

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

RECOMMENDED FOR APPROVAL _____
R. P. Saget, Director
Quality Systems Division

APPROVED _____
J. H. Anttonen, Assistant Manager
for Commercial Nuclear Waste

APPROVED _____
Associate Director
Office of Geologic Repositories

BASALT WASTE ISOLATION PROJECT

QUALITY ASSURANCE PLAN, REV. 3

TABLE OF CONTENTS

POLICY STATEMENT vii

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. 3
1.2.5 Project Participants on Subcontract 3
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. 6

1.4 QA INTERFACE WITH DOE HEADQUARTERS 7

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 17
2.2.3.2 QL-2 18
2.2.3.3 QL-3 18

TABLE OF CONTENTS

2.2.4 AMC Evaluation Role 18

2.3 INDOCTRINATION, TRAINING AND QUALIFICATION 19

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

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS. 20

2.5 PROJECT QUALITY ASSURANCE STATUS REPORTING 20

2.5.1 Report Content. 21
2.5.2 Submittal Requirements. 21

3.0 DESIGN CONTROL. 31

3.1 POLICY 31

3.2 COMPUTER SOFTWARE. 31

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION 31

3.3.1 Design Control versus Test Control. 31
3.3.2 Existing Data 32
3.3.3 Current Data. 32
3.3.4 Published Studies 33

3.4 DESIGN CONTROLS FOR SITE CHARACTERIZATION STUDIES AND DESIGN OF EQUIPMENT, FACILITY, WASTE FORM AND WASTE PACKAGING 33

3.4.1 Design Verification by Formal Design Review 34
3.4.2 Design Verification by Testing. 34
3.4.3 Design Verification by Alternate Calculations 34
3.4.4 Design Verification by Similarity 34

3.5 PEER REVIEW. 35

3.6 DESIGN CHANGES 35

3.7 DESIGN INTERFACES. 35

3.8 REVIEW PLAN. 35

3.9 AMC COGNIZANCE 36

3.9.1 DOE-RL AMC Technical Surveillance 36
3.9.2 DOE-RL AMC Participation in Peer Reviews. 36
3.9.3 Document Review 36
3.9.4 Documented Review Meetings 37

TABLE OF CONTENTS

3.9.5 AMC QS Division Audit and Surveillance of Design Controls 37
3.9.6 Readiness Reviews 37

4.0 PROCUREMENT DOCUMENT CONTROLS 38

4.1 PROJECT PARTICIPANTS 38

4.2 INTEGRATING CONTRACTOR ROLE. 38

4.3 AMC EVALUATION ROLE. 39

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS 40

5.1 ADMINISTRATIVE PROCEDURES. 40

5.2 TECHNICAL PROCEDURES 40

5.3 INSTRUCTIONS 40

5.4 DRAWINGS 41

5.5 ACCEPTANCE CRITERIA. 41

5.6 USE AND AVAILABILITY 41

5.7 AMC PREPARATION OF BASALT PROCEDURES (BPs) 42

6.0 DOCUMENT CONTROL. 43

6.1 CONTROL ELEMENTS 43

6.2 AMC DOCUMENT CONTROL 43

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL 44

6.3.1 AMC QA Documents. 44
6.3.2 Integrating Contractor, Construction Management Contractor and Architect/Engineer Documents 44
6.3.3 Other Participants' Documents 44
6.3.4 Technical Documents 44

6.4 REVIEW AND APPROVAL PROCESS. 44

6.5 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS. 45

6.6 CONFIGURATION MANAGEMENT 45

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES 46

7.1 SUPPLIER QA PROGRAMS 46

TABLE OF CONTENTS

7.2 SUPPLIER SELECTION AND EVALUATION. 46

7.3 VERIFICATION 47

7.3.1 Verification of Work in Progress. 47
7.3.2 Acceptance. 47

7.4 SUPPLIER-FURNISHED DOCUMENTATION 48

7.5 AMC CONTROL OF PURCHASED ITEMS AND SERVICES. 48

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES. 49

9.0 CONTROL OF SPECIAL PROCESSES. 50

9.1 SPECIAL PROCESS - DEFINITION 50

9.2 IDENTIFICATION AND QUALIFICATION 50

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES. 50

9.4 STANDARD "SPECIAL PROCESSES" 50

10.0 INSPECTION. 52

10.1 INSPECTION ACTIVITIES. 52

10.2 INSPECTOR QUALIFICATION. 52

10.3 RESPONSIBILITIES 52

10.4 INSPECTION PROCEDURES. 53

10.5 INSPECTION RESULTS 53

10.6 DOCUMENTATION AND RECORDS. 54

11.0 TEST CONTROL. 55

11.1 TEST ACTIVITIES. 55

11.2 TEST PLANS AND PROCEDURES REVIEW 55

11.3 UNCERTAINTIES AND ERROR. 55

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION. 56

11.5 PERSONNEL QUALIFICATION. 56

11.6 TEST PROCEDURE CONTENT 56

TABLE OF CONTENTS

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE 57

11.8 DOE-RL AMC TEST CONTROL RESPONSIBILITIES 57

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE). 58

12.1 CALIBRATION PROGRAM. 58

12.2 QA INVOLVEMENT 58

12.3 DOE AMC OVERVIEW 58

13.0 HANDLING, STORAGE AND SHIPPING OF ITEMS, MATERIALS AND SAMPLES. 59

14.0 INSPECTION, TEST AND OPERATING STATUS 60

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES 61

15.1 IDENTIFICATION AND CONTROL 61

15.2 EVALUATION AND DISPOSITION 61

15.3 ACCOMPLISHMENT OF DISPOSITIONS 62

15.4 TRENDS 62

16.0 CORRECTIVE ACTION 63

16.1 CORRECTIVE ACTION PROGRAM. 63

17.0 RECORDS MANAGEMENT. 64

17.1 RECORDS MANAGEMENT SYSTEM. 64

17.2 DOE-RL AMC RECORDS 64

17.3 ARCHIVAL FACILITY. 65

17.4 RECORDS PROGRAM OVERVIEW 65

18.0 AUDIT AND SURVEILLANCE. 66

18.1 AUDIT - GENERAL 66

18.2 AUDIT PROGRAM CONTENT 66

18.3 AUDIT SCHEDULING 67

18.4 AUDITOR QUALIFICATION 68

18.5 AUDIT PREPARATION 68

TABLE OF CONTENTS

18.6 AUDIT PERFORMANCE 68

18.7 AUDIT REPORTS 69

18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS 69

18.9 SURVEILLANCE - GENERAL 69

18.10 QUALIFICATION FOR SURVEILLANCE 70

18.11 AMC QS DIVISION SURVEILLANCE 70

18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS 70

18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES 70

18.13.1 By Audited or Surveilled Activity 70
18.13.2 By Auditing or Surveilling Organization 71

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 . . . 22

TABLE 2-2 Matrix: NRC Review Plan vs QAP 23

TABLE 2-3 Matrix: BWIP QA Program Responsibility Matrix 30

APPENDIX

APPENDIX A Clarifications to Requirements Documents. 72

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.

1.2 BASALT WASTE ISOLATION PROJECT ORGANIZATION RESPONSIBILITIES

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

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

1.2.2 Project

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

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

1.2.3 Integrating Contractor

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.2.5 Project Participants on Subcontract

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

1.2.6 Stop Work Authority

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

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

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

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

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

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

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

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

1.2.7 Resolution of Disputes Involving Quality

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

1.3 DOE-RL INTERNAL ORGANIZATION FOR AMC PROJECT QUALITY ASSURANCE

1.3.1 AMC BWIP Organization

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

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

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

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

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

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

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

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

e. Effectively implementing the quality assurance program.

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

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

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

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

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

1.3.2 AMC BWI Division

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

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

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

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

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

1.3.3 AMC Quality Systems Division

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.4 QA INTERFACE WITH DOE HEADQUARTERS

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

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

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

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

1.5 INTERDIVISION INTERFACES WITHIN DOE-RL

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

a. Procurement Division (PRO)

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

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

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

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

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

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

b. Personnel Division

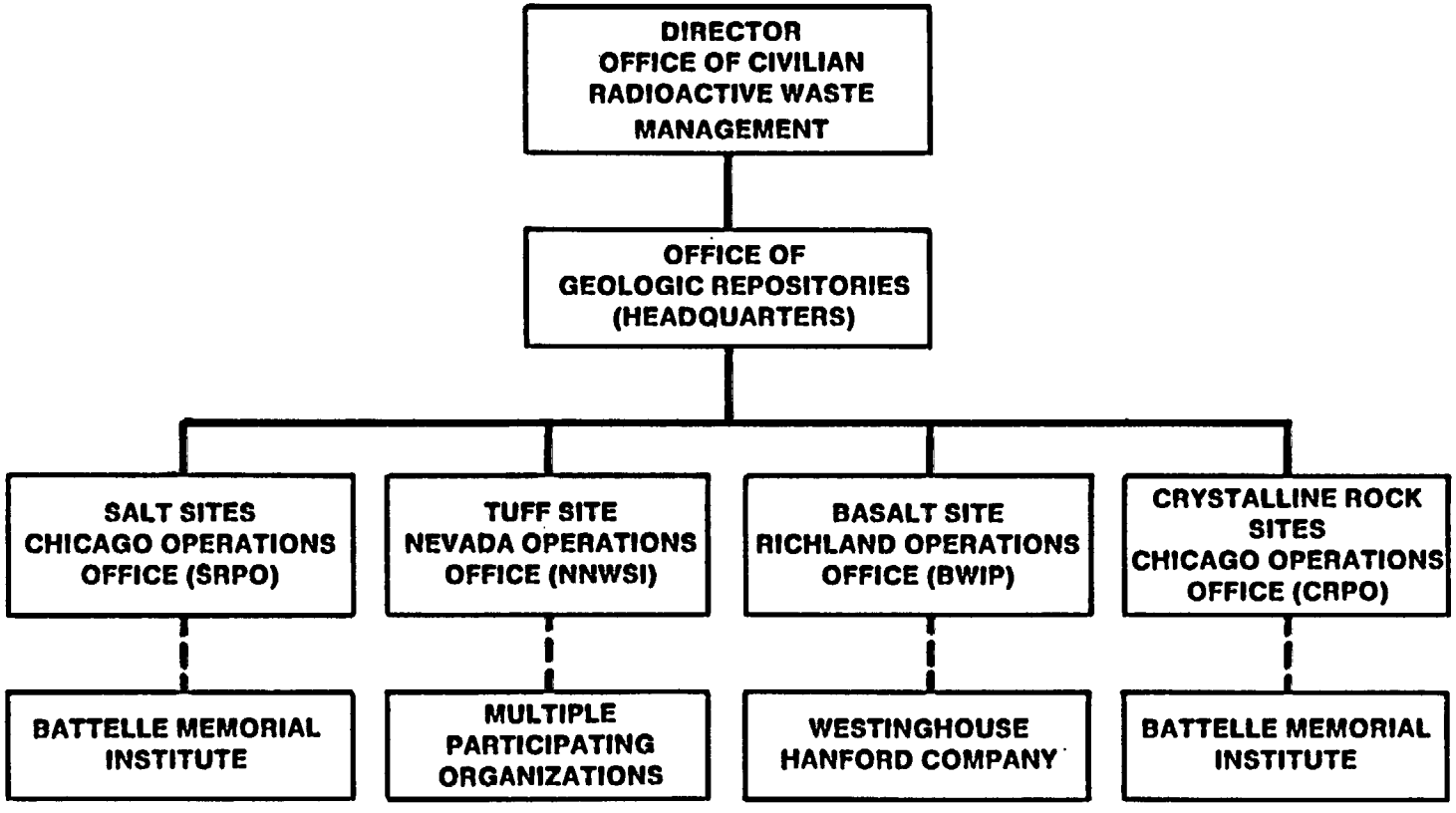
AMC relies on the Director, Personnel Division, to provide personnel for AMC positions and to verify that such personnel meet applicable position qualification requirements defined by the AMC Divisions.

c. ES&H Division

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

FIGURE 1-1

GEOLOGIC REPOSITORY PROGRAM



LEGEND:

——— PROGRAM/PROJECT MANAGEMENT RESPONSIBILITY

— — — MAJOR CONTRACTOR SUPPORT

FIGURE 1-2

BWI PROJECT ORGANIZATION

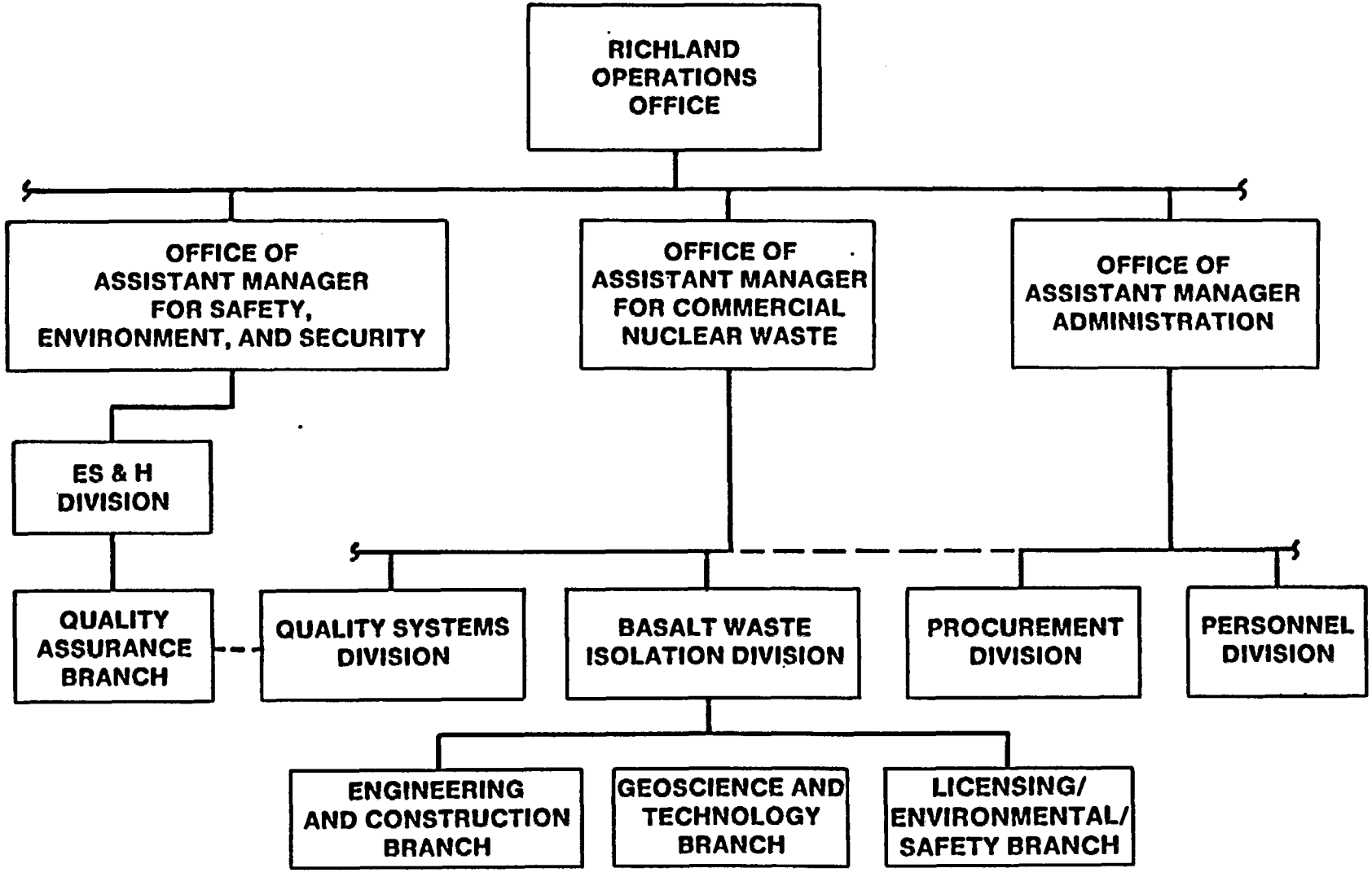


FIGURE 1-3
BWI PROJECT QA PROGRAM MANAGEMENT RESPONSIBILITIES

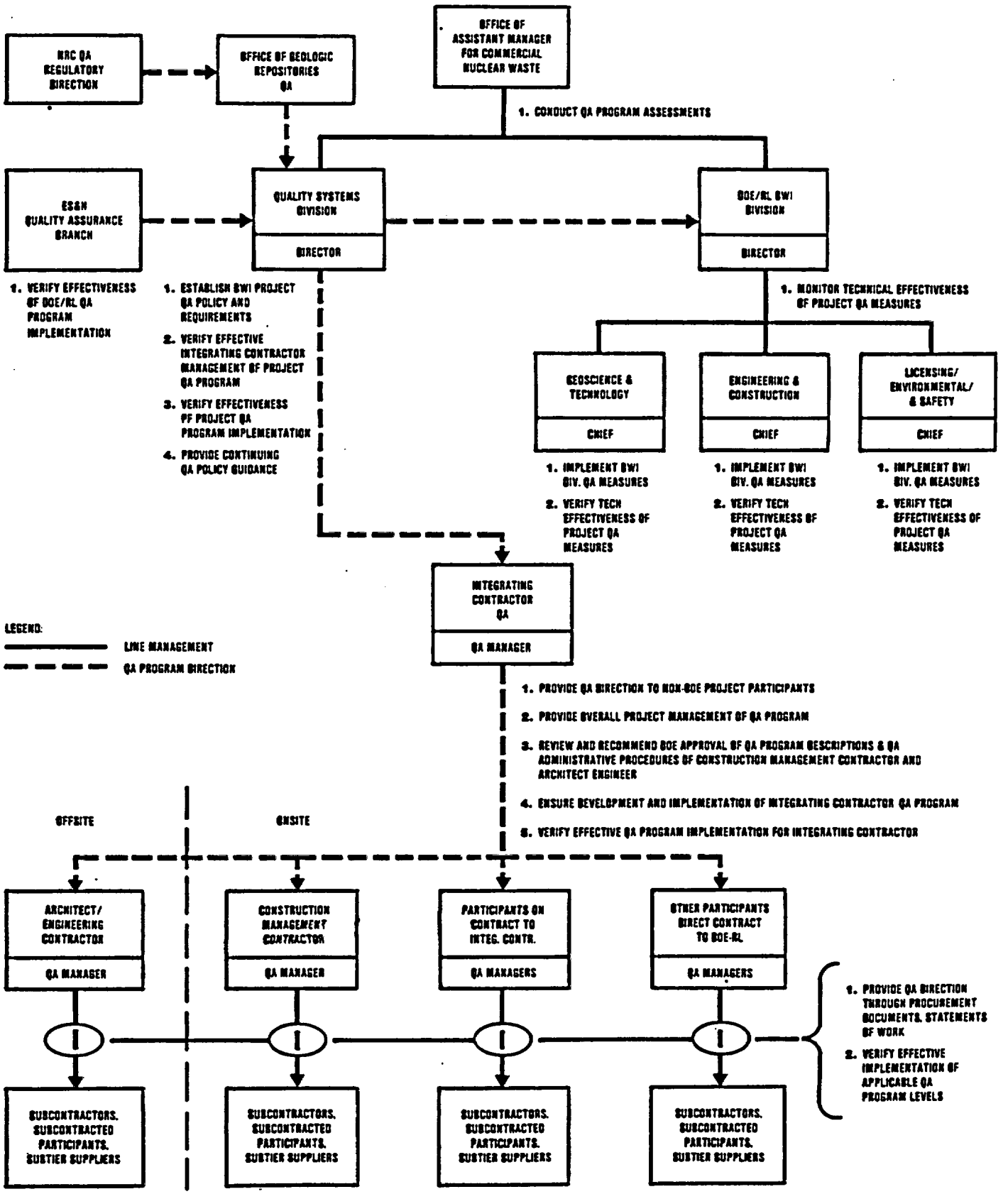
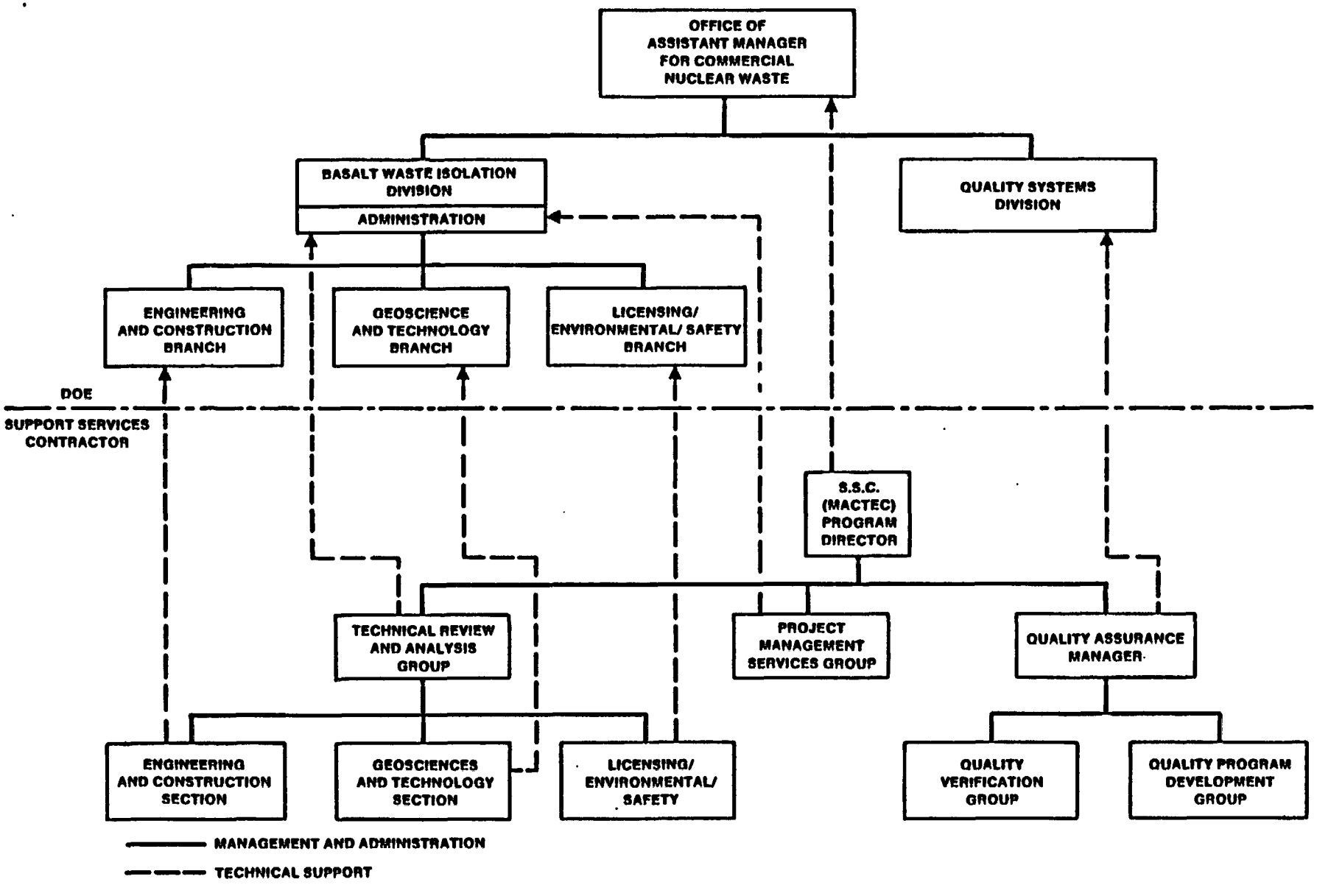


FIGURE 1-4

BWI PROJECT ORGANIZATION WITH SUPPORT SERVICES CONTRACTOR



2.0 QUALITY ASSURANCE PROGRAM

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

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

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES

a. DOE Order 5700.6B, Quality Assurance

b. DOE/RL Order 5700.1A, Quality Assurance

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

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

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

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

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

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

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

j. DOE Order 4700.1, Project Management System.

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

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

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

2.2 BWI PROJECT QA PROGRAM STRUCTURE AND EXECUTION

2.2.1 QA Program Controls

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

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

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

2.2.2 Project QA Program Documentation

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

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

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

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

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

2.2.3 Graded Quality Assurance

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

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

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

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

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

2.2.3.1 QL-1

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

All Q-List Items/Activities.

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

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

2.2.3.2 QL-2

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

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

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

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

2.2.3.3 QL-3

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

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

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

2.2.4 <u>AMC Evaluation Role</u>

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

2.3 INDOCTRINATION, TRAINING AND QUALIFICATION

2.3.1 Indoctrination

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

2.3.2 Training

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

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

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

2.3.3 Qualification

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

Qualification in the "designated skills" indicated above is established by education and/or training, evaluation of credentials, and demonstration of the specific capabilities in question. Such special skills qualification is certified by specifically authorized individuals, and certifications become part of the record that substantiates work performed by those personnel. For NDE inspection acceptance, the inspection personnel shall be certified as Level II or higher in accord with SNT-TC-1A.
Qualification of individuals in job assignments is assured by use of valid position descriptions, verification of qualification evidence submitted or referenced by the position applicant or incumbent, and continuing management evaluation of performance. Individual task assignments require supervisory matching of personnel qualifications to the needs of the specific task.

2.3.4 Documentation and Records

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

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

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

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

2.5 PROJECT QUALITY ASSURANCE STATUS REPORTING

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

2.5.1 Report Content

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

- 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
- Results and/or issues raised based upon interactions with major contractors, the regulatory agencies, etc.
- Results of any management assessment activity.

2.5.2 Submittal Requirements

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

TABLE 2-1

DOE-RL AMC BWI PROJECT QA ADMINISTRATIVE PROCEDURES

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

TABLE 2-2

REQUIREMENTS MATRIX

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

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

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

Responsible organizations:

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

Responsibility:

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

3.0 DESIGN CONTROL

3.1 POLICY

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

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

3.2 COMPUTER SOFTWARE

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

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION

3.3.1 Design Control versus Test Control

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

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

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

3.3.2 Existing Data

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

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

3.3.3 Current Data

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

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

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

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

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

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

3.3.4 Published Studies

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

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

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

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

b. Documentation of design assumptions, including rationale,

c. Approved and correct computer software and controls,

d. Competent checking and independent review,

e. Approval by designated authority,

f. Documented independent design verification,

g. Control of design interfaces,

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

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

3.4.1 Design Verification by Formal Design Review

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

3.4.2 Design Verification by Testing

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

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

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

3.4.3 Design Verification by Alternate Calculations

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

3.4.4 Design Verification by Similarity

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

3.5 PEER REVIEW

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

3.6 DESIGN CHANGES

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

3.7 DESIGN INTERFACES

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

3.8 REVIEW PLAN

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

3.9 AMC COGNIZANCE

3.9.1 DOE-RL AMC Technical Surveillance

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

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

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

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

3.9.2 DOE-RL AMC Participation in Peer Reviews

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

3.9.3 Document Review

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

3.9.4 Documented Review Meetings

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

3.9.5 AMC QS Division Audit and Surveillance of Design Controls

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

3.9.6 Readiness Reviews

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

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

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

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

4.0 PROCUREMENT DOCUMENT CONTROLS

4.1 PROJECT PARTICIPANTS

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

a. Procurement planning,

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

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

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

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

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

4.2 INTEGRATING CONTRACTOR ROLE

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

4.3 AMC EVALUATION ROLE

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

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

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

5.1 ADMINISTRATIVE PROCEDURES

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

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

5.2 TECHNICAL PROCEDURES

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

5.3 INSTRUCTIONS

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

5.4 DRAWINGS

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

5.5 ACCEPTANCE CRITERIA

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

5.6 USE AND AVAILABILITY

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

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

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

5.7 AMC PREPARATION OF BASALT PROCEDURES (BPs)

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

6.0 DOCUMENT CONTROL

6.1 CONTROL ELEMENTS

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

a. Identification of documents to be controlled,

b. Identification of responsibility assignments for preparing, reviewing, approving and issuing documents,

c. Review of documents and document changes for adequacy, completeness and correctness prior to approval and issuance,

d. Coordination and control of interface documents,

e. Availability of correct and applicable documents at the work place,

f. Ascertaining that proper documents are being used,

g. Ensuring that obsolete or superseded documents are not available for inadvertent use,

h. Establishment and maintenance of up-to-date distribution lists,

i. An effective way for document users to determine whether a document is current and in effect, and

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

6.2 AMC DOCUMENT CONTROL

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

6.3 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL

6.3.1 AMC QA Documents

The BWI Project QA Plan, the 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.

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

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

7.3 VERIFICATION

7.3.1 Verification of Work in Progress

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

7.3.2 Acceptance

Acceptance of completed items or services is accomplished as follows:

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

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

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

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

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

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

7.4 SUPPLIER-FURNISHED DOCUMENTATION

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

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

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

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

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

7.5 AMC CONTROL OF PURCHASED ITEMS AND SERVICES

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

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

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS AND SAMPLES

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

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

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

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SPECIAL PROCESS - DEFINITION

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

9.2 IDENTIFICATION AND QUALIFICATION

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

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES

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

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

9.4 STANDARD "SPECIAL PROCESSES"

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

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

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

10.0 INSPECTION

10.1 INSPECTION ACTIVITIES

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

a. Source inspection during designated procurements,

b. Receipt inspection for procured items and materials,

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

d. Inspection of samples.

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

10.2 INSPECTOR QUALIFICATION

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

10.3 RESPONSIBILITIES

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

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

10.4 INSPECTION PROCEDURES

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

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

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

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

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

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

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

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

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

h. Date of inspection.

10.5 INSPECTION RESULTS

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

10.6 DOCUMENTATION AND RECORDS

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

11.0 TEST CONTROL

11.1 TEST ACTIVITIES

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

11.2 TEST PLANS AND PROCEDURES REVIEW

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

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

11.3 UNCERTAINTIES AND ERROR

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

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION

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

11.5 PERSONNEL QUALIFICATION

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

11.6 TEST PROCEDURE CONTENT

Test procedures shall include as appropriate the following elements:

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

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

c. Instructions for performing the test.

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

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

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

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

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

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE

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

a. A description of the type of observation,

b. The date and results of the test,

c. Information related to conditions adverse to quality,

d. Data recorder identify,

e. Evidence as to acceptability of results, and

f. Action taken to resolve any discrepancies noted.

11.8 DOE-RL AMC TEST CONTROL RESPONSIBILITIES

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

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

12.1 CALIBRATION PROGRAM

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

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

12.2 QA INVOLVEMENT

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

12.3 DOE AMC OVERVIEW

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

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

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

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

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

14.0 INSPECTION, TEST AND OPERATING STATUS

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

a. Ensuring that required inspections or tests, or required inspection or test steps, are not inadvertently bypassed, and

b. Ensuring that personnel working on, or in the vicinity of, site characterization test or operating equipment are aware of the operating status of the equipment.

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

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

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES

15.1 IDENTIFICATION AND CONTROL

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

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

15.2 EVALUATION AND DISPOSITION

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

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

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

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

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

15.3 ACCOMPLISHMENT OF DISPOSITIONS

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

15.4 TRENDS

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

16.0 CORRECTIVE ACTION

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

16.1 CORRECTIVE ACTION PROGRAM

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

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

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

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

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

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

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

17.0 RECORDS MANAGEMENT

17.1 RECORDS MANAGEMENT SYSTEM

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

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

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

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

17.2 DOE-RL AMC RECORDS

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

17.3 ARCHIVAL FACILITY

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

17.4 RECORDS PROGRAM OVERVIEW

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

18.0 AUDIT AND SURVEILLANCE

18.1 AUDIT - GENERAL

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

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

AMC QS Division audits Project activities indicated below:

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

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

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

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

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

18.2 AUDIT PROGRAM CONTENT

QA audit within the BWI Project addresses the following questions:

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

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

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

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

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

18.3 AUDIT SCHEDULING

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

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

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

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

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

18.4 AUDITOR QUALIFICATION

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

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

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

18.5 AUDIT PREPARATION

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

18.6 AUDIT PERFORMANCE

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

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

18.7 AUDIT REPORTS

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

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

18.8 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS

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

Typical situations justifying this approach include the following:

a. Academic institutions

b. Government agencies participating under memoranda of understanding

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

18.9 SURVEILLANCE - GENERAL

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

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

a. Actual observation of the physical performance of work,

b. Observation of the work place for presence of suitable conditions and adequate housekeeping and safety measures,

c. Observation of related access control, fire prevention provisions, etc.,

d. Review or spot checks of documents in preparation,

e. Review or spot checks of procedures or instructions governing the work,

f. Evaluation or verification of the presence and effectiveness of applicable controls, and

g. Discussion with personnel performing or supervising the work.

18.10 QUALIFICATION FOR SURVEILLANCE

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

18.11 AMC QS DIVISION SURVEILLANCE

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

18.12 SURVEILLANCE ACTIVITIES BY PROJECT PARTICIPANTS

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

18.13 AUDIT AND SURVEILLANCE FOLLOW-ON ACTIVITIES

18.13.1 By Audited or Surveilled Activity

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

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

18.13.2 By Auditing or Surveilling Organization

The auditing or surveilling QA organization shall:

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

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

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

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

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

APPENDIX A: CLARIFICATIONS TO THE NRC REVIEW PLAN

PREAMBLE

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

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

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

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

CLARIFICATIONS TO NRC REVIEW PLAN

1. NRC REVIEW PLAN SECTION 1.1

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

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

6. NRC REVIEW PLAN, SECTION 3.6

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

Clarification

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

10. NRC REVIEW PLAN, SECTION 14.1

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

Clarification

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

11. NRC REVIEW PLAN, SECTION 16.2

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

Clarification

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

12. NRC REVIEW PLAN, SECTION 16.4

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

Clarification

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

RECORD OF CORRESPONDENCE CONCURRENCE AND DISTRIBUTION

SUBJECT: Computerized file system for OGR QA Records

FROM: Carl Newton

TO: James P. Knight

PC CODE: CN141 (MARIE ADAMS' IBM)

ORIGINATOR: CARL NEWTON, 6-5059

DISTRIBUTION

QA FILE # F1
OCRWM CCRU, RW-13 (5)
OCRWM ARCHIVES (2)
ORIGINATOR'S CHRON: NEWTON
OGR READING FILE
S,L,& QA DIV CHRON
* K. Sommer, RW-24
~~J. Knight, RW-24~~
M. E. Langston, RW-40
H. Steinberg, RW-33
S. Echols, GC-11
R. Poe, EH-32
L. Barrett, RW-33

D. Siefken, Weston
L. Skoblar, Weston
* G. Faust, Weston
~~J. Kennedy, NRC~~

CONCURRENCES:

C. Newton 7/16/87
C. Newton, RW-24

* with copy of attachments (file listing)

DOE F 1325.8
(12-84)

United States Government **Department of Energy**

memorandum

DATE: JUL 16 1987

REPLY TO ATTN OF: RW-24

SUBJECT: Computerized File System for OGR QA Records

TO: James P. Knight, RW-24

Attached is a listing of all the OGR Quality Assurance Subject File Categories (on the sheet labeled OGR Quality Assurance Document File System - March 27, 1987).

Also attached are two computer listings of all the material we have placed into the OGR QA files since we began keeping a computerized data base (April, 1985). We have kept all outgoing correspondence as well as significant incoming material. One of the attached listings is by subject file category the other listing is by date.

Beginning in April of 1985 we also discontinued physically placing mater into subject file folders. Instead, each piece of incoming and outgoing correspondence is assigned a number (item number) which was marked in the lower right corner of the front sheet and the material was then filed in item number sequence. Each file folder was labeled wi the beginning and ending item numbers of material in the folder. Each file drawer in the file cabinet was likewise labeled.

This makes retrieval of material very fast, providing one knows the item number. It also makes one absolutely dependent on the computer. For this reason, our computer data base is updated weekly, a duplicate copy on a floppy diskette made, and a copy put on Marie Adams' computer. With the material in these three locations (my computer, Marie's computer, and a floppy diskette) we feel secure against losing it.

There are many ways the material in our data base can be accessed, sorted, and printed out. The only two regular printed report listings I make are by date and by subject file category. One can also do searches, of course, using: a key word for a subject; or the name of the person the correspondence was sent to (or from), or a range of dates. Other searches are limited only by one's imagination. In the event Karl Sommer and myself were both out of the office, anyone familiar with the DBASE III computer program could also assist in on-line searches. The computer program name is "Q". It is a data base file. There are six fields in the data base file as follows:

Field	Field Name	Width	Information in Field
1	FRM	18	WHO FROM
2	TO	18	WHO TO
3	SUBJECT	136	SUBJECT
4	ITEMNBR	6	ITEM NUMBER
5	FILECAT	6	OGR QA FILE CATEGORY
6	MO-DAY-YR	8	DATE OF MEMO

There are three indexed data bases also in the computer:

1 BYDATE (indexed by the date of the correspondence)
2 BYFILE# (indexed by both file category and date)
3 BYItEM# (indexed by assigned item number)

I would be happy to give you a demonstration of the system or answer any questions you may have.

Carl Newton

Carl Newton, RW-24

Attachments

OGR Quality Assurance Document File System - March 27, 1987

A - Policy & Guidance
- A1 - DOE
- A2 - OCRWM
- A3 - OGR
- A4 - NRC

B - Milestones/Reports/Budget
- B1 - QA Weekly Highlights
- B2 - Quarterly QA Status Rpts
- B3 - Weekly Action Tracking

C - Weston: Cost/Schedule

D - Briefings/Papers

E - QA Plans
- E1 - OCRWM
- E2 - OGR
- E3 - BWIP
- E4 - WMPO
- E5 - SRPO
- E6 - CRPO
- E7 - OSTS

F - QA Procedures
- F1 - OGR
- F2 - BWIP
- F3 - WMPO
- F4 - SRPO
- F5 - CRPO
- F6 - OSTS

G - Auditor Training
- G1 - Courses
- G2 - Certification Records

H - OGR Staff Training

I - Audit Records
- I1 - OGR Audits
  - I1A - Internal
  - I1B - of BWIP
  - I1C - of WMPO
  - I1D - of SRPO
  - I1E - of CRPO
- I2 - OGR Staff on Proj Audits
- I3 - Proj Audits of Contractors
  - I3A - Summaries/Schedules
  - I3B - BWIP
  - I3C - WMPO
  - I3D - SRPO
  - I3E - CRPO

J - Problem Reporting/Stop Work
- J1 - OGR
- J2 - BWIP
- J3 - WMPO
- J4 - SRPO
- J5 - Status Reports
- J6 - OSTS

K - NRC QA Interactions

L - QA Coordinating Group (QACG)
- L1 - Charter
- L2 - Correspondence
- L3 - Meeting Minutes
- L4 - Monthly Newsletter
- L5 - State/Tribe Interactions

M - Other QA Interactions
- M1 - Project Manager Meeting
- M2 - Input to Mission Plan
- M3 - Input to EA's
- M4 - Input to SCP's
- M5 - QA Handbook for Geo Inv
- M6 - Q-List Methodology
- M7 - Graded QA
- M8 - Defense Waste Interactions

N - Q-List for OGR

P - Safety Plans
- P1 - OCRWM
- P2 - OGR
- P3 - BWIP
- P4 - WMPO
- P5 - SRPO
- P6 - OSTS

Q - Tech Code Coord Group