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Site Char. Sec. 8.6 rec'd 1/5/87
101.8

CONTROLLED DRAFT 0
DECEMBER 15, 1986

SITE CHARACTERIZATION PLAN

Chapter 8 - SITE CHARACTERIZATION PROGRAM

Section 8.6 Quality Assurance Program

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8.6 QUALITY ASSURANCE PROGRAM

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8.6.0 INTRODUCTION

Section 8.6 of the Site Characterization Plan for the Basalt Waste Isolation Project (BWIP) describes the quality assurance program that will ensure the quality of work and activities conducted by the U.S. Department of Energy-Richland Operations Office (DOE-RL) and BWIP participant contractors during the site characterization phase of the BWIP. Site characterization, which commenced on May 28, 1986, involves the performance of laboratory and field investigations involving various technical areas such as geology, hydrology, seismology, geophysics, geochemistry, and rock mechanics (all of which are generally considered part of geotechnical studies or investigations). In addition, waste package testing and conceptual design activities are to be performed, including development of performance requirements for repository system components. Information gathered and data collected and analyzed will be used to support a license application to the U.S. Nuclear Regulatory Commission (NRC) for the construction and operation of a geologic repository to be used for permanent disposal of high-level nuclear wastes. As part of the regulatory requirements, DOE-RL must implement a quality assurance program to provide confidence in the work performed during development of the repository, including information developed in support of licensing proceedings.

Quality assurance consists of all planned and systematic actions necessary to ensure that the geologic repository and subsystems or components will perform satisfactorily. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system and which provides a means to control the quality of the material, structure, component, or system to predetermined requirements. The quality assurance program applies to all systems, structures, and components of the proposed repository, its design, the characterization of the site, and all related activities. These related activities include facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

The subjects included in this section are as follows:

- o Section 8.6.1 contains a description of the BWIP philosophy on quality assurance and the DOE-RL BWIP Quality Assurance Plan, which implements this philosophy and provides guidance for the implementation of federally mandated quality assurance requirements.
- o Section 8.6.2 contains a discussion of the origins of the quality assurance requirements and a summary of those requirements to be implemented during site characterization by DOE-RL and the BWIP participant contractors.
- o Section 8.6.3 contains a description of the general organization of the BWIP, organization of project management, delegation of work, lines of communication, and quality assurance responsibilities for DOE-RL and BWIP participant contractors.
- o Section 8.6.4 contains a description of the quality controls during site exploration and characterization, repository design, and waste package design.
- o Section 8.6.5 contains lists of the Quality Assurance Administrative procedures that establish how the quality assurance programs of the DOE-RL and BWIP participant contractors will be implemented.
- o Section 8.6.6 contains lists of the detailed procedures generated by the DOE-RL and the BWIP participant contractors that provide for the application and implementation of quality assurance administrative procedural requirements to specific program areas.

8.6.1 QUALITY ASSURANCE PLAN SUMMARY

An effective quality assurance program is required to be maintained by the BWIP management and staff for all work and activities performed in support of the BWIP. The quality assurance program is planned, documented, and implemented to support activities affecting quality that occur as the BWIP moves through site investigation, characterization, repository design, and possible repository site selection.

The assurance of quality is an interdisciplinary activity involving many organizational components and is not the sole domain of any organization. It is the responsibility of both the DOE-RL staff and each BWIP participant contractor, in accordance with the federally mandated requirements, (1) to plan and perform activities affecting quality and (2) to develop and implement self-assessment activities ensuring compliance with those requirements.

The quality assurance department for DOE-RL and each contractor performing work or activities for BWIP is responsible for describing, monitoring, and verifying satisfactory accomplishment of quality-affecting

activities of the BWIP. This designated obligation does not, however, relieve the line organizations of responsibility for performing quality-related activities in accordance with federally mandated requirements and for ensuring compliance of quality-related activities with those requirements.

Based on the DOE-RL responsibility to assure, achieve, and verify the quality of items and activities associated with the BWIP site characterization and design, the DOE-RL has prepared the BWIP Quality Assurance Plan (DOE-RL, 1986b) to ensure a systematically controlled approach to the BWIP work. This plan describes how federally mandated quality assurance program requirements are to be translated effectively into plans and procedures for implementation. It identifies quality assurance administrative and implementing procedures, groups responsible for implementation of procedural requirements, and describes the interaction of those groups to accomplish quality requirements.

The DOE-RL BWIP Quality Assurance Plan is the top BWIP quality assurance planning document. It is intended to implement the plan specified by DOE Order 5700.6A (DOE, 1981), the Department of Energy Quality Assurance Management Policies and Requirements (DOE, 1985), the Office of Geologic Repositories Quality Assurance Plan for High-Level Waste Repositories (DOE, 1986a), and DOE-RL Order 5700.1A (DOE-RL, 1986d). This quality assurance plan establishes controls necessary to satisfy federally mandated quality assurance requirements applicable to BWIP work and activities. Compliance with applicable provisions of this quality assurance plan by the DOE-RL Office of Commercial Nuclear Waste and all BWIP participant contractors is mandatory.

The DOE-RL/Office of Commercial Nuclear Waste (see Fig. 8.6-4) is the overall project manager and is responsible for the direction, content, and effective implementation of quality requirements governing all BWIP activities. This responsibility includes the coordination and implementation of quality assurance programs by all BWIP participant contractors. In this management role, certain BWIP work and the implementation of quality assurance program requirements applicable to that work has been delegated to the BWIP participant contractors. The DOE-RL/Office of Commercial Nuclear Waste, however, retains ultimate responsibility for delegated functions and activities, including quality, and for ensuring that all BWIP participant contractors effectively respond to applicable quality requirements. The implementing responsibilities of the DOE-RL and three BWIP participant contractors (the integrating contractor, Rockwell Hanford Operations (Rockwell), BWIP), the construction manager (Morrison-Knudsen Company, Inc.), and the architect-engineer (Kaiser Engineers, Inc./Parsons, Brinckerhoff, Quade & Douglas, Inc.) are shown in Table 8.6-1. The hierarchy relationship of the various quality assurance documents is depicted in Figure 8.6-1.

Based on the quality requirements of the DOE-RL BWIP Quality Assurance Plan (DOE-RL, 1986b) and project management directives issued by the DOE-RL to specify how certain management activities are to be conducted, each BWIP

participant contractor will establish a quality assurance program. These programs will consist of required plans (see Section 8.6.6 for list of specific quality assurance plans); quality assurance administrative procedures that provide instruction for implementation of applicable requirements; and detailed technical implementing procedures that (1) incorporate the applicable requirements specified in the administrative quality assurance procedures and (2) contain instructions for the performance of work and activities such as design, testing, etc.

The DOE-RL/Office of Commercial Nuclear Waste is responsible for the approval of quality assurance plans and quality assurance administrative procedures prepared by the integrating contractor, the construction manager, and the architect-engineer. Each participant contractor is responsible for review and approval of the quality assurance program descriptions and quality assurance administrative procedures prepared by its subcontractors.

The quality assurance plan for each BWIP participant contractor includes a policy statement signed by the senior project officer of that participant contractor, mandating compliance with that contractor's approved quality assurance plan and procedures for work within the scope of the BWIP.

The quality assurance program consists primarily of controls over technical activities. These controls are exercised by the participants' line organizations performing the activities. The extent of these controls is established by a joint effort of cognizant (qualified) technical and quality assurance organizations. The DOE project management responsibility requires establishment of project objectives, oversight of participants' management, and verification that participants implement planned controls effectively. The DOE-RL/Office of Commercial Nuclear Waste technical personnel, in the course of evaluating contractor technical progress, must be satisfied 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).

The project oversight of contractor performance by the DOE-RL/Office of Commercial Nuclear Waste; therefore, includes (1) Basalt Quality Systems Division verification that contractors are effectively implementing the control systems that constitute the required project quality assurance program and (2) Basalt Waste Isolation Division evaluation of the technical effectiveness of those controls (see Fig. 8.6-5).

Certain activities performed by the DOE-RL/Office of Commercial Nuclear Waste personnel directly affect technical outcome of the project (i.e., decisions selecting from among technical alternatives, approval of contractor technical recommendations, direction with respect to approaches, etc.). Quality assurance controls affecting these activities are specified in

DOE-RL/Office of Commercial Nuclear Waste procedures. The Basalt Quality Systems Division verifies effective implementation of specified controls by quality assurance audit and surveillance.

At intervals determined by the Project Manager, BWIP, but not exceeding 1 yr, a management team assesses effectiveness of the overall BWIP quality assurance program implementation. The assessment team structure and assessment process mechanics are addressed by an approved procedure.

In addition, each BWIP participant contractor is required to assess the effectiveness of its quality assurance program. Such assessment is required to include regular contact with program status through reports, meetings, and audits, as well as performance of a procedurally controlled, preplanned, documented assessment, with corrective action identified and tracked.

Disputes involving differences of opinion regarding quality assurance matters between quality assurance personnel and other department personnel anywhere in the BWIP are expected to be escalated to a level where agreement can be reached, up to and including the U.S. Department of Energy-Headquarters (DOE-HQ) Office of Civilian Radioactive Waste Management (OCRWM).

8.6.2 QUALITY ASSURANCE PROGRAM REQUIREMENTS

The quality assurance requirements for the BWIP originate from two main sources: the NRC and the U.S. Department of Energy (DOE) (see Fig. 8.6-1).

The NRC, by way of 10 CFR 60 (NRC, 1983), has made the quality provisions of 10 CFR 50, Appendix B (NRC, 1979), mandatory for all systems, structures, components, and activities designated as "important to safety" or "waste isolation." In addition, the NRC published the NRC Review Plan; Quality Assurance Programs for Site Characterization of High-Level Waste Repositories (NRC, 1984) to define the criteria and methods for NRC review of the quality assurance program for site characterization during the precicensing phase and to provide guidance for establishing an acceptable program for items and activities designated as "important to safety" or "waste isolation."

DOE Order 5700.6A (DOE, 1981) and DOE-RL Order 5700.1A (DOE-RL, 1980) provide that the basic and supplementary requirements included in the American National Standards Institute/American Society of Mechanical Engineers (ANSI/ASME) NQA-1 (ANSI/ASME, 1986) are the preferred standards for the implementation of quality assurance programs for DOE projects. The NQA-1 requirements (ANSI/ASME 1986) also provide an adequate basis for interpreting the pertinent quality assurance requirements of 10 CFR 50, Appendix B (NRC, 1979a) for the establishment and execution of quality assurance programs during the design and construction phases of nuclear facilities. For site characterization activities, however, the additional requirements of the NRC Review Plan (NRC, 1984) must be incorporated for items and activities important to safety and waste isolation and the requirements of ANSI/ASME

(1986) must be evaluated to assure that its provisions are applicable to site characterization activities as opposed to construction activities, and do not contradict the requirements of the NRC Review Plan (NRC, 1984).

In addition, where the Office of Geologic Repositories has determined it necessary for each project office to perform certain quality-related activities (e.g., peer review, graded quality assurance) in a uniform manner, supplements to the OGR/B-3 quality assurance plan (DOE, 1986b) have been issued.

To ensure uniform and acceptable interpretation of the requirements for quality assurance, the Basalt Quality Assurance Requirements Document (DOE-RL, 1986a) has been prepared by the DOE-RL for the BWIP site characterization activities. The purpose of this document is to provide BWIP participant contractors with interpretations of the quality assurance requirements appropriate for site characterization, design, and license application phases of an NRC-licensed geologic repository. The Basalt Quality Assurance Requirements Document (DOE-RL, 1986a) consolidates all requirements of the above DOE and NRC documents into a single, site-specific document that provides clear interpretations of the federally mandated quality assurance requirements as they apply to geologic repository work important to safety or waste isolation.

The Basalt Quality Assurance Requirements Document (DOE-RL, 1986a) is divided into 18 sections which are titled and organized to coincide with the format and content of the 18 criteria of 10 CFR 50, Appendix B (NRC, 1979a), the NRC Review Plan (NRC, 1984), and the Quality Assurance Program Requirements (ANSI/ASME, 1986). A brief description of the major elements of these criteria follows along with a method of implementation of each section of the Basalt Quality Assurance Requirements Document for work or activities designated as important to safety of waste isolation (see Section 8.6.4.2).

8.6.2.1 Criterion 1.0, Organization

This criterion requires documentation of organizational structures, levels of authority, functional responsibilities, and lines of communication for activities affecting quality. The description is provided in Section 8.6.3.

8.6.2.2 Criterion 2.0, Quality Assurance Program

This criterion requires the establishment of a documented quality assurance program that is planned, implemented, and maintained and that identifies the activities and items to which it applies. The program must provide for the indoctrination and training necessary to ensure that suitable proficiency is achieved and maintained by those personnel performing quality-related work. Management must regularly assess the adequacy of the program. The description of the quality assurance program is provided in this section.

8.6.2.3 Criterion 3.0, Design Control

This criterion provides for the control of design, design information, and design activities for the BWIP. The terms of design, design information, and design activities as used in this section need to be defined. The term "design" refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). "Design information" and "design activities" refer to data collection and analyses activities used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information (e.g., test results and analysis). Data analysis includes the initial step of data reduction and broad-level systems analyses (e.g., performance assessments), which integrate many other data and analyses of individual parameters.

The BWIP design controls include not only controls traditionally used to ensure correct translation of design inputs into designs but also 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 that are governed by controls described in Section 8.6.2.3.

The BWIP participant contractors are expected to include provisions in their design control procedures for (1) documenting design errors and deficiencies on discovery, (2) ensuring that resulting corrections are properly reflected across all affected design interfaces, and (3) verifying that design documents reflect as-built conditions documented on nonconformances dispositioned as repair or accept-as-is.

8.6.2.3.1 Computer software

Computer software for technical computer codes important to safety or waste isolation is to be controlled by participant contractor procedures consistent with guidelines established in NUREG 0856 (NRC, 1986).

8.6.2.3.2 Application of design control to data acquisition

The processes of identifying data needs, planning data acquisition work and sequence, and experiment design (e.g., preparation of the necessary test procedures) for the BWIP are based on and developed concurrently by establishing (1) how much of the physical characteristics of the repository site must be determined, (2) how, and in what sequence, this characterization is to be done, and (3) what processes of data acquisition best assure the validity of such site characterization. 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.

While preparation, review, and approval of data acquisition planning and procedure generation are controlled under the design control provisions of the quality assurance program, actual performance of the experiments, measurement, collection, etc., for acquiring data is controlled under applicable provisions shown in Criterion 11.0.

A considerable body of data relevant to site characterization (e.g., geotechnical, climatological, etc.) has been accumulated during activities predating establishment of the BWIP and (or) data acquired without the current level of approved management controls in effect. The level of qualification of such existing data for site characterization purposes will be established on a case-by-case basis. Criteria for determining data qualification levels will be developed by the BWIP, with due regard to relevant NRC and (or) Office of Geologic Repositories guidance.

Reduction and analysis of data collected during BWIP site characterization, or of prior data that have 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 the following:

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

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

8.6.2.3.3 Design controls for site characterization studies and design of equipment, facility, waste form, and waste form packaging

Participant contractors responsible for strategy, test planning, test procedures, site characterization studies, or design of (1) facilities or equipment that could subsequently be used if the Hanford Site is selected as a repository site, (2) equipment with characteristics that could affect validity of site characterization, or (3) conceptual designs on which site characterization approaches or analyses will be based, will perform such activities in accordance with approved procedures that provide the following controls:

- o Traceable documentation of design inputs, including the rationale for design decisions.
- o Documentation of design assumptions, including rationale.
- o Approved computer software controls.
- o Competent, independent review.
- o Approval by designated authority.
- o Independent design verification.
- o Control of design interfaces.
- o Control of design changes equivalent to the controls applied to original design.
- o Review of design drawings, specification, criteria, and analyses by personnel of the cognizant quality assurance organization to ensure compliance with governing procedures and quality assurance program requirements.

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

Verification by testing is intended to establish the ability of some or all design features 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 determined by safety analysis to be credible. Such occurrences arise when adverse conditions reinforce each other if they were to occur simultaneously

(e.g., seismic events and outbreak of fire). Where testing reveals design (or fabrication) deficiencies, the testing shall be repeated after correction of the deficiency(ies).

Design calculations may be verified by use of alternate calculations. Such calculations may be made by simplified methods verifying that results of the formal calculations are reasonable.

Where all or portions of a design are verified by similarity to prior designs, verification shall establish the following:

- o The conditions under which the prior design operated were the same as, or more severe than, relevant conditions in which the present design will operate.
- o The prior design operated or was tested under the most adverse combination of design conditions applicable to the present design.
- o The designer has determined and appropriately accounted for any deficiencies discovered during operation of the prior design.

8.6.2.3.4 Peer review

A peer review is a documented critical review performed by personnel who are independent of those who performed the work, but who have technical expertise in pertinent areas at least equivalent to those who performed the original work. Peer reviews are indepth, critical reviews and evaluations of documents, material, or data requiring interpretation or judgment to verify or validate assumptions, plans, results, or conclusions. When conclusions, material, or data contained in a report go beyond the existing state of the art, a peer review is necessary.

Peer reviews are not to be confused with technical reviews, which are documented, traceable reviews, critical reviews, analyses, and evaluations of documents, material, or data that require technical verification and (or) validation for applicability, correctness, adequacy, and completeness.

Peer reviews are required for activities that support a license application and involve use of data collection or analysis procedures and methods that are untried or beyond the state of the art or where detailed technical criteria and requirements do not exist or are being developed. Other instances where a peer review should be considered in lieu of a technical review include situations in which (1) analytical modeling techniques are (or will be) applied to a range of conditions outside of their normally accepted boundaries, (2) data collection results are not predictable with a high degree of certainty, (3) activities are not feasibly repeatable, or (4) data collection was performed prior to formal quality assurance provisions being established or data were collected in nonconformance with established quality assurance provisions.

8.6.2.3.4.1 Peer review group selection

Each organization responsible for establishing a peer review program shall document procedures that define the selection process for a peer review group. The peer review group shall be composed of individual(s) who have qualifications at least equivalent to those required for performance of the original work and who are independent of performing the work being reviewed. The peer reviewer's qualifications shall be documented and verified by the organization requesting the peer review.

8.6.2.3.4.2 Peer review performance

Peer reviews shall address the following areas as applicable:

- o Validity of basic assumptions or functional requirements.
- o Appropriateness of methodology.
- o Logic of methodology.
- o Verification of calculations or computer software.

Peer reviews shall be conducted in accordance with written procedures that shall address the following:

- o The review process and reviewer responsibilities.
- o Handling of comment resolution.
- o Reporting minority positions.
- o Involvement of the quality assurance organization.
- o Changes to previously peer-reviewed documents.
- o Rereview of revised documents.
- o Records of the review.

Rereview of previously peer-reviewed documents shall be performed whenever the technical content or results presented in the documents are significantly revised.

8.6.2.3.4.3 Peer review records

Peer review records shall include the personnel qualifications of the reviewers, results of the review, disposition or replies to reviewer comments, and minority positions. The peer review records shall be retained commensurate with the retention requirements of the data or document the records support.

8.6.2.3.5 Design changes

Design changes require technical controls commensurate with controls exercised on the original design, including review by the design organization responsible for the original design (unless otherwise specified by the DOE).

In addition, design changes that might entail significant impact to project concept, cost, schedules, or safety apportionments must be submitted for Project Change Control Board approval.

8.6.2.3.6 Design interfaces

Design interfaces are identified and controlled and the design efforts are coordinated among the participating organizations. Interface controls include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces is documented and controlled. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal is confirmed promptly by a controlled document. 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.

8.6.2.3.7 Review plan

It is intended that a general plan be developed by each participant contractor and be 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.

8.6.2.3.7.1 U.S. Department of Energy-Richland Operations Office/Office of Commercial Nuclear Waste reviews

The DOE-RL Office of Commercial Nuclear Waste personnel exercise regular and frequent technical overview and quality verification within their areas of expertise over technical work being performed by project participants. Technical surveillance includes the following:

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

The Basalt Waste Isolation Division technical personnel will be involved in the peer review process in two ways. The cognizant Basalt Waste Isolation Division individual will participate in or observe selected peer reviews convened by BWIP participants, and any Basalt Waste Isolation Division technical individuals may initiate peer reviews if they have reason to believe BWIP work in their areas of expertise meets one or more of the peer review criteria.

The Basalt Waste Isolation Division technical personnel review technical documents (e.g., test reports, analyses, reports of study results, etc.) for appropriateness of approach, reasonableness of conclusions, clarity, and evidence of necessary supporting inputs. 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.

Any member of the DOE-RL/Office of Commercial Nuclear Waste staff may initiate a documented review meeting to resolve a concern. Typically, a documented review meeting is convened if a staff member feels that too many controversial issues have surfaced during a peer review or has unresolved questions concerning technical or quality-related questions after reviewing questions a document generated by one of the BWIP participant contractors.

8.6.2.4 Criterion 4.0, Procurement Document Controls

Procurement document controls in the BWIP are intended to ensure that the responsible participant contractor communicates needs and requirements clearly and accurately to the supplier. The BWIP participant contractors 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 activities:

- o Procurement planning.
- o Preparation, review, approval, and control of procurement documents.
- o Review of procurement documents by the participants' quality assurance 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 quality assurance program has been specified; and that the procurement documents have been prepared in accordance with the applicable procedure(s) (NRC, 1984).
- o Bid evaluation, with participation by the initiator and (or) quality assurance (as applicable) for bids that restate or interpret technical and quality assurance requirements.

- o Review of, and concurrence with, the supplier quality assurance 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 Criterion 11.0.

The Rockwell Basalt Quality Assurance Department will evaluate selected procurement document packages prepared by other BWIP participants during audits and surveillances of those participants' quality assurance program implementation. The Basalt Quality Systems Division will review selected procurement document packages prepared by BWIP participants, including those prepared by the integrating contractor during quality assurance audits and surveillances of BWIP activities.

8.6.2.5 Criterion 5.0, Instructions, Procedures, and Drawings

The BWIP activities are prescribed by, and performed in accordance with, written instructions, procedures, or drawings appropriate to the work. Such procedures, instructions, or drawings are to be reviewed for accuracy and adequacy by personnel who are both competent in the subject matter addressed and who are independent of the preparation of the document being reviewed.

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 BWIP is governed by two basic categories of administrative procedures: (1) procedures that define and direct operation of the BWIP management system, covering such areas as the work breakdown system, and the various project baselines and (2) procedures that define and direct controls and control systems making up the BWIP quality assurance program. Requirements of this section, relative to administrative procedures, apply to the second category, which is designated "quality assurance administrative procedures."

Each participating entity (i.e., government agency, public institution, or civilian contractor) in the project is responsible for quality assurance administrative procedures necessary to complement its approved quality assurance plan (quality assurance program description).

The BWIP technical work is prescribed by, and performed in accordance with, detailed procedures (e.g., laboratory procedures, special process procedures, test procedures, etc.). Each participant contractor 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 contractors' quality assurance personnel prior to use to verify that the necessary control features have been included.

Written instructions ordinarily are 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.

8.6.2.6 Criterion 6.0, Document Control

All BWIP project participants are required to maintain document control systems for documents that direct or affect work within the scope of the project quality assurance program. These document control systems are required to adhere to the DOE-RL project management directive to establish a uniform document control system and are to provide for the following:

- o Identification of documents to be controlled.
- o Identification of responsibility assignments to prepare review, approve, and issue documents.
- o Review of documents and document changes for adequacy, completeness, and correctness prior to approval and issuance.
- o Coordination and control of interface documents.
- o Availability of correct and applicable documents at the work place.
- o Assurance that proper documents are being used and that obsolete or superseded documents are not available for inadvertent use.
- o Establishment and maintenance of up-to-date distribution lists.
- o Establishment of effective way for document users to determine whether a document is current and in effect.
- o Explicit identification and control of documents released prior to required verification (e.g., technical review) and of any project data resulting from the use of such unverified documents prior to their verification.

8.6.2.6.1 The U.S. Department of Energy-Richland Operations Office/Office of Commercial Nuclear Waste quality assurance documents

The BWIP Quality Assurance Plan (DOE, 1986b), Basalt Quality Assurance Requirements Document (DOE, 1986a), and implementing DOE-RL/Office of Commercial Nuclear Waste quality assurance administrative procedures require Office of Geologic Repositories review and approval.

8.6.2.6.2 Integrating contractor, construction management contractor, and architect-engineer documents

Quality assurance plans and quality assurance administrative procedures prepared by the integrating contractor, construction manager, and architect-engineer require DOE-RL/Office of Commercial Nuclear Waste approval.

8.6.2.6.3 Other participant contractor documents

Other participant contractors are required to submit their quality assurance plans and implementing quality assurance administrative procedures for review and approval by the next higher participant in the project hierarchy. However, the DOE-RL Office of Commercial Nuclear Waste will review and approve quality assurance plans, quality assurance administrative procedures, and any substantive changes thereto for other government agencies performing BWIP work under memoranda of understanding with the DOE and for public institutions performing BWIP work on direct contract with the DOE.

8.6.2.6.4 Technical documents

Technical documents prepared by BWIP participants as a basis for, or as part of, BWIP site characterization, waste form, waste package design, or repository design, require DOE-RL/Office of Commercial Nuclear Waste review and approval (see the Project Management Plan (DOE-RL, 1986c) and the System Engineering Management Plan (DOE-RL, 1986d)).

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.

8.6.2.7 Criterion 7.0, Control of Purchased Items and Services

The DOE-RL and BWIP participant contractors are required to institute measures to ensure that purchased items and services conform to the requirements specified in applicable procurement documents. Controls include evaluation and selection of suppliers with a demonstrated capability of providing the required items or services, verification that applicable controls are exercised during item processing or performance of the contracted services, and verification that completed items or services conform to procurement acceptance criteria. The cognizant quality assurance organization is required to ensure that these controls are adequate and appropriate to the

procurement. For precautions during procurement of instrumentation or equipment that is to be used for data collection during site characterization (where failure or malfunction would not be readily detectable either during data collection or evaluation), see Criterion 11.0.

8.6.2.7.1 Supplier quality assurance programs

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

8.6.2.7.2 Supplier selection and evaluation

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

Except where technical requirements dictate selection on the basis of unique capabilities, procurement of BWIP project items or services within the scope of the BWIP quality assurance program will be made from suppliers who are preapproved by the responsible quality assurance organization in the BWIP.

Continued or repeat procurement from active suppliers or suppliers who have previously been used for BWIP work will be based, in part, on an evaluation of performance of that work.

8.6.2.7.3 Verification

The extent and nature of verification activities to be accomplished for procured items or services within the scope of the BWIP quality assurance program will be planned at the outset. Such verification is expected to include mandatory hold points for inspection or witnessing, where appropriate,

and surveillance and (or) audit. In-progress inspection, witnessing, and surveillance is expected to include review of the status of required documentation.

Acceptance of completed items or services is accomplished as follows:

- o For items and materials, either one or a combination of the following: receipt inspection; certificate of conformance; source inspection, surveillance, and (or) audit; and post-installation testing.
- o For services, in-progress audit and surveillance, as appropriate, and review/approval of the completed survey(s) (including technical reports, completed studies, etc.).

The responsible DOE-RL or participant contractor quality assurance organization is expected to verify that required documentation is received and that it complies with procurement quality assurance requirements. Acceptability of the results of technical services (e.g., studies, analyses, etc.) will be determined by the organization initiating the procurement.

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

8.6.2.7.4 Supplier furnished documentation

Within the scope of the BWIP quality assurance program, the BWIP participant contractors are required to include provisions in procurement documents for the following supplier-furnished documentation:

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

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

8.6.2.7.5 U.S. Department of Energy-Richland Operations
Office control of purchased items and services

The DOE-RL occupies the role of owner on the BWIP. The BWIP work is accomplished in the following ways:

- o On contracts between the DOE-RL and major contractors.
- o On interdepartment agreements between the DOE and other Federal agencies.
- o On various contractual arrangements with non-Federal public agencies and institutions.
- o On subcontracts issued by major contractors. The entire project, therefore, comprises a DOE-RL procurement network.

The DOE-RL is responsible for administering the entire procurement network, specifying the necessary quality assurance program, and ensuring that delivered items, materials, and services comply with applicable quality assurance requirements. Compliance with applicable provisions of the quality assurance program described in the DOE-RL Quality Assurance Plan is a condition of all BWIP procurement contracts.

8.6.2.8 Criterion 8.0, Identification and Control
of Items, Materials, and Samples

Items, materials, and samples are identified and controlled at the BWIP in order to ensure (1) that the history of items and materials is fully known from the time of receipt to the point of use (including traceability to nonconformances) and (2) that samples are traceable from the sampling point to the point of consumption or long-term storage. (Note: continued traceability of samples in storage is a part of records management.)

Each BWIP participant is responsible for identification and control of items, materials, 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. They 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 is expected to be readily traceable to the original sample.

8.6.2.9 Criterion 9.0, Control of Special Processes

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

Special processes used at the BWIP are explicitly identified in appropriate quality assurance program documents (quality assurance plan or quality assurance-related administrative procedures), and it is expected that each participant contractor will develop and maintain a list of those processes that are to be controlled as special processes. The procedures that specify how individual special processes are to be performed are qualified by demonstrating that, when performed as specified, the process yields required results. Special process personnel are qualified by training (where appropriate) and demonstrating 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 quality assurance plan describes the role the quality assurance organization plays in qualification of special process procedures, personnel, and equipment.

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.

Site characterization may involve laboratory processes (e.g., chemical analyses) 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 BWIP. 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 contractor.

8.6.2.10 Criterion 10.0, Inspection

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

- o Source inspection during designated procurements.
- o Receipt inspection for procured items and materials.

- o In-process and acceptance inspections during and after fabrication, construction, installation, test, or modification work performed by BWIP participants.
- o Inspection of samples.

Acceptance of the results of technical studies, design activities, etc., is not an inspection activity as discussed here.

Formal inspection is performed either by inspectors reporting to a participant's quality assurance organization or, where appropriate, by personnel possessing particular expertise. Quality assurance personnel performing inspection functions will be qualified in accordance with ANSI/ASME NQA-1-1986, Appendix 2A-1 (ANSI/ASME, 1986). Where inspection requires special expertise, the expert(s) will be selected on the basis of the required expertise, without regard to formal inspector qualification. In these cases, the participant's quality assurance inspection function will ensure that the specialist is properly oriented in the use of the necessary inspection equipment, forms, accept/reject practices, and reporting method.

The integrating contractor shall require BWIP-wide standardization of certain inspection practices and formats to facilitate processing and later use of results. The integrating contractor also is responsible for ensuring the effectiveness of BWIP inspection activities. The DOE Basalt Quality Systems Division verifies that BWIP inspection activities are achieving intended results through audit and surveillance.

The BWIP inspection is performed in accordance with procedures, checklists, or explicit inspection steps in the work procedures. Regardless of the method, such instructions are reviewed and approved by authorized quality assurance personnel prior to use.

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

- o Identification of the characteristics and (or) activities to be inspected.
- o The method(s) of inspection to be used.
- o Identification of the individual(s) or group(s) responsible for performing the inspection.
- o Identification of required prerequisites (including required procedures, drawings, specifications, and revisions) and working conditions for the work to be inspected.
- o A means for recording inspector or data recorder identity and the results of the inspection operation.

- o Specification of measuring and test equipment required to perform the inspection, as well as accuracy requirements.
- o Acceptance and rejection criteria, or reference to the requirements documents (e.g., drawings) that specify these criteria.

Participant contractors whose activities include work requiring inspection will establish and implement procedural requirements for documentation of inspection results and documented evaluation of the acceptability of results. Verification that activities have been accomplished in accordance with, and that results conform to, established requirements is documented as performed and is retained as part of the formal BWIP record.

8.6.2.11 Criterion 11.0, Test Control

8.6.2.11.1 Test activities

In addition to testing accomplished in traditional construction projects, BWIP activities conducted for the purpose of acquiring physical data for site characterization (e.g., 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 needs will be recognized during planning and provisions will be made for field decisions and (or) other appropriate actions. The intent is to ensure a controlled degree of necessary flexibility.

8.6.2.11.2 Test plans and procedures review

Testing requirements are derived basically from information needs specified in 10 CFR 60 (NRC, 1983) and DOE site characterization guidelines in 10 CFR 960 (DOE, 1984a) and the issues are identified in the geologic repository program Mission Plan (DOE, 1986a). The four major issues identified in the Mission Plan have been translated into more detailed issues directly applicable to characterization of the Hanford 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 Criterion 3.0 (see Section 8.6.2.3). Planning for data acquisition and preparation of data acquisition procedures are primary links in the definition of inputs to subsequent design and, therefore, are 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.

8.6.2.11.3 Uncertainties and error

To the extent practicable, test planning is expected to include (1) identification of potential sources of error and (or) uncertainty and (2) 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.

8.6.2.11.4 Special considerations for some test equipment and instrumentation

For instrumentation or equipment used in data collection, BWIP participant contractors are expected to consider whether failure or malfunction of the instrumentation during test will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, (1) technical and quality procurement requirements will be selected specifically to minimize the likelihood of undetectable anomalies and (2) 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.

8.6.2.11.5 Personnel qualification

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

8.6.2.11.6 Test procedure content

Test procedures are expected to include the following elements:

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

- o 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 provisions for data collection and storage. For tests of long duration, it is expected that specific provisions will be made for instrumentation with calibration intervals shorter than expected test duration. Such provisions are to be designed to ensure validity of data throughout the test.
- o Instructions for performing the test.
- o Mandatory inspection or witness points (as required).
- o Acceptance/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 that, 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.)
- o Methods of data analysis (which may, however, appear in data analysis procedures other than the procedures used for performing the testing).
- o Methods of documenting or recording test data and results.
- o Provisions for assuring and documenting the fact that test prerequisites were met.

8.6.2.11.7 Test results evaluation and acceptance

The BWIP participant contractors are expected to assure that test results are evaluated and their acceptability determined by the responsible individual or groups, as indicated in applicable subsections of Criterion 3.0 (design control). Test records are expected to include the following information where applicable:

- o A description of the type of observation.
- o The date and results of the test.
- o Information related to conditions adverse to quality.

- o Data recorder identity.
- o Evidence as to acceptability of results.
- o Action taken to resolve any discrepancies noted.

The DOE-RL/Office of Commercial Nuclear Waste will verify by technical surveillance, quality assurance surveillance, and quality assurance audit that the integrating contractor's direction and management is producing effective test controls throughout the BWIP.

8.6.2.12 Criterion 12.0, Control of Measuring and Test Equipment

The integrating contractor is responsible for ensuring that adequate calibration control systems are implemented for measuring and test equipment to be used at the BWIP. These systems are expected to provide for the following:

- o Use of calibration standards traceable to nationally recognized standards.
- o Selection of measuring and test equipment on the basis of application requirements.
- o Tagging or other appropriate and effective means of knowing calibration status of individual items of measuring and test equipment.
- o Calibration intervals based on measuring and test equipment found to be damaged or consistently outside allowable calibration limits.
- o Reevaluation of results obtained by use of measuring and test equipment subsequently determined to be out of calibration.

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

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

The DOE Basalt Quality Systems Division verifies effectiveness of the integrating contractor's management of the calibration control system by surveillance and audit.

8.6.2.13 Criterion 13.0, Handling, Storage, and Shipping of Items, Materials, and Samples

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

The integrating contractor is responsible for ensuring BWIP-wide controls for handling storage and shipping of items, and the DOE Basalt Quality Systems Division verifies effectiveness of these controls by surveillance and audit.

8.6.2.14 Criterion 14.0, Inspection, Test, and Operating Status

Controls for maintaining and indicating the status of BWIP inspections, test, and operations are established and implemented for the following purposes:

- o Ensuring that required inspections or tests, or required inspection or test steps, are not inadvertently bypassed.
- o 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.

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

8.6.2.15 Criterion 15.0, Control of Nonconforming Items or Samples

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

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

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

Decisions to use the nonconforming items, materials, or samples as is (i.e., use-as-is), or to restore it to usable condition without returning it to a fully conforming condition (i.e., repair), require technical review and approval at the next higher level of BWIP participation (e.g., disposition decisions of "use-as-is" or "repair" made by the integrating contractor require DOE-RL Office of Commercial Nuclear Waste review and approval). 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.

Each participant contractors' procedures for control of nonconforming items, materials, or samples 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.

Prior to initiation of site characterization activities, the BWIP will establish a system for monitoring and analyzing nonconformance trends on a BWIP-wide basis and for initiating appropriate action where the need is indicated.

8.6.2.16 Criterion 16.0, Corrective Action

Corrective action on the BWIP consists of (1) action to correct observed conditions that do not conform to specified requirements and (2) action to prevent recurrence of problems. Problems are defined as conditions that could have an adverse effect on safety or waste isolation, that could adversely affect the credibility of site characterization conclusions, that could endanger BWIP personnel or property, or that could have a major impact on BWIP costs or schedules.

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

- o Evaluation of participant contractor reported problems to determine significance, including potential implications to previously completed BWIP work.
- o Investigation to determine the root cause of problems determined to be significant.
- o Action to eliminate or compensate for the identified root cause.
- o Quality assurance verification that defined preventive action is accomplished.
- o Quality assurance verification that the preventive action actually prevents recurrence.

8.6.2.17 Criterion 17.0, Quality Records

The integrating contractor is responsible for establishment and operation of the BWIP records management system in accordance with the DOE-RL project management directive for the records program. The system is described in the BWIP Records Management Plan (Rockwell, 1986), which provides direction to all BWIP personnel regarding collection, administration, storage, and retrieval of BWIP records/documents and one-of-a-kind items after their preparation for the BWIP. It is important to distinguish between a document (which is any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results) and a record (which furnishes documentary evidence of the quality of items and of activities affecting quality; e.g., boring logs, maps, geologic survey notes, geophysical data, results of peer reviews, laboratory data, and data reduction and interpretation). A document is considered to be a quality assurance record when the document has been completed. Documents and items (e.g., core samples) that are to become part of the formal record are transmitted directly to the integrating contractor for the necessary processing and storage. Organizational responsibilities for the records management system are specified in appropriate procedures.

The BWIP records in long-term storage are expected to be kept in a facility that meets all applicable requirements relative to record protection from deterioration and disaster.

8.6.2.18 Criterion 18.0, Audit and Surveillance

The DOE-RL Office of Commercial Nuclear Waste and each BWIP participant contractor are required to establish and maintain formal internal quality assurance audit programs that comply with requirements stated in the Basalt Quality Assurance Requirements Document (DOE-RL, 1986a) and in the Basalt Quality Assurance Plan (DOE-RL, 1986b). Participant contractors who award subcontracts for BWIP work (thus establishing subtier participant contractors) are required to conduct external audits of the quality assurance programs of the subtier participants for whom they are responsible. The integrating contractor, in its project management role, also is required to schedule and conduct audits of all other major contractors, including the construction management contractor and the architect-engineer.

The Basalt Quality Systems Division audits the BWIP activities indicated below:

- o Activities within the scope of this quality assurance program performed by the nonquality systems branches within the DOE-RL/Office of Commercial Nuclear Waste.
- o Implementation of the BWIP quality assurance program as established and managed by the integrating contractor.
- o Selected activities throughout the BWIP, with emphasis on performance of major contractors in their implementation of the BWIP quality assurance program as it applies to them and on effectiveness of contractor audit programs.

In addition, Basalt Quality Systems Division auditors accompany audit teams of the integrating contractor and other BWIP participant contractors on selected audits to observe audit performance and to evaluate effectiveness of contractor audit processes. The DOE-RL/Office of Commercial Nuclear Waste is audited by Office of Geologic Repositories and the Environmental Health Safety and Quality Assurance Division at regular intervals.

8.6.2.18.1 Audit program content

Quality assurance audits within the BWIP address the following questions:

- o Is the audited participant carrying out its approved quality assurance program?
- o Are the controls and (or) control systems defined in the audited participant's quality assurance program working effectively?
- o 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)?

- o Does the audited participant contractor exhibit an acceptable degree of procedural discipline?

8.6.2.18.2 Audit scheduling

The Basalt Quality Systems Division and every BWIP participant contractor who is required to conduct a quality assurance 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 BWIP work. Schedules are required to provide for (1) verification early in the life of a discrete task or work phase that approved controls are in place and are being applied and (2) verification at appropriate later points in the life of the task or work phase that comprehensive, credible evidence exists to demonstrate control effectiveness.

The audit scheduling process is required to consider surveillance results as an important factor. That is, surveillance and audit are regarded as complementary methods of assessing quality assurance 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 that (1) scheduled audits should be rescheduled or should have their scope or direction changed or (2) additional audits should be scheduled.

Special audits will be scheduled in the event of (1) major changes to a participant's quality assurance program or organization or (2) discovery of major areas of concern. Participant contractors are required to submit audit schedules and schedule changes that occur between regular issues of updated schedules to the next higher participant in the BWIP hierarchy. Change submittals shall include the rationale for the reported change(s).

8.6.2.18.3 Auditor qualification

The use of a certified lead auditor as team leader for every quality assurance audit is a formal BWIP requirement. Lead auditor qualification complies with the requirements of NQA-1 (ANSI/ASME, 1986).

The team leader shall participate in the selection of auditors to staff the team and shall be responsible for assuring that all team members are competent to perform 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 that individual was directly responsible or had provided direction or guidance).

8.6.2.18.4 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.

8.6.2.18.5 Audit performance

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

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

8.6.2.18.6 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 DOE-RL/Office of Commercial Nuclear Waste for BWIP compliance. These distribution requirements will reflect higher DOE-HQ direction.

Audit reports will explicitly recognize those quality assurance programs within their scope that are being implemented effectively, as well as identifying deficiencies in implementation.

8.6.2.18.7 Exemptions from internal audit requirements

Some research and development organizations have no prior experience with internal quality assurance audits and it would not be an effective application of project resources to insist on development of the audit capability. In such instances, the responsible participant contractor at the next higher level in the BWIP hierarchy may elect to perform the necessary audits or may require that a third party be engaged to perform the audits.

Typical situations justifying this approach include the following:

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

8.6.2.18.8 Surveillance

The DOE-RL/Office of Commercial Nuclear Waste and each BWIP participant contractor required to conduct a quality assurance audit program also will develop and implement an approved surveillance plan that will be updated and reissued at periodic intervals.

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

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

8.6.2.18.9 Qualification for surveillance

Surveillance of the BWIP 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 specialty of the individual performing surveillance is expected to bear a clear relationship to the field under surveillance. Quality assurance personnel performing surveillance of controls applied to technical activities are not required to be qualified in the technical discipline(s) involved.

8.6.2.18.10 Basalt Quality Systems Division surveillance

Surveillance performed by Basalt Quality Systems Division personnel is controlled by DOE-RL/Office of Commercial Nuclear Waste procedure. Technical personnel perform surveillance of work within their areas of expertise and evaluate technical effectiveness of applicable controls. The Basalt Quality Systems Division personnel perform surveillance of ongoing control activities.

8.6.2.18.11 Surveillance by participant contractors

The BWIP participant contractors 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.

8.6.2.18.12 Audit and surveillance follow-on activities

Each participant contractor is expected to address deficiencies identified by audit or surveillance with prompt, vigorous corrective action. Adverse findings identified as significant are to be investigated to determine the root cause of the deficiency and to define action that will prevent recurrence. The auditing or surveilling organization is expected to perform the following:

- o 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.
- o Confirm timely implementation of approved corrective action(s).
- o Verify that the corrective action was effective in preventing recurrence.

The BWIP participant contractors shall maintain tracking and trending systems that will provide long-term visibility of significant problems so that any recurrence will immediately be recognized.

8.6.3 ORGANIZATION OF THE BASALT WASTE ISOLATION PROJECT WITH RESPECT TO QUALITY ASSURANCE

8.6.3.1 Office of Civilian Radioactive-Waste Management

The Office of the Director, DOE-HQ Office of Civilian Radioactive Waste Management, is charged with the implementation of the Nuclear Waste Policy Act of 1982 (NWP, 1983). The specific functions of the director's office are to provide overall policy recommendations to the Office of the Secretary of Energy; to ensure that the overall direction and pace of the program proceed as mandated by the Nuclear Waste Policy Act of 1982 (NWP, 1983); to provide policy guidance, direction, and control to the associate directors; and to provide policy guidance to the project offices in implementing major decisions beyond the scope of the day-to-day authority of the associate directors (Fig. 8.6-2). The director of the Office of Civilian Radioactive Waste Management has ultimate responsibility for establishing and maintaining an effective program-wide quality assurance program. The Director of the Office of Civilian Radioactive Waste Management assigns management functions, responsibilities, and authorities to the director for Policy and Outreach and to three associate directors for Resource Management, Geologic Repositories, and Storage and Transportation Systems.

Within Policy and Outreach of Civilian Radioactive Waste Management, the quality assurance manager has the lead responsibility for quality assurance management policy overview and coordination for the overall program. Within the Office of Civilian Radioactive Waste Management, the quality assurance manager has direct access to the director to report on the status and adequacy of quality assurance policies, plans, and activities for the overall program and to recommend or cause resolution of general quality assurance management policy issues.

8.6.3.2 Office of Geologic Repositories

Within the Office of Civilian Radioactive Waste Management, the associate director of the Office of Geologic Repositories (Fig. 8.6-3) is responsible for the screening and selection of sites; the design, licensing, construction, and operation of repositories; the management of research and development for repositories; and the implementation and management of specific quality assurance requirements, plans, and policies. Technical, programmatic, and quality assurance direction originate from this office to the respective repository project offices. A full-time, dedicated quality assurance management position has been established within each respective project organization (BWIP, Nevada, and Texas projects) that has responsibility and authority to verify the adequacy and effectiveness of quality assurance plans, requirements, and activities for that organization and its subsidiary organizations. Additional details regarding the responsibilities of this office are contained in the Office of Geologic Repositories Quality Assurance Plan for high-level radioactive waste repositories (DOE, 1986b).

8.6.3.3 U.S. Department of Energy-Richland Operations Office

Within the DOE-RL, the manager, DOE-RL, has the ultimate responsibility and authority for maintaining an effective program of quality assurance for the BWIP in compliance with mandated requirements. Delegations to DOE-RL organizations associated with the implementation of quality assurance are depicted in Figure 8.6-4.

The manager, DOE-RL, has assigned the assistant manager, Office of Commercial Nuclear Waste (BWIP Project Manager), the authority to implement and direct the BWIP. The assistant manager, Office of Commercial Nuclear Waste, serves as the project manager and is responsible for providing overall DOE management of the BWIP in compliance with the BWIP quality assurance plan through all phases of the BWIP, including siting, site characterization, design, construction, operation, and institutional interfacing. The assistant manager, Office of Commercial Nuclear Waste, has established two divisions to provide day-to-day management of the BWIP, the Basalt Waste Isolation Division, and the Basalt Quality Systems Division.

In quality-assurance-related matters, the assistant manager is responsible for the following:

- o Approving the BWIP quality assurance plan and the procedures necessary for its implementation.
- o Approving project plans, as necessary, to permit the Basalt Waste Isolation Divisions to fulfill their technical and quality assurance program requirements.
- o Ensuring adequate funding for technical and quality assurance activities.
- o Effectively implementing the quality assurance program.
- o Approving formal quality and technical program direction issued by the Basalt Waste Isolation Division and Basalt Quality Systems Division to Basalt Waste Isolation Division project participants.
- o Ensuring and evaluating the effectiveness of implementation of the quality assurance program.
- o Evaluating the quality of delegated work as reported by the Basalt Waste Isolation and Basalt Quality Systems Divisions.
- o Evaluating management assessment reports of quality assurance program implementation.
- o Fulfilling other management responsibilities, as assigned by the DOE-RL manager.

The deputy assistant manager, Office of Commercial Nuclear Waste, chairs the DOE-RL Readiness Review Board.

The director, Basalt Quality Systems Division, reports on quality assurance program status to the Assessment Review Committee and directs implementation of recommendations and (or) required program changes. The assistant manager, Office of Commercial Nuclear Waste, convenes an Assessment Review Committee meeting at least annually to assess the scope, adequacy, status, and effectiveness of the BWIP quality assurance program. The assistant manager selects not less than two committee members from the DOE-RL director level or above and (or) executive level management of consultant or other organizations, as appropriate.

The director, Procurement Division, reports to the manager, DOE-RL, through the assistant manager, Offices of Assistant Manager for Administration. The director, Procurement Division, is responsible for establishing and implementing a procurement process in compliance with Federal procurement regulations and executing contracts that are consistent with BWIP quality assurance requirements. These responsibilities include reviewing procurement documents in accordance with approved procedures (e.g., statements of work, procurement requests, and preprocurement plans and administering the process that results in approved contracts and subcontracts).

The Basalt Quality Systems Division and Basalt Waste Isolation Division participate in evaluation boards, and review and concur in final contract and subcontract packages prior to award.

In addition, the Procurement Division provides review and approval of project management procedures that affect procurement activities. The director of the Procurement Division fulfills other responsibilities as assigned in the BWIP Quality Assurance Plan (DOE-RL, 1986).

The director, Basalt Waste Isolation Division, reports to the assistant manager, Office of Commercial Nuclear Waste, and is responsible for the following:

- o Effectively implementing the quality assurance plan in the engineering, geoscience, and licensing areas.
- o Evaluating technical effectiveness of quality assurance program control by participants prior to and during ongoing work.
- o Serving on and providing support for the DOE-RL Readiness Review Board.
- o Preparing and issuing management plans and instructions as required.

The director, Basalt Quality Systems Division, reports to the assistant manager, Office of Commercial Nuclear Waste, and exercises the highest direct-line authority in the BWIP for quality. The director, Basalt Quality Systems

Division, has no other responsibilities that prevent the devotion of full attention to quality activities. The director's responsibilities include the following:

- o Preparing and maintaining the BWIP Quality Assurance Plan (DOE-RL, 1986b) and procedures necessary for its implementation.
- o Establishing requirements for BWIP participants' programs.
- o Reviewing and approving the quality assurance plan and implementing quality assurance administrative procedures prepared by the integrating contractor.
- o 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.
- o Approving the quality assurance program and administrative procedures of the construction management contractor and the architect-engineer for use on the BWIP.
- o Exercising BWIP oversight of overall quality assurance program implementation.
- o Verifying effective implementation of the BWIP quality assurance plan by the Basalt Waste Isolation Division.
- o Reviewing and (or) specifying quality assurance requirements in procurement documents.
- o Approving contractor and subcontractor quality assurance programs when their work is not subject to cognizance by the integrating contractor.
- o Approving government agency quality programs when the scope of work is covered by a Memorandum of Understanding.
- o Providing direct quality assurance support to the Basalt Waste Isolation Division.
- o Serving on and providing support for the DOE-RL Readiness Review Board.

To promote communication and to assure positive attention to quality issues within the DOE-RL and between the Basalt Waste Isolation and Basalt Quality Systems Divisions and the BWIP participant contractors, lines of communication are characterized as follows (see Fig. 8.6-5):

- o Quality assurance direction and policy guidance from DOE-HQ reaches DOE-RL through the Office of Geologic Repositories, as specified in

the Office of Geologic Repositories Quality Assurance Plan (DOE, 1986b), the requirements documents it cites, and directives issued from that office.

The BWIP quality assurance plan, Basalt Waste Isolation Division, and Basalt Quality Systems Division quality assurance administrative procedures are submitted to the Office of Geologic Repositories for review and approval. The Office of Geologic Repositories personnel verify effective implementation of the project quality assurance program and project compliance with applicable regulations, codes, and standards.

Free, informal flow of information between DOE-RL personnel engaged in BWIP quality assurance-related activities and cognizant personnel in the Office of Geologic Repositories is encouraged to supplement formal reporting.

- o Formal direction to BWIP participant contractors concerning quality assurance program direction is issued at the project manager or the Basalt Quality Systems Division director level within DOE-RL. Typically, quality assurance guidance is issued by the Basalt Quality Systems Division. This guidance serves to establish a clear line of authority to the contractors for direction of their quality assurance program.
- o Formal internal communications exist among all levels within DOE-RL and between DOE-RL and DOE-HQ. Typically these take the form of memoranda and planned reporting such as weekly and monthly status reports.
- o Individuals are encouraged to identify and report quality problems and to initiate, recommend, and provide solutions. Within the DOE, such activities are documented and tracked by the quality concerns program that notifies individuals of resolutions taken.

The lines of communication are from DOE-RL to the integrating contractor to the architect-engineer, construction manager, other BWIP participant contractors, and government agencies to their suppliers. When a government agency is working under a memorandum of understanding, communications are initiated by DOE-RL (see Fig. 8.6-5).

Communication from DOE-RL regarding quality-assurance-related activities within the DOE-RL organizations are promoted through the following:

- o Periodic staff meetings.
- o Quality assurance program progress and status reports outlining the status of quality assurance activities, problems and non-conformances, quality trends, readiness reviews, and results of audits and surveillances.

At least once each quarter, the DOE-RL Basalt Quality Systems Division chairs a meeting of representatives from each quality assurance organization of the major BWIP participant contractors to receive reports and discuss matters relevant to quality assurance program implementation. The results of these meetings are documented.

Within the DOE-RL and between DOE-RL and DOE-HQ, channels of communication and defined authorities exist to resolve disputes that may arise from differences of opinion on quality-assurance-related issues. Should the principals in any dispute be unable to reach resolution, problems may be elevated to successively higher levels of management within the field office (branch chiefs and team leaders, division directors and project managers, assistant managers, and ultimately the field office manager) and eventually to the DOE-HQ Program Office.

An annual verification plan is prepared and issued by the DOE-RL Basalt Quality Systems Division that identifies scheduled audit, surveillance, and other verification activities to be performed by the DOE-RL Office of Commercial Nuclear Waste, and other DOE-RL organizations on specific tasks in support of the BWIP, either internally by the DOE-RL organizations or externally by the BWIP participant contractors. The plan and any revisions are approved for issuance by the DOE-RL Office of Commercial Nuclear Waste. Revisions are issued to reflect changes in the status or importance of work in progress. In addition, unscheduled verification activities are performed by the DOE-RL Office of Commercial Nuclear Waste as the need is identified.

At times, the Basalt Waste Isolation and (or) Basalt Quality Systems Divisions engage the services of external peer review groups and individuals to provide independent, expert overview of BWIP activities to verify appropriateness of program direction, test results, etc. These reviews are formally documented, and the Basalt Waste Isolation and Basalt Quality Systems Divisions review the qualifications of participants to ensure a level of education, training, and experience commensurate with planned activities.

In addition to daily informal communications between DOE-RL organizations and the BWIP participant contractors, there are formal organizational responsibilities to ensure effective implementation of the quality assurance program. The Basalt Waste Isolation Division and the Basalt Quality Systems Division, through their technical and quality assurance oversight roles, provide the feedback necessary for overall contractor evaluation and the long-term and day-to-day management of work.

Organizations and persons performing quality-assurance-related activities (primarily the Basalt Waste Isolation Division, Basalt Quality Systems Division, and Procurement Division) have direct access, as provided through established surveillance and audit procedures and normal communication channels, to appropriate management levels to permit timely identification of quality-related problems, recommendation and initiation of corrective actions (including review of recommended corrective actions provided by others), and verification of corrective action implementation.

8.6.3.4 BWIP participant contractors

Rockwell BWIP is the DOE-RL operating contractor for Hanford Site waste management and has been assigned as integrating contractor for the BWIP. Rockwell BWIP is responsible for assuring the coordination and implementation of quality assurance programs by all BWIP participant contractors. All BWIP participant contractors are responsible for documenting and implementing effective quality assurance programs in compliance with contractual requirements.

The integrating contractor has two roles in the BWIP: (1) project management under DOE-RL direction and (2) direct performance of specified technical work. In the project management role, the integrating contractor ensures that the activities of all BWIP 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 site characterization.

The integrating contractor's project management role includes responsibility for ensuring that DOE-RL/Office of Commercial Nuclear Waste policy and direction is implemented effectively and consistently across the BWIP while the integrating contractor's quality assurance organization provides the following BWIP services:

- o Reviews and recommends DOE-RL approval of quality assurance program descriptions and quality assurance administrative procedures prepared by the construction management contractor and the architect-engineer.
- o Approves the quality assurance plans and quality assurance administrative procedures prepared by BWIP participant contractors under direct contract to the DOE for their BWIP work (other than the architect-engineer and construction manager) and all BWIP participants under direct contract to the integrating contractor for their BWIP work.
- o Establishes BWIP-wide systems and (or) methods for implementing quality assurance program elements for which such uniformity produces important cost and (or) control benefits.
- o Verifies effective implementation of the quality assurance program by means of audit, surveillance, trending, and management assessment of quality assurance activities of the architect-engineer, construction manager, other BWIP participants under direct contract to the DOE for their BWIP work, and all BWIP participants under direct contract to the integrating contractor for their BWIP work.
- o Ensures that applicable elements of its quality assurance program are effectively implemented for direct work performed in-house.

Each of the other BWIP participant contractors is responsible for the following:

- o Developing and implementing a quality assurance program that meets all applicable requirements identified in the Basalt Quality Assurance Requirements Document (DOE, 1986a), is consistent with the BWIP quality assurance program described in the BWIP Quality Assurance Plan (DOE, 1986b), and reflects any BWIP-wide quality assurance systems or methods specified by the integrating contractor.
- o Approving the quality assurance plans and quality assurance administrative procedures of subcontractors doing BWIP work under contract to them.
- o Verifying effective implementation of their quality assurance program and quality assurance programs of subcontractors doing BWIP work under direct contract to them.

Within DOE-RL Office of Commercial Nuclear Waste and each BWIP participant contractor organization, a management position has been identified that retains overall authority and responsibility for the Quality Assurance program. This position, occupied by an individual with appropriate management and quality assurance knowledge and experience has the following characteristics:

- o Is at the same or higher organizational level as the highest line manager directly responsible for performing activities affecting quality (e.g., design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
- o Has effective communication channels with other senior management positions.
- o Has responsibility for approval of quality assurance plan(s) and manual(s), changes thereto, and interpretations thereof for the contractor.
- o Has no other duties or responsibilities unrelated to quality assurance that would prevent full attention to quality assurance matters.

The persons responsible for directing and managing the overall quality assurance program have appropriate organizational position, responsibilities, and authority to exercise proper control over the quality assurance program. These individuals are free from nonquality assurance duties and, thus, can give full attention to assuring that the quality assurance program is being effectively implemented.

8.6.4 APPLICATION OF QUALITY ASSURANCE

The BWIP has operated under a formal documented quality assurance program from the commencement of site exploration activities to date. The Quality Assurance Program has evolved to support developing phases of the BWIP and to incorporate the most current revision of federally mandated requirements. The following sections describe how quality assurance has been and will be applied.

8.6.4.1 Quality assurance during site exploration

Requirements for a formal, documented quality assurance program for DOE-RL and the BWIP participant contractors were established at the beginning of BWIP site exploration activities (December 1, 1977 to May 28, 1986). These requirements were initially stated in the DOE-HQ Order 5700.6A (DOE, 1981) and DOE-RL Orders 0820 (DOE-RL, 1978), 5700.1 (DOE-RL, 1980) and 5700.1A (DOE-RL, 1980). These quality assurance documents established the requirement that activities affecting quality be defined and documented in appropriate directives, policies, procedures, and instructions, and applied to data gathering and other activities during site exploration. In response, Rockwell BWIP, the integrating contractor responsible for conducting the site exploration activities, established quality assurance plans and quality assurance and technical procedures. Applicable quality assurance procedures (e.g., design and peer review) and technical implementing procedures were identified in the quality assurance plans (Rockwell, 1978; 1979; and 1982). Technical data gathering techniques were documented in procedure manuals.

The quality assurance program for site exploration evolved from 1977 to 1986 and incorporated requirements in effect at the time work was performed. The program was modified as new requirements were imposed or requirements were adopted by BWIP to improve program validity. During site exploration, data was gathered, which now that the BWIP has been selected for site characterization, will be used for characterization and to possibly support license application. This data will be identified and qualified, against the current quality assurance program if required, on a case-by-case basis in accordance with approved procedures incorporating the requirements of Supplement 9 "Reliability of Data" to the Office of Geologic Repositories Quality Assurance Plan (DOE, 1986b).

8.6.4.2 Quality assurance during site characterization

This section consists of two parts. The first part describes the process by which items and activities are determined to be important to safety or waste isolation (identified by the term "Quality" or "Q" list) and the second part describes the graded quality assurance program to be applied to these and other items and activities associated with the BWIP.

8.6.4.2.1 "Q" listed items and activities

This subsection describes the methodology to be used by the BWIP in determining the structures, systems, components, and activities important to safety and waste isolation for the mined geologic disposal system. The resulting list of structures, systems, components, and activities important to safety and waste isolation is called the "quality list" or "Q-list." The items and activities on the list will be subject to the highest quality level of a formal quality assurance program required for site characterization and licensing of the geologic repository and will be subject to NRC licensing review and oversight. While other activities will not be subject to regulatory control, the NRC may examine any item or activity not on the Q-list to ensure that no items or activities important to safety or waste isolation have been omitted from the Q-list.

The Q-list will change over time, with a final list emerging at the completion of the NRC review of the DOE license application. Those items and activities that have been determined to be important to safety or waste isolation and the rationale for this determination are presented in Sections 6.1.4 and 6.1.5, respectively. During the period from site characterization start to license application, two milestones stand out: (1) the Q-list to support the Site Characterization Plan (SCP) data-gathering and design efforts and (2) the Q-list to support the license application design stage. The methodology to generate the SCP-stage Q-list is described in this section. As site characterization and design activities progress to the point of allowing quantification of key input parameters, the license application design stage methodology will be described in the license application documents.

8.6.4.2.1.1 Determination of items and activities important to safety for the site characterization phase

Structures, systems, components, and activities that are important to safety are defined (1983) in 10 CFR 60.2 (NRC, 1983).

"those engineered structures, systems and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure."

Items important to safety must be on the Q-list to ensure that the design addresses their safety requirements and that appropriate quality assurance controls are applied. Central to the above NRC definition is the dose consequence of the failure of the items. The assessment of the dose consequences of the failure of structures, systems, or components, however, requires a detailed assessment of their functions under design basis conditions that are not available until (1) the design effort attains a certain maturity and (2) design basis conditions are identified and

established. Prior to that time, the methodology employed will be based on the application of the criteria specified below through the use of engineering judgment.

The NRC definition of "important to safety" contains a criterion for assigning an item to the Q-list whenever the item can prevent or mitigate an accident that could result in a dose in the uncontrolled area of 0.5 rem or greater. Another criterion may be inferred from the definition, although not explicitly stated: a determination that the accident scenario is credible. The term "credible accident" as used here implies that the accident has an overall probability of occurrence that is smaller than the probability for expected operational events but yet not so small as to be considered insignificant or incredible. The quantitative limit below which an event ceases to be considered credible is not identified in 10 CFR 60 (NRC, 1983). For purposes of identifying structures, system, components, and activities to be placed on the Q-list, failures that would have an annual probability of 1×10^{-5} or less of exceeding the 0.5 rem threshold will be disregarded. The probability of incurring a health effect from a 1-rem whole body exposure is on the order of 1×10^{-4} . The combined annual probability of incurring a health effect among the offsite population is, therefore, less than 1×10^{-9} from a failure with a probability of 1×10^{-5} or less per year of resulting in an offsite dose of 0.5 rem. This risk is significantly smaller than "risks that would be regarded as negligible by the exposed individuals," which are on the order to 1×10^{-6} health effects per year.

The dose consequence estimate should be based on a radiation transport model that uses conservatively estimated parameters where design and site details are lacking. One such model is set forth in NRC Regulatory Guide 1.25, "Assumptions Used for Evaluating the Potential Radiological Consequence of a Fuel Handling Accident in the Fuel Handling and Storage Facility for Boiling and Pressurized Water Reactors" (NRC, 19720).

To summarize, the Q-list at the SCP design stage shall be composed of the structures, systems, components, and activities that have a probability of failure that is greater than $10^{-5}/\text{yr}$, with dose consequences exceeding 0.5 rem.

A list of those items and activities determined to be important to safety and the rationale for this determination is presented in Section 6.1.4.

8.6.4.2.1.2 Determination of items and activities
important to waste isolation for the
Site Characterization Phase

From 10 CFR 60.2 (NRC, 1983), it may be inferred that structures, system, and components important to waste isolation would be those natural and engineered barriers that are relied on to inhibit "...the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits." These items must function in a certain way in order to meet the long-term isolation objective after repository closure.

In 10 CFR 60, paragraph 60.113 (NRC, 1983), the NRC has defined performance objectives for the repository after closure. The four performance objectives are related to the following performance measures:

- o Waste package containment time.
- o Rate of release of radionuclides from the engineered barrier system.
- o Preplacement groundwater travel time.
- o Cumulative release to the accessible environment.

Consequently, structures, systems, and components important to waste isolation may include shaft and borehole seals, engineered barriers (e.g., waste package), and features of the natural site system.

The designation of structures, system, and components to be placed on the Q-list at the SCP design state and all site characterization activities that are essential to adequately evaluate these items shall be based on technical judgment of the items required to comply with or to demonstrate compliance with the repository performance objectives as the repository performance analyses are completed. A list of those items and activities determined to be important to waste isolation and the rationale for that determination is presented in Section 6.1.5. Waste package design containment is discussed in Sections 7.0 and 8.3.5.

As the site characterization activities take place and the understanding of the Hanford Site changes, the performance goals may change. As a consequence, some change to the Q-list is expected as the site characterization program progresses. All site characterization tests and activities, therefore, must be carefully planned and must not only take into account the primary tests for the items initially placed on the Q-list, but also must include some contingency for items that may be later added to the Q-list. A conservative approach at the SCP design stage is to be adopted to ensure that data necessary to demonstrate compliance with 10 CFR 60 (DOE, 1984) are obtained and preserved in accordance with quality assurance requirements.

Retrieval of the waste from the repository is a requirement of 10 CFR 60 (DOE, 1984) and shall be treated in the same manner as waste emplacement. Much of the equipment needed for retrieval is expected to be the same as or similar to the equipment needed for waste emplacement. The same procedures and criteria used to classify the items and activities needed to emplace the waste shall be used to determine if equipment and activities needed to retrieve the waste should be included on the Q-list.

8.6.4.2.2 Graded quality assurance program

During site characterization of BWIP, a graded quality assurance program will be established and implemented. The purpose of a graded quality assurance program is to select the quality assurance measures to be applied to items and activities in the repository program consistent with their

importance to safety, waste isolation, and the achievement of program success. This will be accomplished by deliberate quality planning and selective application of quality assurance requirements to the item or activity to be performed, with varying degrees of quality assurance applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

This approach involves identifying those items and activities whose failure could cause undue risk to the public and facility personnel and (or) extended shutdown of the facility with critical economic losses and ensuring that these items and activities are covered with a commensurate quality assurance program. On the other hand, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may warrant only a quality inspection by the purchaser on delivery of the item. Between these two extremes, there are varying degrees of quality assurance to achieve the desired confidence in the quality of the completed item or activity.

The graded quality assurance approach set forth here provides flexibility in the selection of the level of the quality program to be applied to an item or activity commensurate with the relative importance of the role or function assigned to the item or activity.

The requirements of this section are applicable to all items and activities required during geologic repository site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities.

The three quality assurance levels are defined as follows.

- o Quality Level 1: The highest quality level available for assignment on geologic repository projects. The most stringent quality assurance requirements from Figure 8.6-2 will apply to items or activities on the Q-list in all phases of design, procurement, construction (fabrication), shipping, storage installation, or operations consistent with assuring that safety (Q-list) and (or) waste isolation objectives are met.
- o Quality Level 2: The intermediate quality level available for assignment on geologic repository projects. Stringent quality assurance requirements from NQA-1 (ANSI/ASME, 1986) will apply to items and activities not included under Level 1 in those phases of design, procurement, construction (fabrication), shipping, storage, installation, and operations consistent with accomplishing DOE's mission objective.
- o Quality Level 3: The lowest quality level available for assignment on geologic repository projects. This level is assigned to all items and activities included in the quality assurance program but not assigned Quality Levels 1 or 2. Quality assurance requirements from NQA-1 will apply as determined to items and activities not

included in Level 1 or 2 to provide assurance that good engineering, laboratory, and (or) workmanship practices are met consistent with the high quality expected of the repository.

The appropriate quality level for any item or activity shall be determined by the application of the decision criteria in Table 8.6-2. The basis for the selection of the quality level shall be documented.

Once a quality level is selected, the quality program criteria/requirements of Tables 8.6-3 and 8.6-4 shall be applied. However, further grading beyond the selection of the quality level may be undertaken in accordance with approved procedures to select the specific criteria/requirements to be applied. This shall be accomplished by an evaluation by technical and quality system personnel of the scope and type of work involved and other factors, as appropriate, that may influence the selection of those criteria/requirements that are necessary and sufficient. The Q-list items and activities shall meet the applicable requirements of 10 CFR 50, Appendix B (NRC, 1979a), and conditions of the NRC Quality Assurance Review Plan (NRC, 1984). The scope of work involved in completing an item or activity may be divided into subelements, and the criteria/requirements contained in Tables 8.6-3 and 8.6-4 may be evaluated for application to these subelements.

For example, one Quality Level 1 (Q-list) item may involve an engineered piece of equipment that is very complex to design and manufacture, which calls for special design controls, verification, and development tests in addition to special controls during manufacture. Thus, it may be subject to all the requirements, supplements, appendices, and other requirements set forth in Table 8.6-3 for Quality Level 1. On the other hand, another Quality Level 1 (Q-list) item may actually be a commercial off-the-shelf item that has a proven design, is easy to build, has a good quality history, and is well within the state of the art. The appropriate quality program requirements for this second example may be less than for the first example involving the newly engineered piece of equipment, and several of the criteria/requirements listed in Tables 8.6-3 and 8.6-4 may not be required to ensure that appropriate quality is achieved.

The depth of coverage and comprehensiveness of any given quality program criteria/requirement within a quality level may be additionally increased, decreased, or modified as deemed necessary for each item or activity. The technical and quality assurance system personnel shall evaluate each item and activity to determine the depth and comprehensiveness of coverage within each applicable criterion/requirement appropriate for that item or activity. Factors to be considered in making this determination include complexity of design or fabrication, uniqueness of the item or activity, the need for controls over special processes or tests, ability to demonstrate functional compliance by inspection or test, and the quality history of the item or activity. Appendix 4A-1 of NQA-1 (ANSI/ASME, 1986) may also be used as guidance in applying graded quality assurance.

For example, NQA-1 Basic Requirement 10, Supplement 10S-1 (ANSI/ASME, 1986), and 10 CFR 50 Appendix B, Criterion 10 (NRC, 1979), may all apply to

sealing a repository shaft and welding a shaft liner. Both processes require inspections to verify conformance with design requirements. As it may be difficult to verify that the shaft sealing has been properly performed after placement, continuous surveillance may be appropriate. Conversely, welding is normally verified after completion, and only normal examinations and inspections of completed weldments may be necessary.

Written justification shall be provided for cases where deviations were made from NQA-1 (ANSI/ASME, 1986) basic requirements, supplementary requirements, appendixes, and (or) quality assurance criteria of 10 CFR 50, Appendix B (NRC, 1979a), or other requirements specified in Table 8.6-3 as being necessary and sufficient for a certain quality level. Deviations are defined as additions of specified requirements, deletion of specified requirements, or modifications to specified requirements. The written justification for additions is necessary to support and explain the basis for the additional quality assurance requirements and, thus, justify the corresponding additional cost and effort.

These quality levels, presented in descending order, have decreasing scope of quality program criteria/requirements. This is evident in the matrix comparison of quality levels shown in Table 8.6-3.

A description of each quality level and guidance for application of each level follows.

1. Quality Level 1

Description. This is the highest quality level available and requires the responsible organization to implement a quality assurance program that meets, as a minimum, all applicable requirements of the Basalt Quality Assurance Requirements Document (DOE-RL, 1986a). Quality Level 1 programs require quality planning, preparation of a quality assurance manual/plan and supporting administrative and technical procedures, adherence to procedures and drawings, personnel qualification training programs, documentation of activities performed and results obtained and comprehensive review, inspection, management assessment, verification, surveillance, and auditing activities.

Quality Level 1 programs shall meet the criteria/requirements listed in Table 8.6-3 for Quality Level 1, as a minimum, unless appropriate written justification for any deviation is provided. Other specific requirements that are unique to the item or activity may be specified during the quality level selection process. Certain items and activities with potential for inclusion on the Q-list may be identified and (or) directed by the DOE to be treated as a Quality Level 1.

Application. Quality Level 1 shall be applied to all items that have been identified as important to safety or waste isolation (Q-list items). Activities covered under Quality Level 1 include

site selecting, designing, fabricating, purchasing, handling, shipping, storing, cleaning, erecting, installing, emplacing, inspecting, testing, operating, maintaining, monitoring, repairing, modifying, decommissioning, and site characterization.

2. Quality Level 2

Description. This is the second highest level available for assignment to items and activities on geologic repository projects. Responsible organizations are required to implement quality assurance programs. A quality assurance manual/plan and supporting procedures are required. The same basic NQA-1 quality assurance requirements (ANSI/ASME, 1986) that apply to Quality Level 1 also apply to Quality Level 2. However, 10 CFR 50, Appendix B (NRC, 1979a), and the NRC Quality Assurance Review Plan (NRC, 1984) do not apply to Quality Level 2. Fewer NQA-1 supplemental requirements apply to Quality Level 2 with corresponding reductions in quality assurance controls.

Quality Level 2 programs shall meet the criteria/requirements listed in Table 8.6-3 for Quality Level 2, as a minimum, unless appropriate written justification for any deviation is provided. Other specific requirements unique to the item or activity may be specified by the organization responsible for quality level selection.

Application. Quality Level 2 shall be applied to those items or activities that are not Q-1 list items but are of major importance to the attainment of DOE programmatic objectives. Quality Level 2 is also to be applied to items and activities that have potential impact on public and occupational radiological health and safety under 10 CFR 20 (NRC, 1979b) and to items involving a significant number of field and laboratory investigations and complex manufacturing, assembly, and construction processes.

3. Quality Level 3

Description. This is the lowest quality level available for assignment. Quality Level 3 items and activities may be required to meet appropriate quality and administrative requirements as determined on a case-by-case basis. The quality requirements to be met for each item or activity, including any required documentation, shall be identified and justified. Quality Level 3 items and activities generally require the use of good management, engineering, or laboratory work practices to prepare them for their intended use.

Application. Quality Level 3 shall be applied to those items and activities that do not meet the criteria for Quality Level 1 or 2. This quality level shall be applied to items that can be inspected for acceptance on completion or delivery or to activities that can be accepted by evaluation of a final report. The quality

requirements of subpart 46.202-1 of the Federal Acquisition Regulations (NRC, 1979), which requires that the contractor perform an inspection, are applicable to Quality Level 3 activities. When deemed appropriate, the requirement to obtain a "Certificate of Conformance" from the supplier may be invoked by the organization responsible for quality level selection. Additional requirements may be implemented, as deemed necessary, to effect more uniform management controls.

Typical items and activities that shall be covered by this quality level include the following:

- a. Items that are noncomplex and are normally considered commercially available standard hardware.
- b. Activities that are routine or purely developmental in nature and will not produce data or results that will be used for design, environmental, or licensing applications.

8.6.5 QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES

This section lists the quality assurance administrative procedures for the DOE-RL, Rockwell BWIP (the integrating contractor), Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (the architect-engineer), and Morrison-Knudsen (the construction manager), as contained in their quality assurance manuals for site characterization activities (i.e., those activities commencing after May 28, 1986). Quality assurance administrative procedures are those which define and direct controls and control systems making up the BWIP quality assurance program. These procedures are listed by criterion they implement with the responsible BWIP organization as a subheading.

Criterion 1.0 - Organization

- o The U.S. Department of Energy-Richland Operations Office
 - BP 1.1 Organization
 - BP 1.7 Commitment/Action Item Tracking
 - BP 1.8 Correspondence Control
 - BP 1.11 Stop Work
 - PMD 19.13 Control and Release of Proprietary Information
- o Rockwell Hanford Operations Basalt Waste Isolation Project (integrating contractor)
 - PMPM ORG-1.1 Rockwell BWIP Organization Structure
 - PMPM G4-103 Surveillance Activities
 - PMPM G4-104 Quality Assurance Audits
 - PMPM G4-108 Inspection Activities

MPPM 04-115 Stop Work Order
MPPM 04-116 Resolution of Disputes with Quality Assurance
MPPM 04-120 Quality Concerns Program
MPPM 04-121 Graded Quality Assurance
MPPM 13-106 Administration of Qualification and Training
MPPM 14-102 Software Change Control

o Morrison-Knudsen (construction manager)

QAP 1.1 Organization
QAP 1.2 Stop Work Order

o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

PP 1.2 Project Organization

Criterion 2.0 - Quality Assurance Program

o U.S. Department of Energy-Richland Operations Office

BP 2.1 Quality Assurance Program Assessment
BP 2.2 Work Progress and Design Reviews
BP 2.5 Personnel Training
BP 2.6 Personnel Qualification and Certification
BP 2.7 Appeals on Quality Concerns
BP 2.8 Control and Release of Licensing Documents
BP 2.10 Reporting of Significant Deficiencies

o Rockwell Hanford Operations Basalt Waste Isolation Project

MPPM ORG 1.1 Rockwell Organization and Responsibilities
MPPM 01-114 Project Management and Work Process Control
MPPM 02-112 Construction Acceptance Test Control
MPPM 02-130 Control of Special Processes
MPPM 04-104 Quality Assurance Audits
MPPM 04-108 Inspection Activities
MPPM 04-111 Trend Analysis
MPPM 04-121 Graded Quality Assurance
MPPM 07-108 Control of Standards and Measuring and Test Equipment
MPPM 07-119 Data Collection Test Control
MPPM 08-133 Document Control
MPPM 03-106 Administration of Qualification and Training
MPPM 14-102 Software Change Control

o Morrison-Knudsen (construction manager)

QAP 2.1 Quality Assurance Program
QAP 2.2 Indoctrination and Training

- QAP 2.3 Qualification and Certification of Inspection Personnel
- QAP 2.4 Qualification and Certification of Audit Personnel
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 2.1 Orientation and Training
 - PP 2.2 Quality Assurance Surveillance of Project Activities
 - PP 2.3 Procedure Preparation and Control
 - PP 2.5 Procurement of Services
 - PP 2.6 Corrective Action
 - PP 2.7 Stop Work Order
 - PP 2.8 Records of Quality Assurance Activities
 - PP 2.9 Audits

Criterion 3 - Design Control

- o U.S. Department of Energy-Richland Operations Office
 - BP 3.1 Project Reviews
 - BP 3.3 Peer Reviews
 - BP 3.4 Graded Quality Assurance
 - BP 3.5 Data Qualification Activities
 - PMD 19.11 Readiness Reviews
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 02-126 Design Control Process
 - PMPM 03-102 Peer Review
 - PMPM 14-102 Software Change Control
- o Morrison-Knudsen (construction manager)
 - QAP 3.1 Design/Field Changes
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.0 Conduct of Design Activities
 - PP 6.1 Control of Design Input
 - PP 6.2 Engineering Calculations
 - PP 6.3 Engineering Drawing Control
 - PP 6.4 Engineering Specifications
 - PP 6.4 Drafting Procedures and Standards
 - PP 6.6 Control of Computer Programs
 - PP 6.8 Document Control
 - PP 6.9 General Engineering Support Services
 - PP 6.10 Engineering Disposition of CNCRs
 - PP 6.11 Design Field Changes
 - PP 6.12 Vendor Data

PP 6.13	Engineering Reports
PP 6.14	Acceptance Test
PP 6.15	Supplier Deviation Request
PP 6.16	Engineering Studies
PP 6.17	Interim Design Reviews
PP 6.18	Engineering Design Packages
PP 6.19	RCR Processing
PP 6.20	Preparation, Disposition and Control of Nonconformance Reprints
PP 6.21	Design Verification
PP 6.22	Peer Review

Criterion 4.0 - Procurement Document Control

- o U.S. Department of Energy-Richland Operations Office
 - BP 4.1 Preparation and Control of Procurement Documents
 - BP 4.2 Contractor Initiated Procurements
 - PMD 19.10 Acquisition/Procurement Process Overview
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 06-115 Procurement Management System
 - PMPM 06-117 Major Project Participant Procurement Interface
Activities
 - PMPM 07-119 Data Collection Test Control
- o Morrison-Knudsen (construction manager)
 - QAP 4.1 Procurement
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)
 - PP 2.5 Procurement of Services
 - PP 6.12 Vendor Data
 - PP 6.15 Supplier's Deviation Request

Criterion 5.0 - Plans, Instructions, Procedures, and Drawings

- o U.S. Department of Energy-Richland Operations Office
 - BP 5.1 Procedure Development
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 01-114 Project Management and Work Progress Control

- o Morrison-Knudsen (construction manager)
 - QAP 5.1 Preparation, Revision and Approval of Quality Assurance Procedures and Instructions
 - QAP 5.2 Preparation, Issue and Control of Work Procedures
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 2.1 Orientation and Training
 - PP 2.3 Procedure Preparation and Control

Criterion 6.0 - Document Control

- o U.S. Department of Energy-Richland Operations Office
 - BP 6.1 Preparation and Release of Office of Commercial Nuclear Waste Documents
 - BP 6.2 Controlled Documents Issued to the Office of Commercial Nuclear Waste Staff
 - BP 6.3 Review and Approval of External Documents
 - PMD 19.13 Control and Release of Proprietary Information
 - PMD 19.16 Document Control Program
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 08-133 Document Control
- o Morrison-Knudsen (construction manager)
 - QAP 6.1 Document Control
- o Kaiser Engineers, Inc./Parson Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 1.4 Deviation/Waiver Control
 - PP 2.3 Procedure Preparation and Control
 - PP 2.8 Records of Quality Assurance Activities
 - PP 6.1 Control of Design Input
 - PP 6.3 Engineering Drawing Control
 - PP 6.8 Document Control

Criterion 7.0 - Control of Purchased Material Equipment and Services

- o U.S. Department of Energy-Richland Operations Office
 - BP 7.1 Supplier Evaluation, Selection, and Verification
 - BP 7.2 Supplier Furnished Records

- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 04-103 Surveillance Activities
 - PMPM 04-104 Quality Assurance Audits
 - PMPM 04-105 Nonconformance Reports
 - PMPM 04-106 Construction Nonconformance Reports
 - PMPM 04-108 Inspection Activities
 - PMPM 04-111 Trend Analysis
 - PMPM 04-115 Stop Work Order
 - PMPM 06-115 Procurement Management System
- o Morrison-Knudsen (construction manager)
 - QAP 7.1 Supplier Qualification
 - QAP 7.2 Supplier Surveillance
 - QAP 7.3 Supplier Audits
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 2.5 Procurement of Services
 - PP 6.4 Engineering Specifications
 - PP 6.12 Vendor Data
 - PP 6.14 Supplier Deviation Request

Criterion 8.0 - Identification and Control of Items

- o U.S. Department of Energy-Richland Operations Office
 - NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 08-103 BWIP Records Management System
 - PMPM 07-118 Identification and Control of Samples
 - PMPM 07-120 Identification and Control of Equipment and Components
- o Morrison-Knudsen (construction manager)
 - QAP 8.1 Identification and Control of Items and Samples
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.4 Engineering Specifications

Criterion 9.0 - Control of Special Processes

- o U.S. Department of Energy-Richland Operations Office
 - NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 02-130 Control of Special Processes
 - PMPM 04-103 Surveillance Activities
 - PMPM 04-104 Quality Assurance Audits
 - PMPM 04-108 Inspection Activities
- o Morrison-Knudsen (construction manager)
 - QAP 9.1 Control of Special Processes
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.4 Engineering Specifications

Criterion 10.0 - Inspection

- o U.S. Department of Energy-Richland Operations Office
 - NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 04-103 Surveillance Activities
 - PMPM 04-105 Nonconformance Reports
 - PMPM 04-106 Construction Nonconformance Reports
 - PMPM 04-108 Inspection Activities
 - PMPM 04-111 Trend Analysis
 - PMPM 04-115 Stop Work Order
 - PMPM 04-122 Corrective Action Report
 - PMPM 08-133 Document Control
 - PMPM 13-106 Administration of Qualification and Training
- o Morrison-Knudsen (construction manager)
 - QAP 10.1 Instructions for the Conduct of Inspections
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.4 Engineering Specifications

Criterion 11.0 - Test Control

- o U.S. Department of Energy-Richland Operations Office
 - NA

o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 02-112 Construction Acceptance Test Control
PMPM 04-103 Surveillance Activities
PMPM 04-104 Quality Assurance Audits
PMPM 04-105 Nonconformance Reports
PMPM 04-106 Construction Nonconformance Reports
PMPM 04-108 Inspection Activities
PMPM 07-119 Data Collection Test Control
PMPM 08-103 BWIP Records Management System
PMPM 11-103 Unusual Occurrence Reporting System
PMPM 14-102 Software Change Control
PMPM 14-106 Administration of Qualification and Training

o Morrison-Knudsen (construction manager)

NA

o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

PP 6.4 Engineering Specifications
PP 6.14 Acceptance Test

Criterion 12.0 - Control of Measuring and Test Equipment

o U.S. Department of Energy-Richland Operations Office

NA

o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 07-108 Control of Standards and Measuring and Test Equipment
PMPM 04-105 Nonconformance Reports
PMPM 04-106 Construction Nonconformance Reports
PMPM 04-122 Corrective Action Reports
PMPM 06-115 Procurement Management System

o Morrison-Knudsen (construction manager)

QAP 12.1 Calibration, Control, and Use of Measuring and Test
Equipment

o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

PP 6.4 Engineering Specifications
PP 6.14 Acceptance Test

Criterion 13.0 - Handling, Shipping, and Storage

- o U.S. Department of Energy-Richland Operations Office
NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 06-117 Major Participant Procurement Interface Activities
 - PMPM 06-119 Shipping and Storage Control
 - PMPM 14-106 Administration of Qualification and Training
- o Morrison-Knudsen (construction manager)
 - QAP 13.1 Handling, Storage, and Preservation of Equipment and Materials
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.4 Engineering Specifications

Criterion 14.0 - Inspection Test and Operating Status

- o U.S. Department of Energy-Richland Operations Office
NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 04-105 Nonconformance Reports
 - PMPM 04-106 Construction Nonconformance Reports
 - PMPM 07-121 Inspection, Test and Operating Status
- o Morrison-Knudsen (construction manager)
 - QAP 14.1 Inspection, Test, and Operating Status
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.4 Engineering Specifications

Criterion 15.0 - Control of Nonconforming Items

- o U.S. Department of Energy-Richland Operations Office
 - BP 15.1 Processing Contractor NCRs and Unusual Occurrences
 - BP 15.2 Trend Analysis

- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 01-111 BWIP Action Tracking System
 - PMPM 04-105 Nonconformance-Control System
 - PMPM 04-106 Construction Nonconformance Reports
 - PMPM 04-111 Trend Reporting
 - PMPM 04-122 Corrective Action Report
 - PMPM 07-121 Inspection, Test, and Operating Status
 - PMPM 11-103 Unusual Occurrence Reporting System
- o Morrison-Knudsen (construction manager)
 - QAP 15.1 Control of Nonconformances
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 6.10 Engineering Disposition on CNCRs
 - PP 6.15 Supplier's Deviation Request
 - PP 6.20 Preparation, Disposition, and Control of Nonconformance Reports

Criterion 16.0 - Corrective Action

- o U.S. Department of Energy-Richland Operations Office
 - BP 16.1 Corrective Action
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 01-111 BWIP Action Tracking System
 - PMPM 04-105 Nonconformance Reports
 - PMPM 04-106 Construction Nonconformance Reports
 - PMPM 04-111 Trend Reporting
 - PMPM 04-122 Corrective Action Report
 - PMPM 11-103 Unusual Occurrence Reporting System
- o Morrison-Knudsen (construction manager)
 - QAP 16.1 Corrective Action Requests
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 2.2 Quality Assurance Surveillance
 - PP 2.6 Corrective Action
 - PP 2.7 Stop Work Order
 - PP 2.9 Audits
 - PP 6.20 Preparation, Disposition, and Control of Nonconformance Reports
 - PP 6.25 Unusual Occurrence Reporting

Criterion 17.0 - Quality Assurance Records

- o U.S. Department of Energy-Richland Operations Office
 - BP 17.1 Quality Records
 - PMD 19.15 Records Management Program
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 08-103 BWIP Records Management System
- o Morrison-Knudsen (construction manager)
 - QAP 17.1 Quality Assurance Records
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 2.8 Records of Quality Assurance Activities
 - PP 6.1 Control of Design Inputs
 - PP 6.8 Document Control
 - PP 6.23 QA Records

Criterion 18.0 - Audits

- o U.S. Department of Energy-Richland Operations Office
 - BP 18.1 Audit and Surveillance Planning
 - BP 18.4 Auditor Qualifications
 - BP 18.5 Surveillance of Project Activities
 - BP 18.6 Audits
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 04-104 Quality Assurance Audits
 - PMPM 04-111 Trend Analysis
 - PMPM 08-103 BWIP Records Management System
 - PMPM 13-106 Administration of Qualification and Training
- o Morrison-Knudsen (construction manager)
 - QAP 18.1 Quality Assurance Audits
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - PP 2.2 Quality Assurance Surveillance of Project Activities
 - PP 2.6 Corrective Action
 - PP 2.9 Audits

8.6.6 QUALITY ASSURANCE PLANS AND PROCEDURES FOR SPECIFIC PROGRAM AREAS

This section lists the quality assurance plans and necessary procedures for implementing the quality assurance administrative procedures identified in Section 8.6.5 for the DOE-RL, Rockwell BWIP (the integrating contractor), Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (the architect-engineer), and Morrison-Knudsen (the construction manager) for site characterization activities (e.g., those activities commencing after May 28, 1986). Detailed test plans and studies to be conducted during site characterization to gather data are described in Section 8.3.

These procedures are listed by criterion with the responsible organization as a subheading.

8.6.6.1 Quality Assurance Plans

- o The U.S. Department of Energy-Richland Operations Office
U.S. Department of Energy Quality Assurance Plan for the Basalt Waste Isolation Project (DOE-RL 1986b)
- o Rockwell Hanford Operations Basalt Waste Isolation Project
(integrating contractor)
Rockwell Hanford Operations Basalt Waste Isolation Project Quality Assurance Requirements Manual (RHO-QA-MA-3)
- o Morrison-Knudsen (construction manager)
Quality Assurance Manual for Contract No. DE-AC06-83RL10343, Basalt Waste Isolation Project
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)
Project Quality Assurance Plan Basalt Waste Isolation Project

8.6.6.2 Implementing procedures

Criterion 1.0 - Organization

- o The U.S. Department of Energy-Richland Operations Office
BP 1.1 Organization

- o Rockwell Hanford Operations Basalt Waste Isolation Project
(integrating contractor)

PMPM 01-109 Delegation of Authority
PMPM 06-105 Direction of Technical Work

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 2.0 - Quality Assurance Program

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 02-101 Preparation of Technical Requirements Documents
PMPM 04-113 Preparation of Functional Requirements for Readiness
Reviews
PMPM 04-120 Quality Concerns Program
PMPM 06-105 Direction of Technical Work
PMPM 08-107 Test and Operating Procedure Preparation and Control
PMPM 08-117 Format of Test and Operations Procedures
PMPM 13-108 Qualification of Instructional Staff
PMPM 13-109 Job/Task Analysis
PMPM 13-110 Training Materials Development
PMPM 13-112 Conduct of Training
PMPM 13-113 On-the-Job Training
PMPM 13-114 Writing Learning Objectives
PMPM 13-116 Qualification and Training Documentation and Records
PMPM 13-117 Continuing Employee Performance Evaluation
PMPM 13-119 Trainee Performance Evaluation
PMPM 13-120 Training Program Evaluations
PMPM 13-121 Personnel Training Requirements

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade and Douglas, Inc.
(architect-engineer)

NA

Criterion 3 - Design Control

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 02-101	Preparation of Technical Requirements Documents
PMPM 02-102	Technical Document Review
PMPM 02-104	Design Field Change
PMPM 02-107	BWIP Engineering Order System
PMPM 02-108	Computational Briefs
PMPM 02-113	Preparation and Control of Design Requirements Document
PMPM 02-125	Systems Descriptions
PMPM 03-105	Data Specifications
PMPM 05-101	Change Proposal Processing
PMPM 06-105	Direction of Technical Work
PMPM 07-103	Computer Systems Maintenance
PMPM 07-106	NSTF Drilling Permit
PMPM 08-107	Test and Operations Procedure Preparation and Control
PMPM 14-103	Software Quality Assurance Checklist
PMPM 14-104	Software Development Planning
PMPM 14-105	Software Design
PMPM 14-107	Software Design Review
PMPM 14-108	Final Internal Development Review of Software and Documentation
PMPM 14-112	Preliminary Design Documentation
PMPM 14-113	Detailed Design Documentation
PMPM 14-114	Transfer of Software Data and (or) Documentation
PMPM 14-115	User Requirements Analysis Document
PMPM 14-116	Software Application Control

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)

NA

Criterion 4.0 - Procurement Document Control

- o U.S. Department of Energy-Richland Operations Office

NA

o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 04-119 Review of Supplier Submittals
PMPM 06-105 Direction of Technical Work
PMPM 06-106 Suppliers Qualification and Evaluation
PMPM 06-114 Procurement Documentation and Review
PMPM 06-120 Procurement Process

o Morrison-Knudsen (construction manager)

NA

o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 5.0 - Plans, Instructions, Procedures, and Drawings

o U.S. Department of Energy-Richland Operations Office

NA

o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 01-101 Preparation and Control of Project Management
Procedures
PMPM 01-102 Desk Instructions
PMPM 01-110 Project Directives
PMPM 02-113 Preparation and Control of Design Requirements
Document
PMPM 02-117 Preparation of Engineering Plans
PMPM 03-111 Preparation of Study Plans
PMPM 07-106 NSTF Drilling Permit
PMPM 08-107 Test and Operations Procedure Preparation and Control
PMPM 08-117 Format of Test and Operations Procedures

o Morrison-Knudsen (construction manager)

NA

o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 6.0 - Document Control

o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 01-101 Preparation and Control of Project Management Procedures
 - PMPM 01-110 Project Directives
 - PMPM 02-107 BWIP Engineering Order System
 - PMPM 08-101 BWIP Correspondence Control
 - PMPM 08-102 Review Coordination of Non-BWIP Rockwell Documents
 - PMPM 08-106 Control of Supporting Documents
 - PMPM 08-107 Test and Operations Procedure Preparation and Control
 - PMPM 08-115 Control of In-Process Quality Assurance Records
 - PMPM 08-117 Format of Test and Operations Procedures
 - PMPM 08-121 Document Receipt Control
 - PMPM 08-126 Standard Document Distribution Lists
- o Morrison-Knudsen (construction manager)
 - NA
- o Kaiser Engineers, Inc./Parson Brinckerhoff Quade & Douglas, Inc. (architect-engineer)

NA

Criterion 7.0 - Control of Purchased Material Equipment and Services

- o U.S. Department of Energy-Richland Operations Office
 - NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 04-107 Surveillance of Suppliers of Services
 - PMPM 04-127 Supplier Quality Performance Evaluation
 - PMPM 06-106 Suppliers Qualification and Evaluation
 - PMPM 06-107 Source Inspection
 - PMPM 06-108 Receiving Inspection
 - PMPM 06-112 Procurement Planning Activities
 - PMPM 06-114 Procurement Documentation and Review
 - PMPM 06-116 Procurement Document Control
 - PMPM 06-120 Procurement Process
- o Morrison-Knudsen (construction manager)
 - NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)

NA

Criterion 8.0 - Identification and Control of Items

- o U.S. Department of Energy-Richland Operations Office
NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
PMPM 08-110 Control of Geotechnical Samples
- o Morrison-Knudsen (construction manager)
NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)
NA

Criterion 9.0 - Control of Special Processes

- o U.S. Department of Energy-Richland Operations Office
NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
NA
- o Morrison-Knudsen (construction manager)
NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)
NA

Criterion 10.0 - Inspection

- o U.S. Department of Energy-Richland Operations Office
NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
PMPM 13-116 Qualification and Training Documentation and Records

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 11.0 - Test Control

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 02-103	Acceptance Test
PMPM 02-112	Construction Acceptance Test Control
PMPM 02-120	Borehole Geophysical Logging
PMPM 03-101	Controlled Notebooks
PMPM 03-104	Data Evaluation Reports
PMPM 03-105	Data Specifications
PMPM 03-106	Test Data Collection Specifications
PMPM 03-110	NSTF Test Support Requirements
PMPM 07-107	Locating, Preparing, and Maintaining Surface Borehole Drill Site
PMPM 07-125	Use of Radioactive Tracers for Site Characterization
PMPM 08-107	Test and Operations Procedure Preparation and Control
PMPM 08-113	Records Submittal via Certified Transmittal Packages
PMPM 08-116	ESF Test Design Administration and Control
PMPM 08-117	Format of Test and Operations Procedures

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 12.0 - Control of Measuring and Test Equipment

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 07-109 Calibration/Requirement Specification
 - PMPM 07-110 Control of User Calibration
 - PMPM 07-111 Recall of Standards Measuring and Test Equipment
 - PMPM 07-112 Control of Standards and Test Equipment Status Labels
 - PMPM 07-113 Review of Calibration Records
 - PMPM 07-114 Control of Out-of-Calibration Instruments
 - PMPM 07-115 Control/Tracking of Out-of-Tolerance Conditions
 - PMPM 07-116 Control and Issuance of BWIP Unique Tags
 - PMPM 07-122 Data Gathering Equipment Control
 - PMPM 07-123 Operating Equipment Status Tag Control
- o Morrison-Knudsen (construction manager)
 - NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - NA

Criterion 13.0 - Handling, Shipping, and Storage

- o U.S. Department of Energy-Richland Operations Office
 - NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 06-114 Procurement Documentation and Review
 - PMPM 06-120 Procurement Process
 - PMPM 07-105 NSTF Test Material/Equipment Storage and Handling
 - PMPM 08-110 Control of Geotechnical Samples
- o Morrison-Knudsen (construction manager)
 - NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)
 - NA

Criterion 14.0 - Inspection Test and Operating Status

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - PMPM 04-102 Use of Quality Status Tags
 - PMPM 07-123 Operating Equipment Status Tag Control
 - PMPM 11-104 NSTF Access Control
- o Morrison-Knudsen (construction manager)
 - NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)

NA

Criterion 15.0 - Control of Nonconforming Items

- o U.S. Department of Energy-Richland Operations Office
 - NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - NA
- o Morrison-Knudsen (construction manager)
 - NA
- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc. (architect-engineer)

NA

Criterion 16.0 - Corrective Action

- o U.S. Department of Energy-Richland Operations Office
 - NA
- o Rockwell Hanford Operations Basalt Waste Isolation Project
 - NA
- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 17.0 - Quality Assurance Records

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project

PMPM 06-114 Procurement Documentation and Review
PMPM 06-116 Procurement Document Control
PMPM 07-106 NSTF Drilling Permit
PMPM 08-105 Recording Data for Quality Records and Recording
Corrections
PMPM 08-110 Control of Geotechnical Samples
PMPM 08-115 Control of In-Process Quality Assurance Records
PMPM 11-104 NSTF Access Control
PMPM 14-108 Final Internal Development Review of Software and
Documentation

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

Criterion 18.0 - Audits

- o U.S. Department of Energy-Richland Operations Office

NA

- o Rockwell Hanford Operations Basalt Waste Isolation Project

NA

- o Morrison-Knudsen (construction manager)

NA

- o Kaiser Engineers, Inc./Parsons Brinckerhoff Quade & Douglas, Inc.
(architect-engineer)

NA

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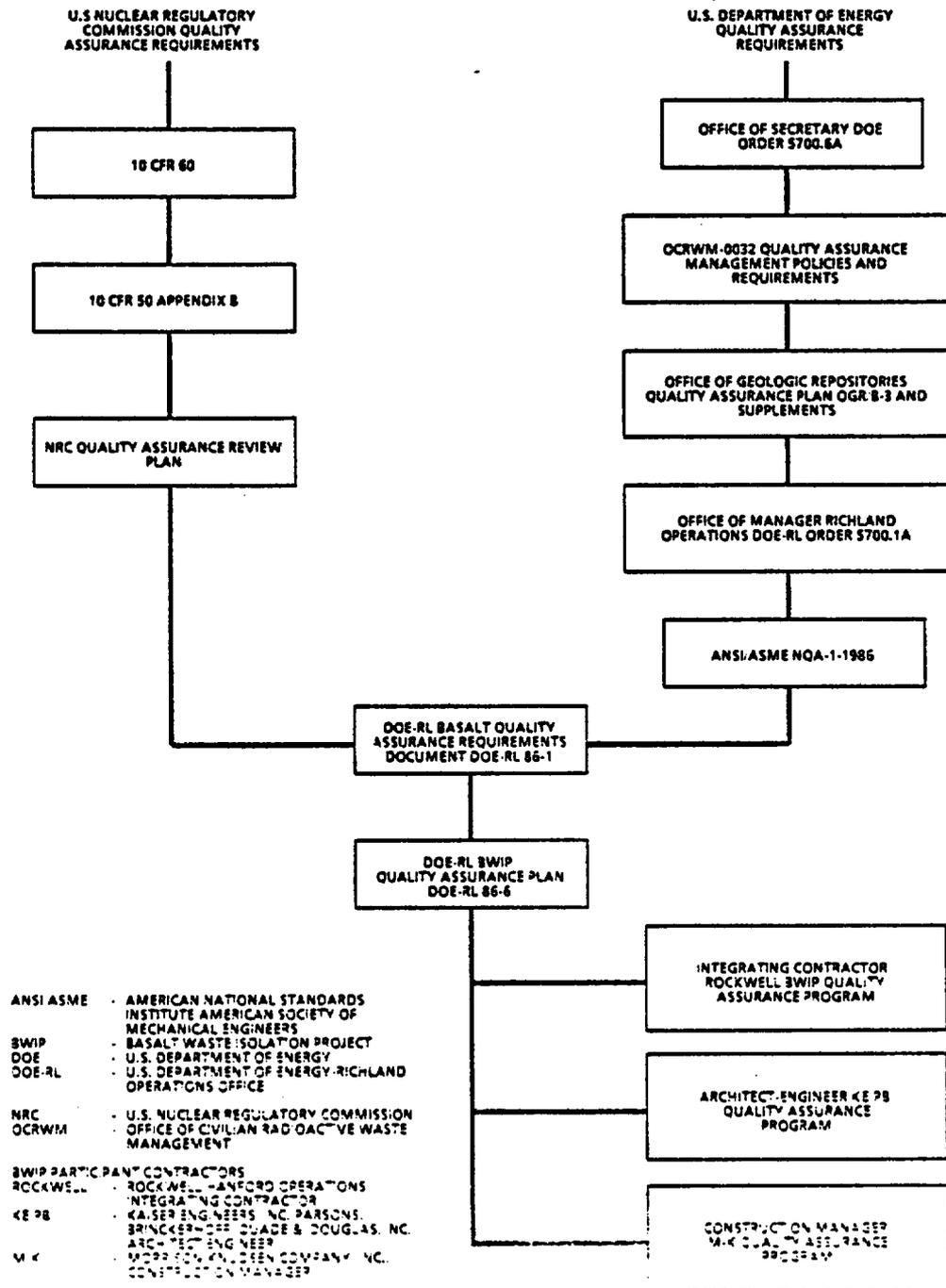


Figure 3.6-1. Quality assurance documents hierarchy.

F.3.6-2

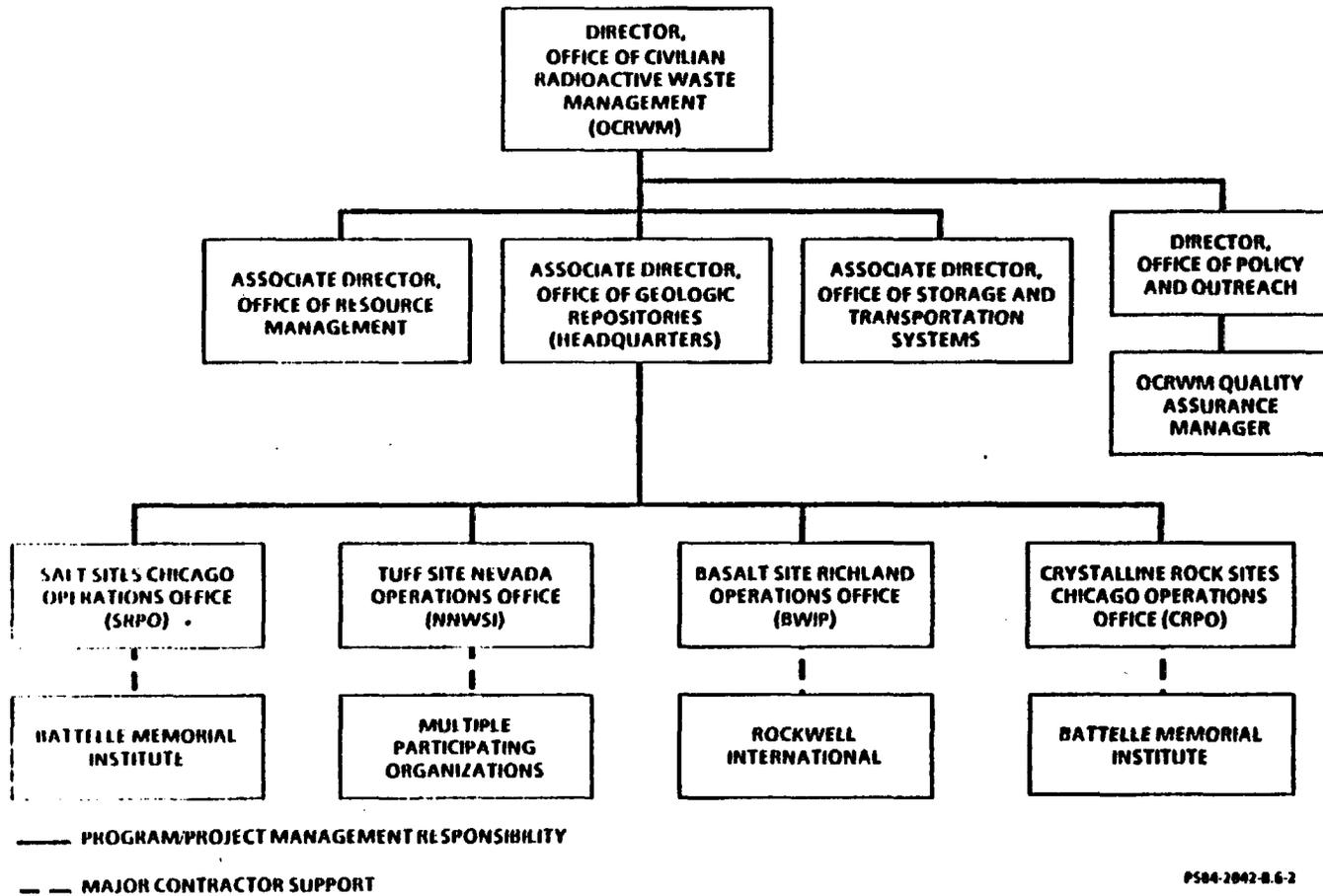
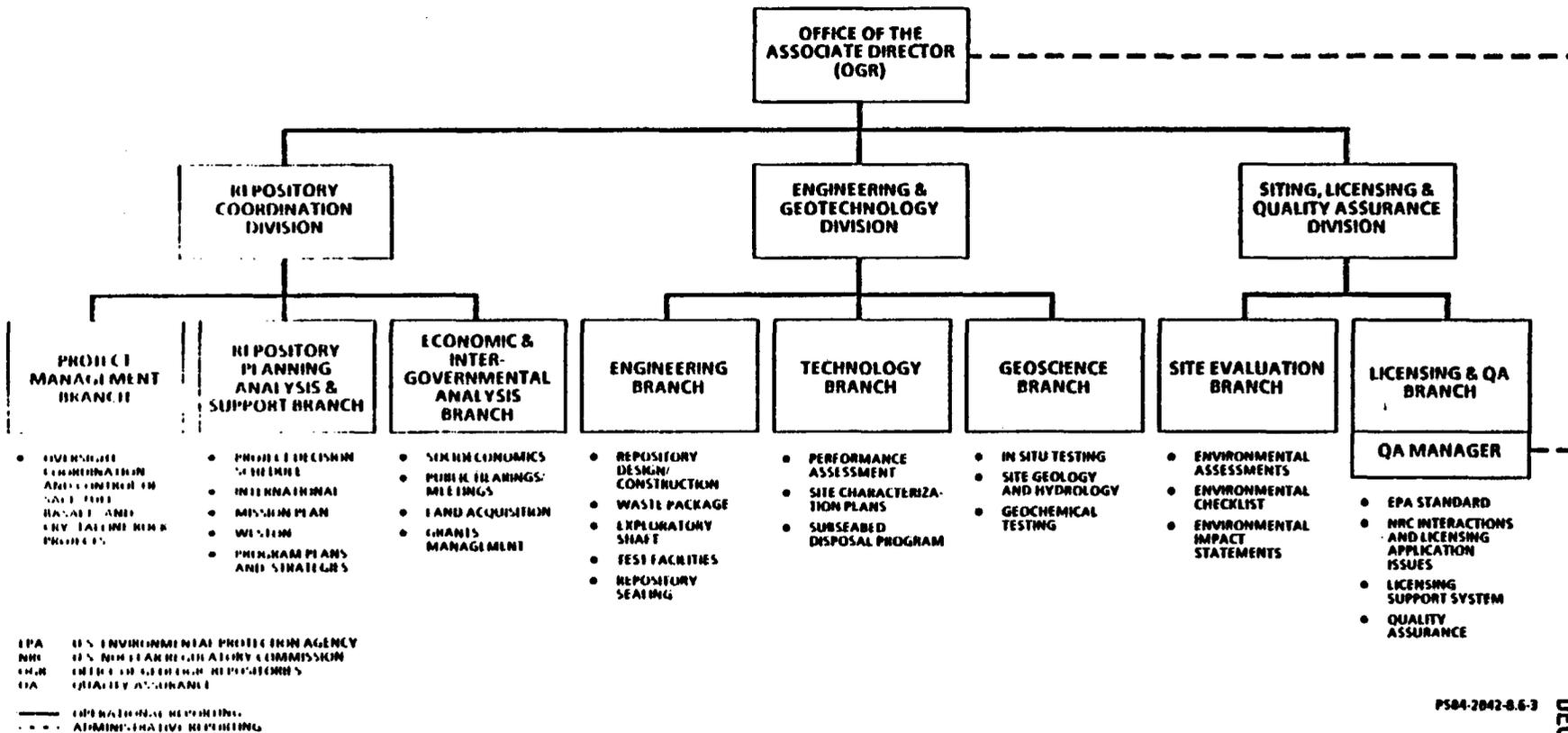


Figure 8.6-2. Office of Civilian Radioactive Waste Management.

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F. 3.6-3



PS84-2042-8.6-3

Figure 8.6-3. Office of Geologic Repositories organization chart.

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F.8.6-4

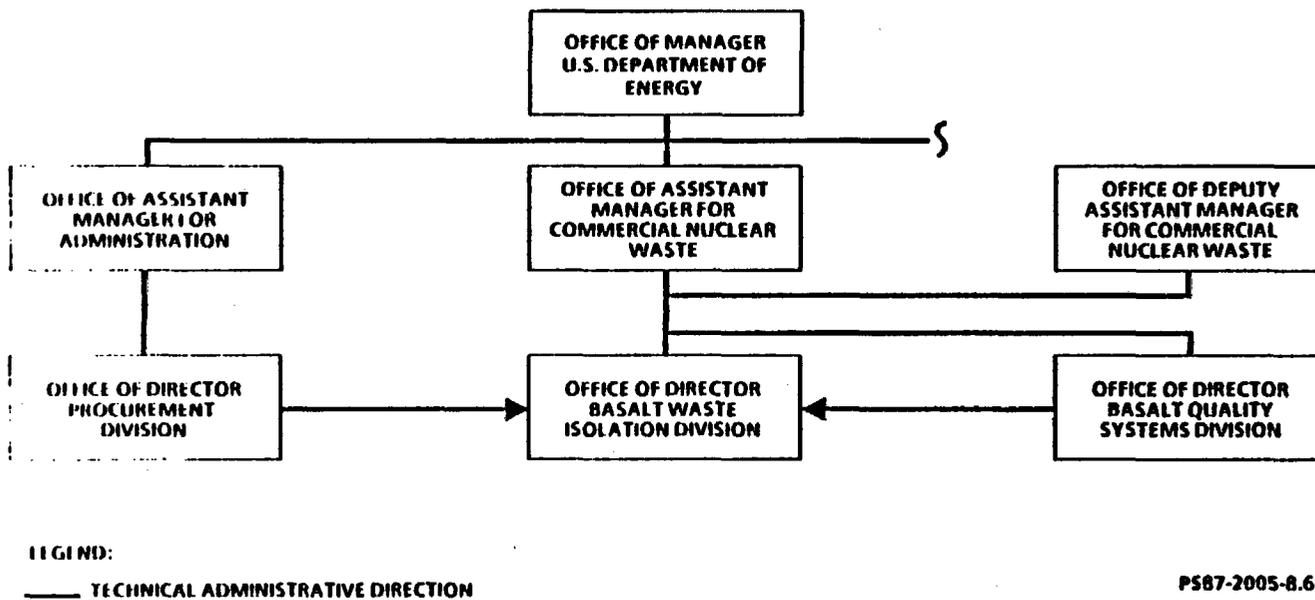
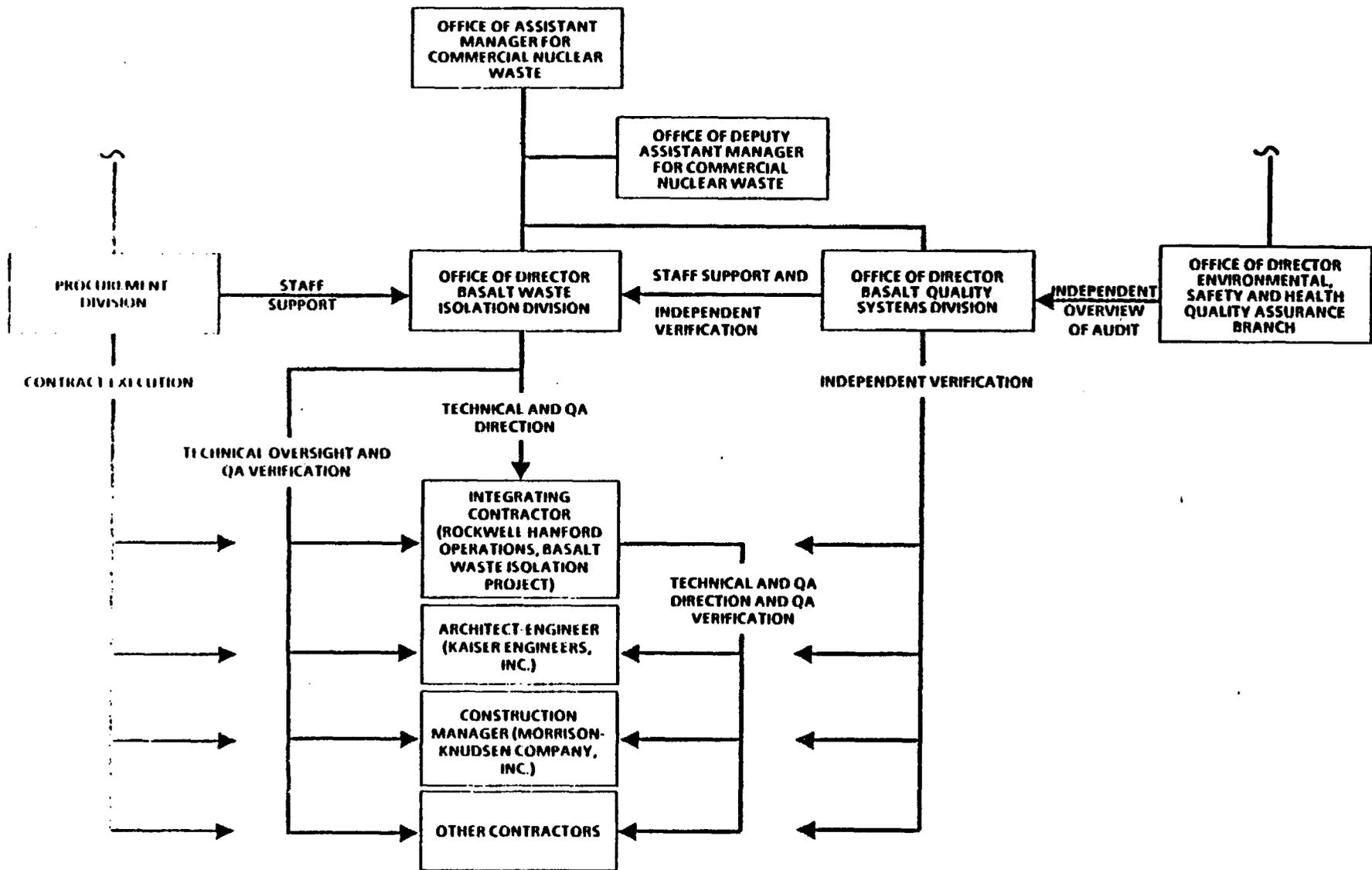


Figure 8.6-4. U.S. Department of Energy-Richland Operations Office Basalt Waste Isolation Project organization chart.

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F.8.6-5



QA - QUALITY ASSURANCE

PS87-2005-8.6-5

Figure 8.6-5. Basalt Waste Isolation Project organization.

Table 8.6-1. Basalt Waste Isolation Project Quality Assurance Program responsibility matrix

Quality assurance 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	S	S
4.0 Procurement document control	P, A, R	S, A, R	S	S	S
5.0 Instructions, procedures, and drawings	P, A, R	S, A, R	S	S	S
6.0 Document control	P, A, R	S, A, R	S	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	S
10.0 Inspection	P, R	S, A, R		S	S
11.0 Test control	P, R	S, A, R	S	S	S
12.0 Control of measuring and testing equipment	P, R	S, R		S	S
13.0 Handling, storage, and shipping	P, R	S, 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, R	S	S	S
18.0 Audits	P, R	S, R	S	S	S

NOTE: Responsible organizations: DOE-RL - U.S. Department of Energy-Richland Operations Office, Basalt Waste Isolation Division
 BWIP Participant Contractors
 IC - Integrating contractor
 CM - Construction manager
 A-E - Architect-engineer
 SUPP - Support contractor and supplier

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

Table 8.6-2. Decision criteria for determining quality levels of items and activities (sheet 1 of 4)

Categories of statements of work	Quality level		
	1	2	3
Items (hardware)			
<ul style="list-style-type: none"> Public health and safety considerations 			
<ul style="list-style-type: none"> Is the item on the Q-list? 	X		
<ul style="list-style-type: none"> DOE programmatic objectives considerations 			
<ul style="list-style-type: none"> Is the item intended to control radiation exposure or release levels and (or) effluent radioactivity within the limits prescribed by 10 CFR 20 (, 19)? 		X	
<ul style="list-style-type: none"> Failure or malfunction of the item could cause the following potential impact on DOE mission objectives: 			
<ul style="list-style-type: none"> Impact on cost or schedule impact > 10,000 K. 		X	
<ul style="list-style-type: none"> Impact on cost or schedule impact ≤ 10,000 K. 			X
<ul style="list-style-type: none"> Worker health and safety considerations 			
<ul style="list-style-type: none"> Failure or malfunction of the item could have potential impact on the radiological or nonradiological health and safety of the workers. 		X	
<ul style="list-style-type: none"> Lead time and cost considerations 			
<ul style="list-style-type: none"> Does procurement of the item involve long lead time and/or is the item extremely costly? 		X	
<ul style="list-style-type: none"> ASME-BPVC applicability considerations 			
<ul style="list-style-type: none"> Section III applies 		X	
<ul style="list-style-type: none"> Section VIII applies. 		X	
Activities			
<ul style="list-style-type: none"> Computer software modeling, development 			
<ul style="list-style-type: none"> Are the computer models used to support an item on the Q-list? 	X		
<ul style="list-style-type: none"> Do the computer models and codes supply data to support a licensing decision such as performance assessment? 	X		
<ul style="list-style-type: none"> Are the computer models complex, and are peer or technical reviews required? 		X	
<ul style="list-style-type: none"> Does the work support critical DOE mission documents? 		X	

Table 8.6-2. Decision criteria for determining quality levels of items and activities (sheet 2 of 4)

Categories of statements of work	Quality level		
	1	2	3
- If the collected data or records were lost/discarded or of indeterminate quality, the following would occur:			
• The quality of a "Q" listed item or activity would be indeterminate.	X		
• Repetition resulting in cost or schedule impact > 10,000 K.		X	
• Repetition would result in a cost or schedule impact ≤ 10,000 K.			X
- Is the computer program only utilized for such tasks as data sorting and collation?			X
• Field testing, data acquisition, data analysis, and reports			
- Are the data utilized to support an engineering design criterion for a Q-list item?	X		
- Do the data support a major licensing document?	X		
- Will the data become part of the technical data base needed to support licensing?	X		
- Does the work provide input to critical DOE mission documents?		X	
- If the collected data or records were lost/discarded or of indeterminate quality, the following would occur:			
• The quality of a "Q" listed item or activity would be indeterminate.	X		
• Repetition resulting in cost or schedule impact > 10,000 K.		X	
• Repetition resulting in cost or schedule impact ≤ 10,000 K.			X
• Storage of records/samples			
- Do records/samples support licensing activities?	X		
- Do records/samples support items on the Q-list items?	X		
- Do records/samples support critical DOE mission documents?		X	

Table 8.6-2. Decision criteria for determining quality levels of items and activities (sheet 3 of 4)

Categories of statements of work	Quality level		
	1	2	3
- If the collected data or records/samples were lost/discarded or of indeterminate quality, the following would occur:			
• The quality of a "Q" listed item or activity would be indeterminate.	X		
• Repetition resulting in cost or schedule impact >10,000 K.		X	
• Repetition with cost or schedule impact ≤10,000 K.			X
• Historical or background studies and reports			
- Will the information produced be used in a licensing document?	X		
- Do the studies support a computer model or design criterion for a Q-list item?	X		
- Does the work support critical DOE mission documents?		X	
- If the collected data or records were lost/discarded or of indeterminate quality, the following would occur:			
• Repetition resulting in cost or schedule impact >10,000 K.		X	
• Repetition with cost or schedule impact ≤10,000 K.			X
• Environmental/socioeconomic studies and reports			
- Do the reports or studies provide critical information to support requirements of the Nuclear Waste Policy Act of 1982 (NWPA, 1983)?	X		
- Will the reports or studies be used for major portions of a licensing document?	X		
- Does the work support DOE mission documents?		X	
- If the collected data or records were lost/discarded or of indeterminate quality, the following would occur:			
• Repetition resulting in major cost or schedule impact >10,000 K.		X	
• Repetition with minor cost or schedule impact ≤10,000 K.			X

Table 8.6-2. Decision criteria for determining quality levels of items and activities (sheet 4 of 4)

Categories of statements of work	Quality level		
	1	2	3
• Laboratory experimental (scoping) or testing/analysis and reports			
- Will the data results be used to support licensing activities?	X		
- Does the experimental testing provide analytical data to support functional design bases?	X		
- If the collected data or records were lost/discarded or of indeterminate quality, the following would occur:			
• The quality of a "Q" listed item or activity would be indeterminate.	X		
• Repetition resulting in cost or schedule impact >10,000 K.		X	
• Repetition with cost or schedule impact ≤10,000 K.			X
• Construction/manufacturing activities			
- Is the construction/manufacturing activity supporting a Q-list structure, system, or component?	X		
- Is the activity intended to control radiation exposure or release levels and (or) effluent radioactivity within the limits prescribed by 10 CFR 20 (, 19)?		X	
- Is the construction/manufacturing activity supporting a highly critical item with a high cost of repair or replacement?		X	
- Is the system important for reliability?		X	

NOTE: DOE - U.S. Department of Energy
ASME-3PVC -

Table 8.6-3. Graded quality program requirements matrix (sheet 1 of 2)

Quality program requirements	Quality level			Quality program requirements	Quality level		
	1	2	3		1	2	3
NQA-1* BASIC REQUIREMENTS			(b)	NQA-1* SUPPLEMENTS			
1. Organization	X	X	--	S-1 Terms and Definitions	X	X	--
2. Quality Assurance Program	X	X	--	15-1 Organization	X	--	--
3. Design Control	X	X	--	25-1 Qualification of Inspection and Test Personnel	X	--	--
4. Procurement Document Control	X	X	--	25-2 Qualification of Nondestructive Examination Personnel	X	--	--
5. Instructions, Procedures, and Drawings	X	X	--	25-3 Qualification of Quality Assurance Program Audit Personnel	X	X	--
6. Document Control	X	X	--	25-4 Supplementary Requirements for Personnel indoctrination and Training	X	X	--
7. Control of Purchased Items and Services	X	X	--	35-1 Design Control	X	X	--
8. Identification and Control of Items	X	X	--	45-1 Procurement Document Control	X	--	--
9. Control of Processes	X	X	--	65-1 Document Control	X	--	--
10. Inspection	X	X	--	75-1 Control of Purchased Items and Services	X	X	--
11. Test Control	X	X	--	85-1 Identification and Control of Items	X	--	--
12. Control of Measuring and Test Equipment	X	X	--	95-1 Control of Processes	X	--	--
13. Handling, Storage, and Shipping	X	X	--	105-1 Inspection	X	X	--
14. Inspection, Test, and Operating Status	X	X	--	115-1 Test Control	X	--	--
15. Control of Nonconforming Items	X	X	--	125-1 Control of Measuring and Test Equipment	X	--	--
16. Corrective Action	X	X	--	135-1 Handling, Storage, and Shipping	X	--	--
17. Quality Assurance Records	X	X	--	155-1 Control of Nonconforming Items	X	--	--
18. Audits	X	X	--	175-1 Quality Assurance Records	X	X	--
19. QAP PLAN	X			185-1 Audits	X	X	--
20. QAP PLAN	X						

Table 8.6-3. Graded quality program requirements matrix (sheet 2 of 2)

Quality program requirements	Quality level		
	1	2	3
NQA-1* APPENDICES			
1A-1 Organization	--	--	--
2A-1 Qualification of Inspection and Test Personnel	X	--	--
2A-2 Quality Assurance Programs	--	--	--
2A-3 Education and Experience of Lead Auditors	--	--	--
3A-1 Design Control	--	--	--
4A-1 Procurement Document Control	--	--	--
7A-1 Control of Purchased Items and Services	--	--	--
17A-1 Quality Assurance Records	--	--	--
18A-1 Audits	--	--	--
OGR QA PLAN SUPPLEMENTS			
S-1 Qualification of Personnel Performing and Verifying Activities Affecting Quality	X	X	--
S-2 Overview of Quality Assurance Activities	X	X	--
S-3 Q-List Methodology	X	X	--
S-4 Quality Assurance Records	X	X	--
S-5 Quality Assurance for (R&D) Experiments	X	X	--
S-6 (Reserved)			
S-7 Peer Review	X	X	--
S-8 Graded Quality Assurance	X	X	--
S-9 Reliability of Data	X	X	--
S-10 (Reserved for Waste Form)			

NOTE: OGR - Office of Geologic Resources.
QA - Quality assurance

*ANSI ASME 1986

Quality program requirements for Level 3 are established by the Basalt Waste Isolation Project and implemented on a case-by-case basis.

WRC 1979

Table 8.6-4. Other requirements descriptions

Reference	Requirement description
NRC Review Plan Para. 2.5 (NRC, 1984)	1. <u>Activity Planning</u> --This applies to the application of graded approach of the QA program to the complexity commensurate with the importance of the work activities. Plans shall be developed and documented to describe how the activities shall be performed, the results expected, the major milestones, and other procedures to be used.
NRC Review Plan Para. 2.7 (NRC, 1984)	2. <u>Management Assessment</u> --This requirement applies to performance of annual management assessment to determine the scope, status, adequacy, and effectiveness of the QA program.
NRC Review Plan Para. 2.8 (NRC, 1984) DOE/OGR Quality Program Requirements (DOE, 1986b)	3. <u>Personnel Qualification and Certification</u> --This requires that personnel who perform quality-related activities be properly trained, indoctrinated, and qualified. Personnel shall receive training in technical and quality assurance procedures. Management is required to monitor the performance of individuals involved in activities affecting quality and determine the need for retraining and/or replacement.
NRC Review Plan Para. 3.8 (NRC, 1984)	4. <u>Technical and Peer Reviews</u> --These are the requirements that define technical and peer reviews, and when they should be accomplished.
NRC Review Plan Para. 15.4 Para. 18.4 (NRC, 1984)	5. <u>Trend Analysis</u> --This requires that nonconformance reports be periodically analyzed to indicate quality trends and to help identify root causes of nonconformances. Results are to be reported to upper management for review and assessment.
DOE Order 5000.3 (DOE, 1984b)	6. <u>Unusual Occurrence Reporting</u> --Contractors are required to report any significant event that results in any deviation from the planned or expected behavior of an activity or operation or course of events that has or could have significant programmatic (reliability, cost, or schedule), safety, health, or environmental impacts. Significant events are to be reported in accordance with DOE Order 5000.3.
NRC Review Plan Para. 2.2 (NRC, 1984) DOE OGR Quality Program Requirements (DOE, 1986b)	7. <u>Software Control</u> --These are detailed computer software quality assurance requirements that include validation, verification, code custodial and transfer requirements, and conformance with NUREG-0856 (NRC, 1986).
NRC Review Plan Para. 8.3 Para. 13.1, 13.2 (NRC, 1984)	8. <u>Sample Handling</u> --This requires that samples of geological media (e.g., rock, core, soil) be shipped, handled, and stored in accordance with special procedures that describe the control of the activities related to handling of samples.
DOE OGR Quality Program Requirements (DOE, 1986b)	9. <u>Data Acquisition, Verification, and Analysis</u> --This requires that data and information that is received from literature searches be validated from the technical adequacy perspective and for correct application.
DOE OGR Quality Program Requirements (DOE, 1986b)	10. <u>Reporting and Submittals</u> --These are requirements that identify the types of reports and the frequency of submittals. Examples: Audit Reports and Schedule -- each report, and each audit Revisions per OGR-3-3 -- schedule revision Surveillance Reports -- each report Summary Reports -- quarterly, per OGR-3-3 Unusual Occurrence Reports -- Records Management Plan --
NRC Review Plan Para. 3.10 (NRC, 1984)	11. <u>Configuration Control</u> --Configuration systems shall be established and maintained to ensure that design changes are analyzed and properly identified and documented.
DOE OGR Quality Program Requirements (DOE, 1986b)	12. <u>Records Management</u> --Records shall be stored, identified and retrieved as described in the Records Management Plan.

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