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Office of Civilian Radioactive Waste Management



Office of Geologic Repositories
**Quality Assurance Plan
For High-Level Radioactive
Waste Repositories**

(OGR/B-3)

REVISION 2

DRAFT A

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U.S. Department of Energy
Office of Civilian Radioactive Waste Management
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This Quality Assurance Plan (QAP) OGR/B-3 is the top Office of Geologic Repositories QA planning document. It establishes the HQ-OGR Program QA responsibilities authorities and requirements and describes the overall QA program for HQ-OGR and provides direction and guidance for the Project Offices. It constitutes the implementation plan specified by DOE Order 5700.6B and the OCRWM Quality Assurance Management Policies and Requirements (QAMPR) DOE/RW-0032, and establishes controls necessary to satisfy the QA requirements identified in Title 10 CFR 60, Subpart G and the NRC's Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories. It does not contain requirements that would be specific to the Operations Offices and Project Offices, only for the Repository Projects. Compliance with applicable provisions of this QA Plan is mandatory for HQ-OGR, the Project Offices and their Participants.

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

Note: The term "participant" when used in this document, refers to organizations working under contract or Memorandum of Understanding with HQ-OGR or the Project Offices.

SECTION 1**OFFICE OF GEOLOGIC REPOSITORIES****GENERAL PROGRAM DESCRIPTION****1.0 INTRODUCTION**

The DOE concept of project management for major acquisition holds contractor technical processes and results to be inseparable from the controls under which they are performed. In Managing for Quality, Quality Assurance (QA) is an important subset. This management begins with the Director, Office of Civilian Radioactive Waste Management and is operative throughout the Civilian Radioactive Waste Management Program. The fundamental precept of DOE's Managing for Quality is that responsibility for achieving quality objectives rests with line management, and that the quality assurance organization provides a dedicated staff of QA professionals to assist line management at every level in meeting that responsibility and in verifying that quality objectives are met. In particular, it is important to distinguish between direct controls and the "Quality Assurance functions" as defined in Criterion I of 10 CFR 50, Appendix B; (i.e., (a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as checking, auditing and inspection, that activities affecting the safety related functions have been correctly performed"). Almost all controls that make up the Quality Assurance program are exercised by line organizations of the participating contractors who primarily work for the project offices. Nothing in the wording of regulatory requirements or DOE QA program description's should give the appearance of relieving the highest line official of responsibility for effective implementation of these controls. The highest ranking DOE QA officials in the HQ-OGR and the project offices are accountable for QA functions as defined in Criterion 1, 10 CFR 50, Appendix B. That official is at a level so that he or she can deal directly and effectively with the top DOE and participant line officials, so that communication concerning status and effectiveness of the QA program produces timely appropriate line management action in their overall responsibility for implementing the QA program.

2.0 PURPOSE

The purpose of this document is to set forth geologic repository program-wide quality assurance requirements establish quality assurance program responsibilities and authority, and provide guidance and consistency in interpretation of QA requirements for the repository projects.

3.0 SCOPE

The geologic repository quality assurance program described in this document is based on DOE quality assurance policy and on regulatory quality assurance requirements specified by the Nuclear Regulatory Commission. The program is applicable to all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. Affected activities include: site characterization, facility and equipment design and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

In addition, requirements of the repository QA program apply to activities that do not affect radiological safety or waste isolation within the strict sense of 10 CFR 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures," but which may have secondary effects or other important licensing implications, as specified in Section 2, Subsection 2.2.3.2 of this Plan.

In terms of the graded QA concept in effect for the geologic repository program, the QA program described here embraces Quality Levels I and II under the graded QA groundrules described in Section 2 of this document. Items and activities classified as Quality Level III are controlled separately.

4.0 OVERALL QA PROGRAM STRUCTURE

In accordance with DOE program management philosophy the Director, Office of Civilian Radioactive Waste Management, has established basic quality assurance policy for the mined geologic repository program and has delegated responsibility for definition and implementation of the required program-wide quality assurance program to the Office of Geologic Repositories (OGR).

HQ-OGR has established an internal QA program for affected activities performed within the office, has defined responsibilities and authorities across interfaces between OGR and the individual projects, and approves the QA program defined by each of the projects. Inasmuch as working relationships and details of the technical regime within each project are unique, OGR has recognized the importance of designing QA programs to the situation. QA program plans of the project offices, while responsive to all mandated QA requirements, have incorporated implementation details adapted to their circumstances. The OGR role in approving QA plans and QA administrative procedures has been (a) to assure that each program is responsive to regulatory requirements and Department policy, and (b) to assure that the QA program subsystems defined by each project provide positive control.

Within its approved QA program, each field project office is responsible for implementation and for verification that its QA program is functioning effectively. However, OGR's role includes overview verification of the effectiveness of project QA programs.

5.0 HQ-OGR'S INTERNAL QA

HQ-OGR has been assigned overall responsibility for managing site characterization activities across the geologic repository program. Because that responsibility includes certain activities that may have direct impact on project decisions and on work important to safety or waste isolation, internal HQ-OGR QA program provides necessary controls over such activities. This Plan therefore describes both the internal OGR QA program and the overall QA program for the Mined Geologic Repositories Program.

SECTION 2**OFFICE OF GEOLOGIC REPOSITORIES
QA PROGRAM DESCRIPTION****1.0 ORGANIZATION****1.1 OVERALL ORGANIZATION**

The DOE Office of Civilian Radioactive Waste Management (OCRWM) has established the Offices of Policy and Outreach (OPO), Transportation Systems (OSTS), Geologic Repositories (OGR), and Resource Management (ORM) in response to the Nuclear Waste Policy Act of 1982 (PL 97-425) (The Act) to direct and carry out the responsibilities assigned to the Department of Energy. Their relationships are shown in Figure 1-1. Within the Office of Geologic Repositories (OGR), QA Management functions and responsibilities have been assigned by the Director OCRWM to the Associate Director OGR who serves as the Program Manager. Under provisions of the Act, the HQ-OGR Program Office has established Project Offices who with their contractors will evaluate possible repository geological settings for safe disposal of High Level Nuclear Waste. The Project Offices are established within three DOE Operations Offices as shown in Figure 1-2.

1.2 HEADQUARTERS OFFICE OF GEOLOGIC REPOSITORIES, (HQ-OGR) PROGRAM OFFICE RESPONSIBILITIES**1.2.1 HQ-OGR Program Office**

The Director, Office of Civilian Waste Management (OCRWM) has established the Office of Associate Director for Geologic Repositories (HQ-OGR) and assigned responsibility for the full range of activities which are undertaken within the Program Management System (PMS) for a major systems acquisition. To meet the Mission Plans and goals in Managing for Quality (MFQ) within the spectrum of repository MFQ activities, Quality Assurance is an important program element. The Repository Coordination, Engineering and Geotechnology, Siting and Licensing, and Quality Assurance divisions establish program policy within the constraints of requirements and guidelines set forth in licensing regulations and overall DOE policy (see Section 2.1, "Quality Assurance - Policy and Requirements Sources").

1.2.2 HQ-OGR Program Office and Participants

HQ-OGR Program Office is organized for quality as shown in Figure 1-4. The OGR Quality Assurance Division establishes QA policy as contained in the OCRWM Quality Assurance Management Policies and Requirements (QAMPR) which defines the overall QA program for HQ-OGR and approves the QA plans and QA administrative procedures prepared by the project offices and verifies effective implementation of the OGR QA program by performing QA audits of headquarters and the project offices; participating in and reviewing reports of the project office QA audits of their participants; and participating in headquarters technical reviews, peer reviews, readiness reviews, and technical and management assessments of project activities. HQ-OGR quality affecting activities are performed in accordance with approved quality implementing procedures (see Table 2-1 for a list of HQ-OGR procedures).

Personnel within HQ-OGR and project QA organizations shall have direct access to management levels which assure their ability to a) identify quality problems; b) initiate, recommend or provide solutions through designated channels; and c) verify implementation of solutions. HQ-OGR and the project offices shall provide formal methods for assuring that this avenue is available for quality, technical and administrative personnel within DOE and their support contractors. (The project's participants' QA plans and administrative procedures shall provide similar freedom for QA personnel).

1.2.3 Stop Work Authority

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

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

Work may also be stopped by any participants' management upon QA recommendation if:

- a. Corrective action for substantive quality problems has not been established, and the responsible organization(s)

has/have not established an acceptable plan of corrective action or the approved corrective action is not being implemented in a timely manner, or

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

HQ-OGR personnel who perceive such problems during project overviews, shall alert the appropriate Project QA Director who will coordinate the required stop work actions at the project level through the Project Managers in accordance with their approved procedures.

When a stop work at the project offices by their participants is initiated, the project manager shall be immediately notified. Notification shall include the intended criteria for resumption of work. Each project manager has the authority to require that work be resumed only upon his approval.

Similarly, within the program or project management hierarchy the participants' program or project manager is to be notified of any Stop Work issued by a lower-tier participant, and has the authority to require that work only be resumed with his approval. Stop Work and resulting corrective action documents become lifetime project records.

1.2.4 Resolution of Disputes Involving Quality

Disputes involving differences of opinion regarding quality assurance and other organization personnel anywhere in the program or projects shall be elevated to a level where agreement can be reached, up to and including DOE OCRWM.

1.3 OCRWM INTERNAL ORGANIZATION FOR HQ-OGR PROGRAM QUALITY ASSURANCE

1.3.1 HQ-OGR Organization

The Associate Director Office of Geologic Repositories has the line management responsibility and accountability for the overall repository program. The Associate Director has established four divisions and appointed a QA Director to provide management and technical guidance and support to the project offices. The project offices reporting through the field office managers are responsible for management and direction of their projects. Figures 1-2 and 1-3 show these reporting relationships which are established in accordance with DOE Orders and the OCRWM Project Management System Manual

(DOE/RW-0043). The Associate Director, Office of Geological Repositories has primary responsibility and accountability for the execution and implementation of the program in accordance with the OGR Quality Assurance Plan for High-Level Radioactive Waste Repositories (OGR/B-3) through all phases of the program including siting, site characterization, design, construction, operation, decommissioning, closure and institutional interfacing. The Associate Director, Office of Geologic Repositories has established four divisions and appointed a QA Director to provide day-to-day program management and guidance to the project offices.

In quality assurance-related matters, the Associate Director is responsible for the following:

- a. Provide overall QA policy guidance and direction to the HQ-OGR and projects, and translate this policy into specific QA management systems and controls to ensure effective implementation of the OGR QA program by all projects.
- b. Establish and provide management controls on program-specific QA requirements, plans, and procedures that are consistent with the QA management policies and requirements of the QAMPR.
- c. Approve the QA plans and QA Administration procedures of project offices.
- d. Approve the OGR QA Plan and HQ-OGR QA administrative procedures.
- e. Appointing the OGR Training coordinator and approving the OGR training plans and authorizing the QA indoctrination and training of HQ-OGR personnel performing quality-related activities for the repository program.
- f. Approving program plans as necessary to permit the OGR Divisions to fulfill their technical and quality assurance program requirements. Provide for, and participate in, the continuing interactions with OCRWM Management, relevant Federal regulatory agencies (such as the NRC and EPA), affected States and Indian Tribes on QA matters specifically related to their respective areas of concern.
- g. Effectively implementing the quality assurance program.
- j. Approving formal quality and program direction issued by the Repository Coordination, Engineering and Geotechnology, Siting and Licensing, and Quality Assurance Divisions to project offices or OGR participants.

- k. Evaluating the quality of delegated work as reported by the program divisions/managers.
- l. Evaluating the management assessment reports of quality assurance program implementation by OGR and the Project Offices.
- m. Fulfilling other management responsibilities as assigned by the Director, OCRWM.

1.3.2 Repository Coordination Division

The Director RC Division reports to the Associate Director OGR and is responsible for the following:

- a. Effectively implementing the quality assurance plans and OGR procedures in oversight, coordination and control of project management, planning analysis, and socioeconomics.
- b. Evaluating technical effectiveness of quality assurance program control of project offices and the major participants in concert with other OGR Divisions.
- c. Preparing and issuing management plans and instructions as required.
- d. Ensure that personnel who perform or verify technical or quality-related work are qualified and have completed any required QA training prior to being assigned to perform the work.
- e. Ensure the technical adequacy of management controls by appropriate overview methods.
- f. Identify and report to the OGR Associate Director, and ensure the resolution of any significant quality-related problems or issues in cognizant areas that potentially affect the division activities.

1.3.3 Engineering and Geotechnology Division

The Director Engineering and Technology Division reports to the Associate Director OGR and is responsible for the following:

- a. Effectively implementing the quality assurance plan and OGR procedures in oversight coordinating reviews and control in engineering performance assessment, site characterization plans and geoscience areas.

- b. Evaluate technical effectiveness of quality assurance program control of project office and their major participants in concert with other OGR divisions.
- c. Ensure that personnel who perform or verify technical or quality-related work are qualified and have completed any required QA training prior to being assigned to perform the work.
- d. Preparing and issuing management plans and instructions as required.
- e. Ensure the technical adequacy of management controls in their area of expertise by appropriate overview methods.
- f. Identify and report to the OGR Associate Director, and ensure the resolution of any significant quality-related problems or issues in cognizant areas that potentially affect the division activities.

1.3.4 Siting and Licensing Division

The Director, Siting and Licensing Division reports to the Associate Director and is responsible for the following:

- a. Effectively implement the quality assurance plans and OGR procedures in concert, coordination, review and control in site environmental assessments, NRC interactions, licensing application and support.
- b. Evaluate technical effectiveness of quality assurance program controls of project office in concert with other OGR divisions.
- c. Ensure that personnel who perform or verify technical or quality-related work are qualified and have completed any required QA training prior to being assigned to perform the work.
- d. Preparing and issuing management plans and instructions as required.
- e. Ensure the technical adequacy of management controls in their area of expertise by appropriate overview activities.
- f. Review OGR QA policy guidance, OGR QA Plan and QA administrative procedures and recommend approval actions to the Associate Director, OGR.

- g. Review QA funding requirements for the OGR budget and manpower guidance to effectively support the OGR QA Program needs, activities, and objectives and recommend approval action to the Associate director, OGR.
- h. Identify and report to the OGR Associate Director, and assure the resolution of any significant quality-related problems or licensing issues in cognizant areas that potentially affect the division activities.

1.3.5 Quality Assurance Division

The Director, Quality Assurance Division reports to the Associate Director, OGR and exercises the highest direct-line authority in HQ-OGR for QA functions. The Director, Quality Assurance Division, has no other responsibilities that prevent full attention to quality activities. The Director's responsibilities include the following:

- a. Preparing and implementing the OGR Quality Assurance Plan and procedures necessary for its implementation.
- b. Preparing and mandating the QA Training Plan for HQ-OGR personnel.
- c. Establishing requirements for OGR Divisions' participants QA program.
- d. Reviewing and recommending approval of project QA plans and QA administrative procedures.
- e. Exercising OGR oversight of overall quality assurance program implementation.
- f. Verifying effective implementation of the OGR QA Plan by the OGR Divisions.
- g. Reviewing and/or specifying Quality Assurance requirements in procurement documents.
- h. Approving government agency quality programs when the scope of work is covered by the Memorandum of Understanding where the work is not directly applicable to project office activities.
- i. Providing direct quality assurance support to the other OGR Divisions.

- j. Serving on or providing support for HQ-OGR Readiness Review Board activities.
- k. Coordinating the QA programs of the project offices and providing interface with regulatory agencies.
- l. Recommending HQ-OGR QA policy guidance to the OGR Associate Director, and for subsequent transmittal to the projects for implementation.
- m. Identifying quality problems in the HQ-OGR and project office QA program implementation and taking or causing corrective action to be taken on quality problems and issues identified at lower-tier organizations that have reached the HQ-OGR level.
- n. Submitting to the OGR Associate Director quarterly reports on the status of the OGR QA program and annual reports or assessments as to adequacy of the QA program implementation by HQ-OGR and their participants.
- o. Developing, with input from OGR Divisions the total QA budget requirements for OGR activities.
- p. Performing or having performed annual audits of project office QA programs and participating in project office audits of major participants.
- q. Performing surveillances and overview of HQ-OGR and project office activities as specified in the QAMPR.
- r. Performing analysis of project offices surveillances and audit reports of their major participants and issue summary reports.
- s. Serving as the chairman of the Quality Assurance Coordinating Group meetings.
- t. Coordinating interactions with other DOE organizations involving HQ-OGR QA.

1.3.6 HQ-OGR QA Interfaces with Project Offices

HQ-OGR Quality Assurance direction and policy guidance are provided by the OGR QA Plan, the requirements documents cited therein, and by issuance of directives.

Lines of communication shall be established and maintained among HQ-OGR, the project offices and their contractors, and the OCRWM for reporting of QA program status and dissemination

of information regarding significant quality problems and issues, unusual occurrences, and other matters of common interest. The OGR QA Director shall ensure that effective communication channels are maintained through frequent interactions and meetings with the projects, as appropriate, such as in the Quality Assurance Coordinating Group (QACG) meetings.

In addition, an informal flow of information between project office personnel engaged in Project QA-related activities and cognizant personnel in OGR is encouraged to supplement formal reporting.

1.3.7 Inter-division Interfaces Within HQ-DOE

The primary interfaces between HQ-OGR Divisions and other HQ-DOE organizations in establishment and implementation of the HQ-OGR QA Program involves the Procurement, Personnel, and Environment, Safety and Health (ES&H), as follows:

a. Procurement

All direct procurement for the DOE HQ-OGR is accomplished by Procurement. The Procurement organization interfaces with the HQ-OGR Division/Branch that initiated the procurement regarding technical matters, and with HQ-OGR QA Division on quality assurance matters (refer to Section 4.0 and 7.0 of this QA Plan for details). The OGR Divisions and Purchasing interface at the following points during the procurement process:

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

b. Personnel

OGR relies upon the Personnel Division to provide personnel for OGR positions and to verify that such personnel meet applicable position qualification requirements defined by OGR divisions.

c. ES&H

DOE's ES&H is mandated by DOE Order 5000.3 to handle unusual occurrences reporting. Any such reports generated by the project offices are forwarded through the OCRWM QA Manager to ES&H. (DOE ES&H is also responsible for reporting to the Secretary on evaluations conducted for the Secretary). The provisions of DOE Order 5000.3 related to unusual occurrences are outlined in the QAMPR, and coordinated with the appropriate OCRWM Associate Director and the OCRWM QA Manager.

d. Other DOE Organizations

Interactions with other DOE organizations including the Assistant Secretaries for Environment, Safety and Health (AS&H), Nuclear Energy, Defense Programs and Energy Information Administration involving general OCRWM QA policy are conducted through the OCRWM QA Manager.

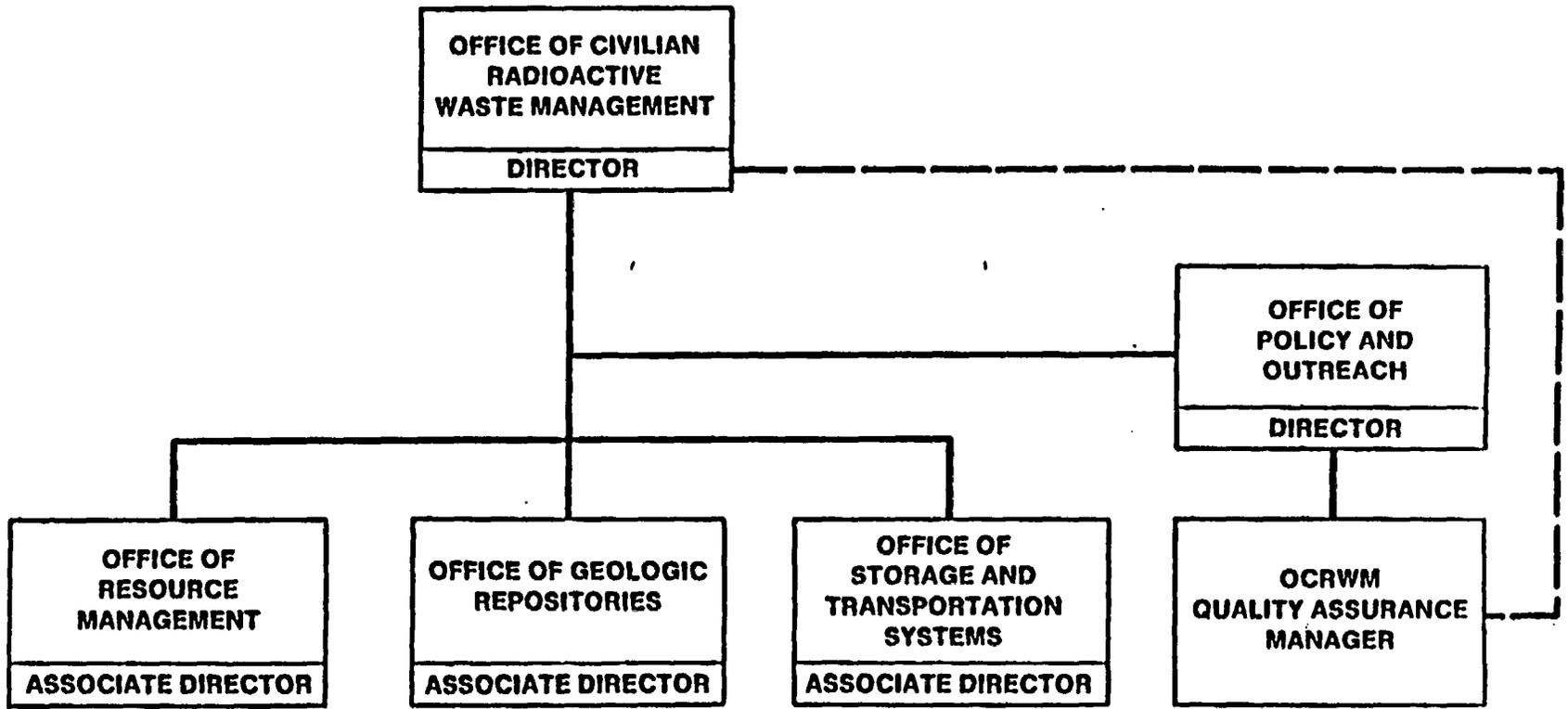
1.3.8 Interactions with NRC and Other Agencies

OGR organization interacting with the NRC and other agencies on QA policies are to notify the OCRWM of such meetings and information regarding such interactions. Interactions with the NRC and other agencies on QA matters having program-wide significance or OCRWM quality management policies are to be executed through or coordinated with the OCRWM QA Manager.

HQ-OGR and project organizations are to provide for continuing interactions with the States and affected Indian Tribes on matters pertaining to QA to facilitate the implementation of the consultation and cooperation provisions of the Nuclear Waste Policy Act of 1982. Consultation and cooperation include participation in QA Coordinating Group (QACG) meetings, participation as observers on HQ-OGR and project office audits, as well as review and comment on OGR program level QA Plans. In addition, copies of audit notification letters, and audit reports prepared by HQ-OGR and the project offices are to be routinely furnished to the appropriate State agencies and affected Indian Tribes along with any related correspondence.

OGR/B-3

HQ-OGR and the project offices also make available copies of DOE prepared Readiness Review Reports, and other documents when requested. HQ-OGR and project offices shall adhere whenever possible with the Policy for participation of State, tribal and NRC representatives as observers of DOE audits issued by the Associate Director, OGR.



— PROGRAM MANAGEMENT/DIRECTION
 - - QA POLICY COORDINATION AND OVERVIEW

FIGURE 1-1 OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

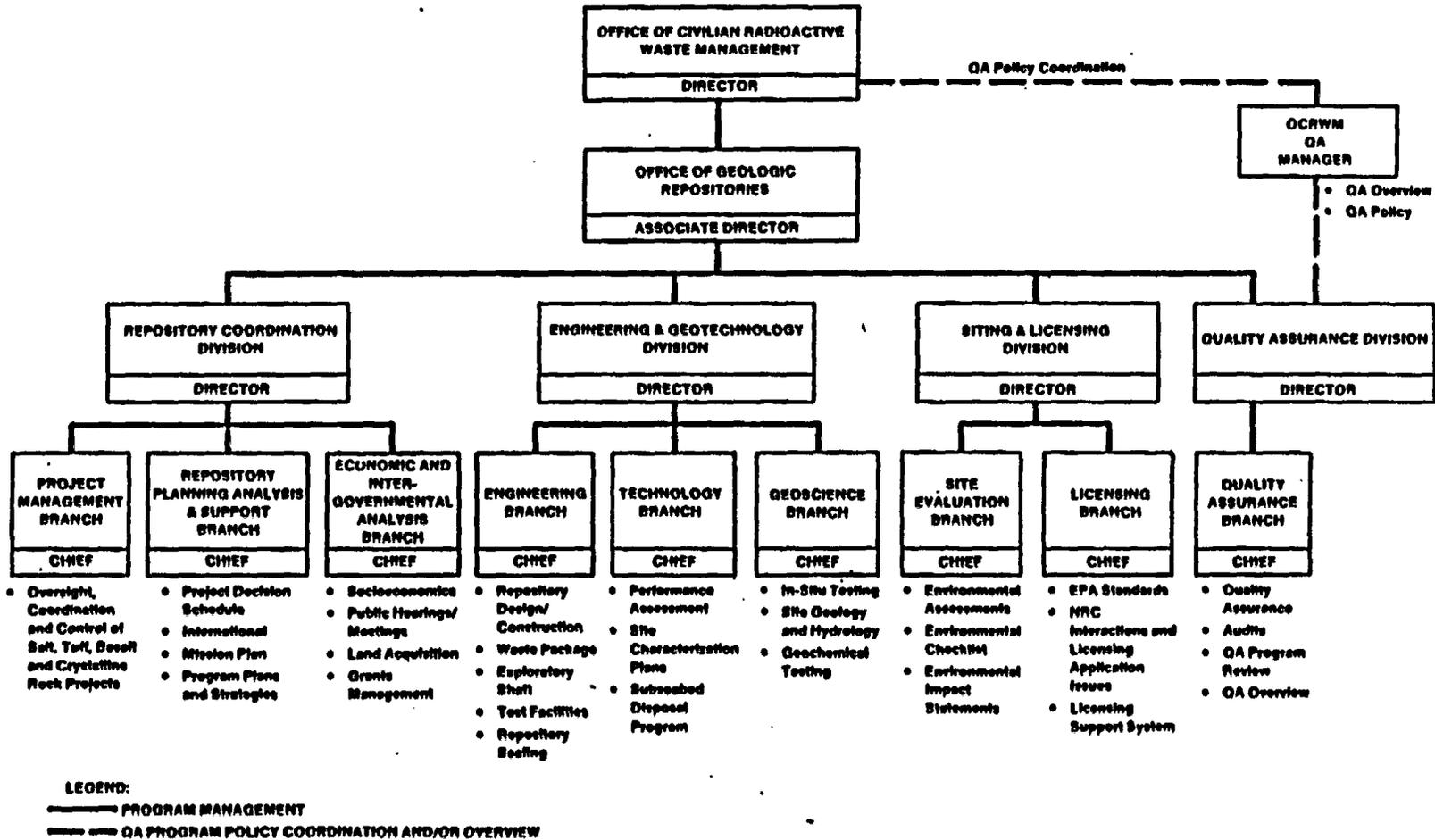
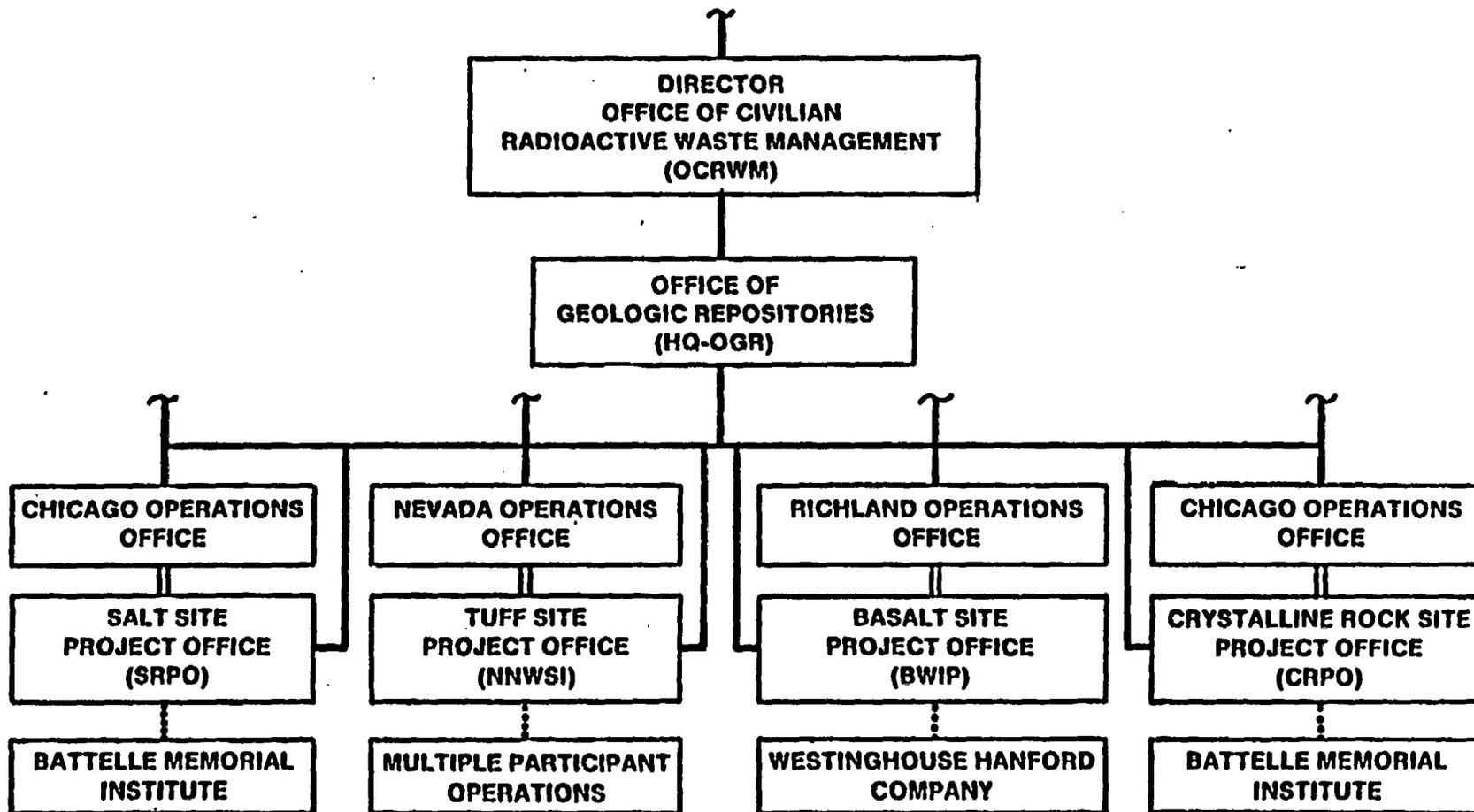


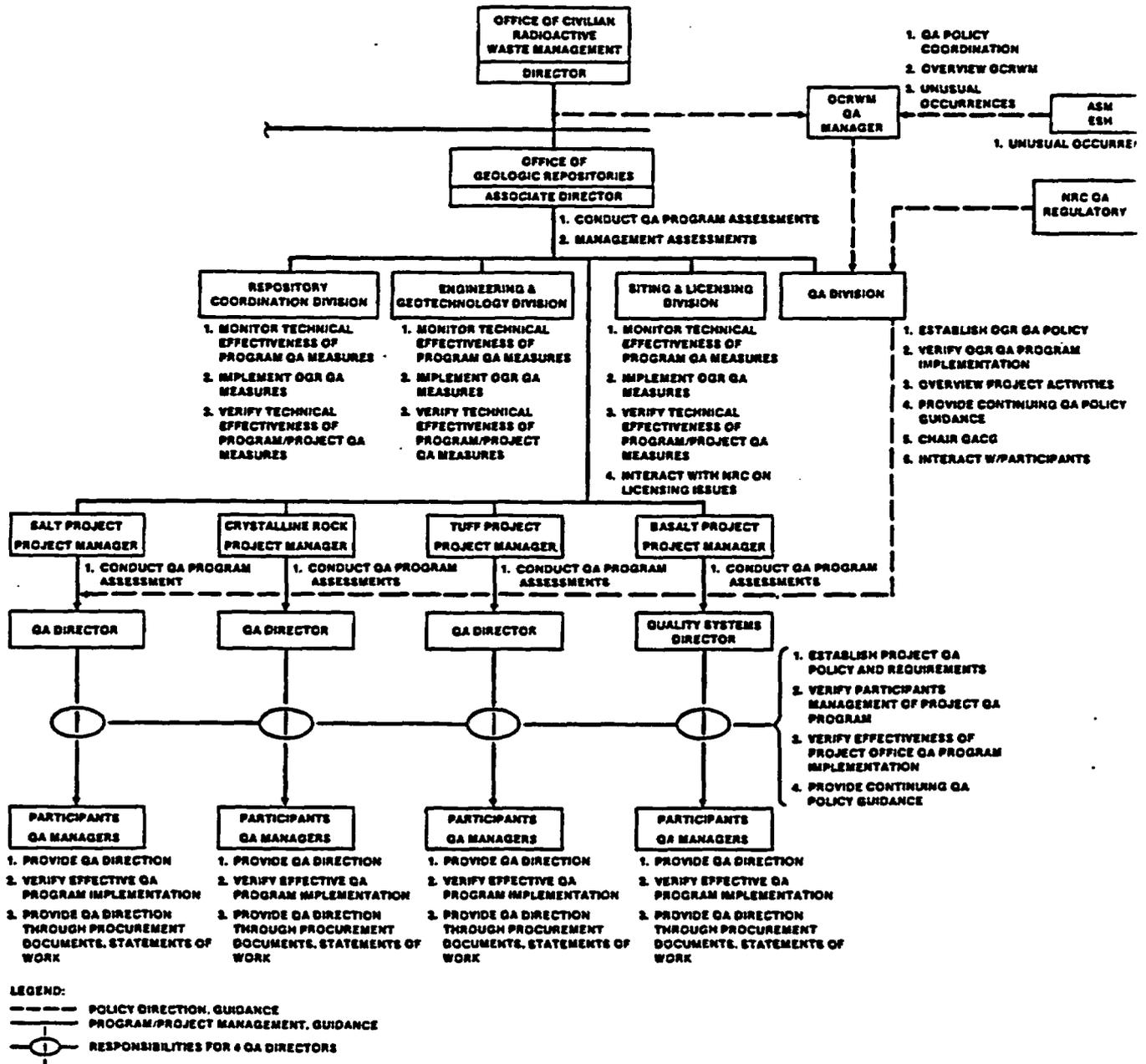
FIGURE 1-2 OFFICE OF GEOLOGIC REPOSITORIES



- PROGRAM POLICY GUIDANCE, AND TECHNICAL DIRECTION
- ===== ADMINISTRATIVE REPORTING, SUPPORT SERVICES AND PROJECT PLAN APPROVAL
- CONTRACTOR SUPERVISION AND DIRECTION

FIGURE 1-3 GEOLOGIC REPOSITORY PROGRAM

**FIGURE 1-4
OFFICE OF GEOLOGIC REPOSITORIES QA
PROGRAM MANAGEMENT RESPONSIBILITIES**



2.0 QUALITY ASSURANCE PROGRAM

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

Important to safety and/or waste isolation is determined by analytical processes involving failure modes, effects analysis and fault tree analysis. Those tools are used to develop numerical performance objectives and standards and includes incorporation of scientific and engineering judgment. Each Project Office describes this process in their Project Performance Assessment Plan with guidance from HQ-OGR. Project QA organizations are involved in the process at appropriate points. This is an iterative process which provides the basis for each project's Q-List and Quality Activities List. In addition, development of the plan provides inputs to assignment of items and activities to quality levels within the graded QA program.

HQ-OGR reviews the projects' Q-Lists and Quality Activities Lists during each phase of the repository project for consistency and completeness.

2.1 QUALITY ASSURANCE POLICY AND REQUIREMENTS SOURCES

The following listed documents provide the detailed requirements that shall be implemented by HQ-OGR, the Project Offices and their participating contractors.

- a. DOE/RW-0032, "Quality Assurance Management and Policies Requirements" (QAMPR)
- b. 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures"
- c. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- d. NRC Review Plan, "Quality Assurance Programs for High-Level Nuclear Waste Repositories", June 1984

- e. ANSI/ASME NQA-1, 1986, "Quality Assurance Program for Nuclear Facilities, Supplements and Appendices"
- f. DOE Order 4700.1, Project Management System
- g. DOE Order 5700.6B, "Quality Assurance"
- h. DOE Order 5000.3, "Unusual Occurrence Reporting System".

The QA program described in this QA plan complies with the applicable provisions of these documents. The Project Offices and their participating contractors QA Plans will comply with the requirements of this QA plan. Where conflicts exist between the above source documents and this QA plan the HQ-OGR QA Director will provide policy guidance.

Activities affecting quality performed by designated HQ-OGR personnel are performed in accordance with technical and administrative Quality Implementing Procedures (QIPs) identified in Table 2-1 in this QA plan.

Table 2-2 is a requirements matrix reflecting the criteria in ANSI/ASME NQA-1, 1986; the NRC Review Plan sections and the sections of the HQ-OGR QA Plan which describe the controls and requirements.

Table 2-3 shows the basic and supplementary requirements of ANSI/ASME NQA-1 and which activities are performed by HQ-OGR and those assigned to the Project Offices and their contractors.

2.2 QA PROGRAM STRUCTURE AND EXECUTION

2.2.1 QA Program Controls

The QA program consists primarily of controls over technical and support activities. These controls are exercised by participants' line organizations that perform the activities. The extent of these controls is established by joint effort of cognizant technical and QA organizations, with successive iterations of the various performance assessment analysis providing the foundation. DOE project management responsibility involves establishment of program and project objectives, oversight of HQ-OGR, Project Offices and participants' management, and verification that at each level participants implement planned controls effectively. HQ-OGR technical personnel along with Project Office

technical personnel in the course of evaluating participants technical progress, satisfy themselves that applicable controls have been and are being exercised effectively -- i.e., not only is the technical approach valid but that it is based upon properly controlled supporting data and analysis.

HQ-OGR and project offices oversight of participants' performance therefore includes (a) QA verification that participants are effectively implementing the control systems that constitute the required QA programs, and (b) technical evaluation of the technical effectiveness of these controls.

Certain activities performed by HQ-OGR and DOE Project Offices personnel directly affect technical outcome of the projects (e.g., decisions selected from among technical alternates, approval of participants technical recommendations, direction with respect to approaches, etc.). QA controls affecting these activities are specified in HQ-OGR and Project Office procedures. HQ-OGR and Project Office QA organizations verify effective implementation of specified procedural controls by QA Audit and surveillance as well as participation in technical evaluations performed by technical personnel within OGR and the Project Offices.

2.2.2 QA Program Documentation

This HQ-OGR Quality Assurance Plan is the top Program QA planning document. It establishes program QA responsibilities, requirements and authorities and describes the overall quality assurance program for the Repository program and project offices. Each project office shall prepare and implement a Project Quality Assurance Plan as the top QA planning document for their project. Such project QA plans shall specify or reference unique or additional quality requirements not included in this document.

HQ-OGR and the Project Offices shall issue procedures providing direction and guidance for in-house management of the program and Project Offices. Project participants are required to prepare a top-level description of their internal QA Program, including a listing of QA administrative procedures necessary to implement project-related activities. Each participant is also required to prepare and maintain a master listing of quality-affecting technical procedures. Approval requirements for Project Office QA plans and QA administrative procedures is covered in Section 2.6. The Project Offices shall specify the review of approval requirements for

their participants' QA plans and QA administrative procedures in their project QA plans.

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

2.2.3 Graded Quality Assurance

A fundamental aspect of the DOE's OCRWM QA concept is the graded QA approach whereby QA program requirements and procedural controls are applied selectively and judiciously to technical activities within a designated quality level based on various considerations such as: intended application, state of the art, design and fabrication complexity, lead time, cost and performance history. Thus it is possible for a complex, engineered and Quality Level 3 (QL-3) item to have QA program requirements and procedural controls which exceed those for a commercially-available, off-the-shelf QL-2 or QL-1 item. The Quality level determination logic is depicted in Figure 2-1. The graded approach establishes three quality levels as follows:

Note: Programmatic interests may justify supplemental quality management controls. In these cases, line management is responsible for identifying such requirements and incorporating them into the appropriate activities plans or procedures.

2.2.3.1 Quality Level 1 (QL-1)

Is reserved for items and activities that are subject to NRC licensing and regulatory compliance and are designated as being important to radiological safety and/or waste isolation on the geologic repository projects Q-list and quality activities list. The quality level and measures applied at this level are based (as appropriate to the item or activity) upon the 18 basic requirements of ANSI/ASME NQA-1, all supplements, non-mandatory Appendices 2A-1 & 2A-3, the 18 criteria of 10 CFR 50, Appendix B, the NRC Review Plan and other NRC guidance. This level applies to items/activities important to public safety, waste isolation, and activities important to waste placement or retrieval and items/activities designated by Associate Director, OGR or the Project Managers. The Q-List and Quality Activity List is developed by each

project based upon the HQ-OGR PMS Manual. The Q-lists developed by each project are reviewed by HQ-OGR to ensure consistency between sites.

Participants whose responsibilities include establishment of the Q-list and application of graded QA shall provide sufficient information including justification and deviations for incorporation into the Site Characterization Plans (SCP) and SCP Progress Reports. Deviation from quality level requirements specified are permitted where written justification is provided and approved by the individual or organization that makes the initial determination of quality level. Deviations do not include deletion of a criterion that is not applicable for an item or activity.

2.2.3.2 Quality Level 2 (QL-2)

The intermediate quality level, is for assignment to items and activities that are related to radiological safety and waste isolation. Such activities may support licensing but are not Q-listed by NRC regulatory definition. QL-2 may also include items or activities designated by HQ-OGR or various subordinate managers which have a strong potential for inclusion to the Q-list, and whose failure or degradation could adversely affect the performance of structures, systems, and components important to safety and waste isolation. QL-2 also applies to items and activities that have potential impact on public and occupational radiological health and safety under 10 CFR 20 and may support licensing but are not Q-listed by definition. It may apply to items involving assessment of a number of Field and Laboratory Investigations and/or complex manufacturing, assembly and construction processes. The QA program for QL-2 shall comply with appropriate ANSI/ASME NQA-1 Basic Requirements and the Supplements and non-mandatory Appendices 2A-1 and 2A-3.

2.2.3.3 Quality Level 3 (QL-3)

QL-3 covers a broad spectrum of mission-oriented objectives other than radiological safety and waste isolation. QL-3 is for assignment to items and activities selectively chosen because of special programmatic importance to design, construction, and performance objectives. These may include mission-oriented items and related activities controlled

under DOE orders such as DOE 4700.1 and the PMS Manual which reflect good technical management, engineering, or laboratory work practices for the assurance of quality.

QL-3 designations are to be made by or with the approval of the Associate Director HQ-OGR or the designated Project Managers. The Associate Director HQ-OGR is to notify the Director, OCRWM of items and activities designated QL-3 (which are not within the scope of this QA Plan unless specifically mandated).

QL-3 items and supporting activities require:

- o A documented, auditable management, activity, program or QA plan that includes identification of applicable DOE Orders, the QAMPR, ANSI/ASME NQA-1, and supplemental procedural controls as determined by cognizant line management;
- o Assignment of responsibility for achieving and verifying quality, and for review and approval of quality-related plans and procedures.
- o Indoctrination and training of personnel in the role and function of requirements and procedures and applicable to QL-3 activity and in their importance to the quality objectives of the program;
- o Verification of procedural adequacy and effectiveness in achieving and assuring quality; and
- o Reporting separately from QL-2 and QL-1 by line management.

2.2.3.4 Project Participants' Line Management Control

Other items/activities not specifically addressed by these three quality levels will require the use of good work practices and will meet appropriate quality program requirements as determined by project participants on a case-by-case basis in managing for quality and as prescribed by DOE Order 4700.1. This would include all other items and activities not included in the above definitions.

2.3 INDOCTRINATION

2.3.1 Indoctrination

New personnel in HQ-OGR, the project offices, and participants and personnel newly assigned duties on the repository program shall receive indoctrination in program and project objectives, the QA program plans and procedures and programmatic documents that apply to their activity area.

2.3.2 Training

Within HQ-OGR the cognizant Division Director/Branch Chiefs are responsible for determining training needs for their personnel. Similarly, within the project offices, the Division Directors/Branch Chiefs are responsible for determining training needs for their personnel. Within HQ-OGR and the project offices the specific Quality Division Director shall determine the QA oriented training needed by non-QA DOE personnel for performing evaluations of participants control effectiveness.

To ensure that all project participant personnel performing activities affecting quality achieve and maintain suitable proficiency, each project shall establish a project-wide program to provide appropriate training and indoctrination. The project managers have the responsibility to determine appropriate scope and content of the training program commensurate with the project phase and for forecasting and planning training needs for future work. The project manager shall designate responsibility to ensure training requirements are completed by project participants and to verify effectiveness of each training program. Participants shall maintain documented training programs, which shall be regularly audited by the cognizant QA organization. Participant management shall monitor personnel performance and determine the need for retraining and/or replacement.

2.3.3 Qualification

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

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

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

2.3.4 Documentation and Records

HQ-OGR, the project offices and participants conducting indoctrination, formal training, and/or qualification programs shall generate documentation of this activity for the formal records program. These records become lifetime quality records. Documentation of formal training sessions shall include the training objective(s), training content, test or on-the-job training results, certifications, attendees and date(s) of attendance.

2.4 MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

Management assessments of the effectiveness of the overall QL-1 and QL-2 QA Program shall be conducted at intervals not exceeding one year. Such assessments shall be conducted by a management team above and outside the QA organization. The management assessments shall evaluate effectiveness of management controls that are established to achieve and assure quality, adequacy of resources, training, organization structure, interfaces and communication. Such assessments shall include frequent contact with program status through reports, meetings and/or audits as well as performance of a preplanned documented assessment, with recommendations or corrective action identified and tracked. Further guidance is provided in DOE/RW-0032 (1987).

Management assessments are performed by HQ-OGR, the project offices, and project participants to determine effectiveness of their QA programs. Such reports shall be addressed to the highest responsible individual for QA program implementation within an organization.

HQ-OGR, the project offices, and participants shall implement QA administrative procedures prescribing details on performing management assessments.

2.5 READINESS REVIEW

Readiness Reviews are systematic preplanned documented reviews of the readiness for startup and/or continued intended use of a facility, process, or activity. Readiness Reviews are typically conducted before proceeding beyond established project milestones, and prior to initiation of a major or critical activity or event commensurate with their importance to safety and/or waste isolation (Readiness Reviews are established during project planning and scheduling activities). Other Readiness Reviews may be scheduled and performed as deemed necessary or desirable.

HQ-OGR, project offices and participants shall prepare and issue procedures for implementation of readiness reviews. The procedures will establish a Readiness Review Board and a formalized method for performing readiness reviews; however, the activities included in a particular readiness review will depend upon the phase or status of the project activities as determined by the Readiness Review Board.

The project offices shall coordinate as necessary Readiness Review activities with HQ-OGR, the NRC, and States and Indian Tribes. Each project office will develop and implement readiness review procedures as required by DOE/RW-0032 (1987).

2.5.1 HQ-OGR Participation in Readiness Reviews

HQ-OGR will participate in project readiness reviews during site characterization, construction, testing, or operation of the geologic repository. HQ-OGR will review the project readiness review plans and readiness review reports for completeness of required actions and documentation, and for conformance with requirements specified in this QA Plan.

2.6 REVIEW AND APPROVAL OF PROJECT QA PLANS AND PROCEDURES AND SUBMITTALS

The project offices shall submit their QA Plans and revisions, the QA administrative procedures and the QA requirements document, if prepared, to the Associate Director, OGR for approval. The project offices shall review their QA Plan annually, and revise as necessary. Revisions should be issued on or near the beginning of the fiscal year.

2.6.1 HQ-OGR Review

The OGR QA Director will review and recommend approval of project office QA Plans, QA requirement documents, and QA administrative procedures in accordance with QIP 2.0.

2.6.2 Project Release of QA Plans and Procedures

The project offices may issue QA Plans and Administrative Procedures for interim use pending HQ-OGR approval, providing they are so identified (normally after initial approval, any revisions required by HQ-OGR should be incorporated in the next revision).

2.6.3 HQ-OGR Approvals

The Associate Director OGR reviews the recommendations from the OGR QA Director, and if in agreement approves the Project QA Plans, and their revisions. The Director, S&L, transmits the OGR QA Plan and the project offices QA Plans and revisions to the NRC for review. The NRC requests for additional information (RAIs) are forwarded to the originating office for appropriate resolution and/or response.

2.6.4 Final Project Release of QA Plans and Procedures

Upon receipt of approval from HQ-OGR, the projects may final release QA Plans and procedures which were interim released in accordance with Section 2.6.2 (if changes are required due to NRC RAIs the changes should be evaluated and incorporated in the next revision when feasible).

2.6.5 Submittal Requirements

In addition to the approval requirements described above, the project offices shall submit the following listed documents to HQ-OGR.

- o A controlled copy of the project office QA plan.
- o A controlled copy of the project office QA administrative procedures.
- o A controlled copy of the QA manual or plan and administrative procedures for participating contractors.
- o Project office audit schedules and revisions.
- o Reports of internal audits and related correspondence.

- o Reports of QA audits and related correspondence of participating contractors performed either by the project office or when delegated to a prime, integrating, or support contractor.
- o Copies of significant quality problem reports and unusual occurrence reports.

**FIGURE 2-1
QUALITY LEVEL DETERMINATION LOGIC**

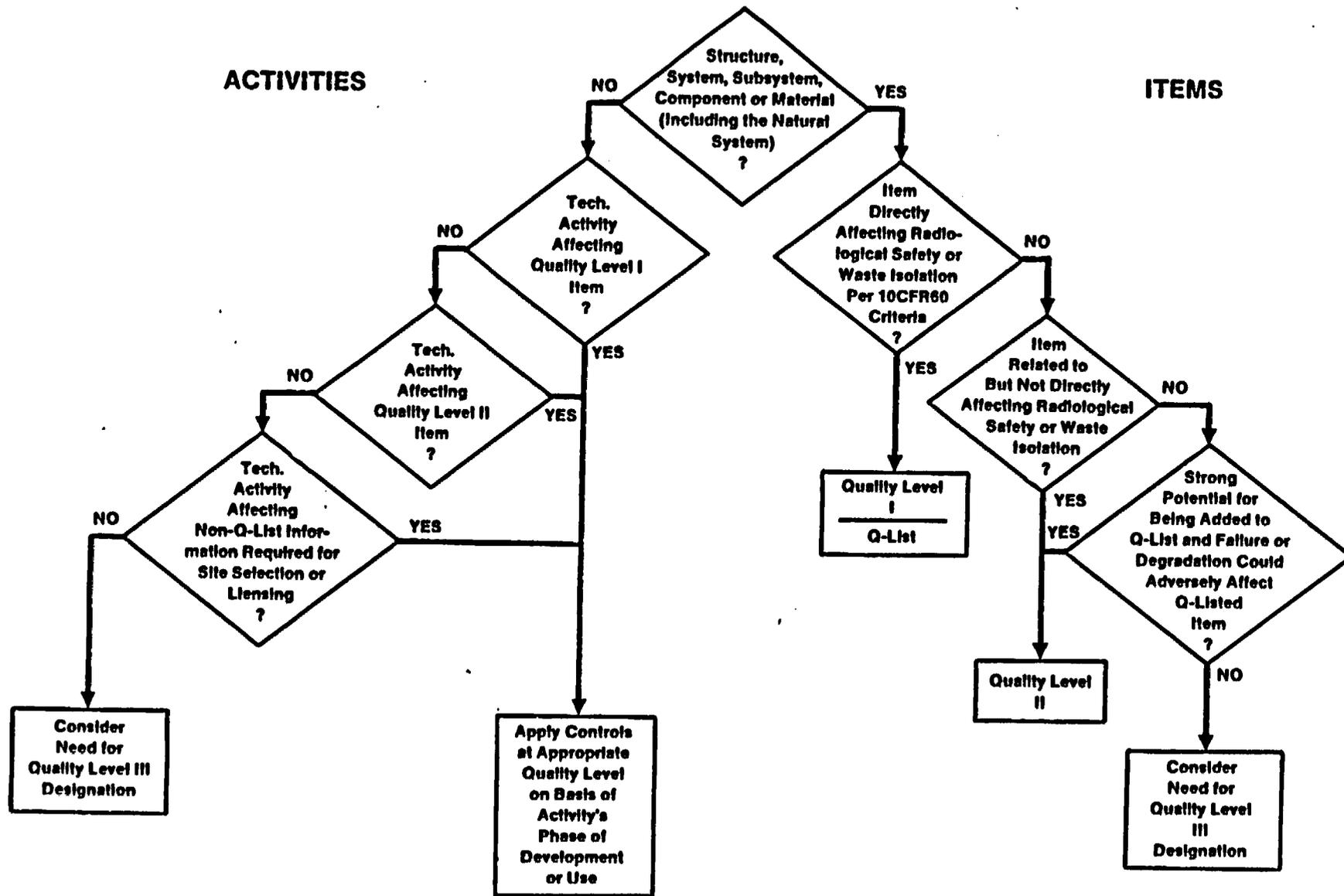


TABLE 2-1
OGR QUALITY IMPLEMENTING PROCEDURE (QIP'S)
(Typical)

2.0	HEADQUARTERS REVIEW OF PROJECT QA PLANS AND ADMINISTRATIVE PROCEDURES
2.1	INDOCTRINATION AND TRAINING
3.0	DESIGN REVIEWS
3.1	PEER REVIEWS
3.2	TECHNICAL REVIEWS
4.0	PROCUREMENT DOCUMENT CONTROL
5.0	PREPARATION AND CONTROL OF OGR QUALITY IMPLEMENTING PROCEDURES
6.0	DOCUMENT CONTROL
7.0	CONTROL OF PURCHASED ITEMS AND SERVICES
16.0	SIGNIFICANT PROBLEMS REPORTING AND CORRECTIVE ACTION
16.1	UNUSUAL OCCURRENCE REPORTING
17.0	QUALITY RECORDS
18.0	EXTERNAL AUDITS
18.1	HQ PARTICIPATION IN PROJECT QA AUDITS OF CONTRACTORS
18.2	REVIEW OF PROJECT SUBMITTED AUDIT REPORTS
18.3	AUDITOR TRAINING, QUALIFICATION, AND CERTIFICATION
18.4	INTERNAL AUDITS

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
1 Basic		1.0
1S-1, Sect. 2.1, 2.2		1.2.2
1S-1, Sect. 2.3		1.2.3
	1.1, Sent. 1	1.3.1, 1.3.2, 1.3.3, Sect. 3 - 1.1, 1.3.4, 1.3.5
	1.1, Sent. 2	1.3.1, 1.3.5, 2.2.1, Fig. 1-1, 1-2, 1-3, 1-4
	1.2	1.2.1
1S-1, Sect. 3.1	1.3	1.2, 1.3.1, 1.3.2, 1.3.3, 1.3.4, 1.3.5, 1.3.6
1S-1, Sect. 3.2		1.2
	1.4, Sent. 1, 2	1.2.2, 1.3.2, 1.3.3, 1.3.4, 18.1
	1.4, Sent. 3	1.2.2, 2.2.1, 18.0
	1.5	1.3.1
	1.6	1.2, Fig. 1-3
	1.7	1.0, Fig. 1-2, 1-3, 1-4
	1.8	1.1.3, 2.2.3
	1.9	1.2, 1.3 Fig 1-4
	1.10	1.2, 1.3, 1.3.5

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
	1.11	1.2, 1.3, 10.2, 10.3
	1.12a, b, c	1.2.2
	1.12d	1.2.3
	1.13	1.2.4
	1.14	QA Policy Statement
	1.15	1.3.1, 1.3.2, 1.3.3, 1.3.4, 1.3.5
2 Basic		2.0
	2.1	2.0
	2.2	3.2
	2.3	2.2.2
	2.4	5.0
	2.5	2.0, 2.2.3
	2.6	2.2.2
	2.7	2.4
	2.8a	2.3.1
	2.8b	2.3.3
	2.8c	2.3.4
	2.8d	2.3.2
	2.8e	2.3.3
2S-1, 2S-2, 2A-1		2.3.3, 10.2
2S-3, 2A-3		2.3.3, 18.4

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	OAP
2S-4		2.3.1, 2.3.2, 18.4
3 Basic		3.0
3S-1, Sect. 2		3.2, 3.3, 3.4, 3.5
3S-1, Sect. 3		3.3, 3.4
	3.1	3.1, 2.2.3
	3.2	3.0, 3.3, 3.4, 3.5, Site Characterization Plans
	3.3	3.3, 3.4, 3.5, 3.7, 3.11.1
	3.4	3.1
3S-1, Sect. 6	3.5	3.8
	3.6	3.41
3S-1, Sect. 4	3.7	3.5
	3.8	3.5.5, 3.7
	3.9	3.3.2, 3.5, 3.6
3S-1, Sect. 5	3.10	3.6, 6.6
3S-1, Sect. 7		17.1
4 Basic		4.0
4S-1, Sect. 2		4.1
4S-1, Sect. 3	4.1	4.1
	4.2	4.1
5 Basic		5.0
	5.1	5.1, 5.3, 3.5, 6.3

TABLE 2-2
REQUIREMENTS MATRIX

NQA-1-1986	NRC REVIEW PLAN	OAP
	5.2	5.6
6 Basic		6.0
6S-1		6.1
	6.1	6.1
	6.2	6.1, 6.3
	6.3	5.7, 6.1e
	6.4	6.1g
	6.5	6.1i
	6.6	6.1j
7 Basic		7.0
	7.1	7.1
7S-1, Sect. 2		7.1
7S-1, Sect. 3	7.2	7.3, 7.4.1, 7.4.2,
7S-1, Sect. 4		7.0
7S-1, Sect 5		7.3
7S-1, Sect. 6, 7, 9	7.3	7.4.2
7S-1, Sect. 8	7.4	7.4.2
	7.5	11.4
7S-1, Sect. 10		7.4.2
8 Basic		8.0
	8.1	8.1

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	OAP
	8.2	8.1
	8.3	8.1
8S-1		8.0
	8.4	8.2
9 Basic		9.0
9S-1, Sect. 2, 3	9.1	9.1, 9.2
	9.2	9.2
	9.3	9.2
	9.4	9.3
	9.5	9.3
10 Basic		10.0
	10.1	10.1
10S-1, Sect. 2	10.2	10.2, 10.3
	10.3	10.2
10S-1, Sect. 3, 4	10.4	10.4
10S-1, Sect. 5	10.5	10.4
	10.6	10.5, 10.6
10S-1, Sect. 6		10.1, 10.5
11 Basic		11.0
11S-1, Sect. 2		11.2
	11.1, Sent. 1	11.1

TABLE 2-2
REQUIREMENTS MATRIX

NQA-1-1986	NRC REVIEW PLAN	OAP
	11.1, Sent. 2	11.2, 11.5
	11.1, Sent. 3	11.5
	11.2	11.2
	11.3	11.3
11S-1, Sect. 3	11.4	11.6
11S-1, Sect. 4, 5	11.5	11.7
12 Basic		12.0
	12.1	12.1
	12.2	12.1, 12.2
12S-1		12.1
	12.3	12.1, 12.2
	12.4	12.1
	12.5	12.1
	12.6	12.1
	12.7	12.1
13 Basic, 13S-1		13.0
	13.1	13.1
	13.2	13.1
14 Basic		14.0
	14.1	14.1
15 Basic		15.0
	15.1	15.1, 15.2, 15.3

TABLE 2-2
REQUIREMENTS MATRIX

NOA-1-1986	NRC REVIEW PLAN	QAP
15S-1, Sect. 2, 3	15.2	15.1, 15.2, 15.3
15S-1, Sect 4	15.3	15.1, 15.2, 15.3
	15.4	15.4
16. Basic		16.0
	16.1	16.1, 16.2
	16.2	16.2, 15.5 Sect. 3-16.1, 16.4
	16.3	16.1
	16.4	16.1 Sect. 3-16.4
17 Basic		17.0
17S-1, Sect. 2, 3, 5		17.2
17S-1, Sect. 4		17.2
	17.1	17.2
	17.2	17.2, 17.5, 17.6
	17.3	10.4, 11.7, 11.8
	17.4	17.2 (See Sect. 2-17.2 for clarification)
18 Basic		18.0
	18.1	18.1
18S-1, Sect. 2	18.2	18.3
18S-1, Sect. 3	18.3	18.2, 18.6
18S-1, Sect. 5	18.4	18.10, 18.15
18S-1, Sect. 4	18.5	18.4, 18.5, 18.6

TABLE 2-2
REQUIREMENTS MATRIX

<u>NOA-1-1986</u>	<u>NRC REVIEW PLAN</u>	<u>OAP</u>
18S-1, Sect. 6, 7	18.6	18.3, 18.15
18S-1, Sect. 7	18.7	18.15
	18.8	18.7, 18.15

TABLE 2 - 3
ANSI/ASME NQA-1

Applicability of Basic and Supplementary Requirements

Requirement No.	TOPICAL	HQ-OGR	All Projects
1	Organization	X	X
2	Quality Assurance Program	X	X
3	Design Control (&Peer Review)	D	X
4	Procurement Document Control	X	X
5	Instructions, Procedures, and Drawings	X	X
6	Document Control	X	X
7	Control of Purchased Items & Services	X	X
8	Identification and Control of Items	D	X
9	Control of Processes	D	X
10	Inspection	D	X
11	Test Control	D	X
12	Control of Measuring and Test Equipment	D	X
13	Handling, Storage, and Shipping	D	X
14	Inspection, Test, and Operating Status	D	X
15	Control of Nonconforming Items	D	X
16	Corrective Action	X	X
17	Quality Assurance Records	X	X
18	Audits	X	X

D- These requirements do not apply to the HQ-OGR program because the activities are performed by the Project Office and/or contractor organizations. The authority for these requirements has been delegated to the Project Office for compliance or delegation to the appropriate contractor. Responsibility for the delegated requirements remains with the delegating organization.

3.0 DESIGN CONTROL

3.1 POLICY

The HQ-OGR and project offices design controls shall include not only the controls traditionally used to ensure correct translation of design inputs, including applicable regulatory requirements and design bases into designs; but they shall include controls to ensure adequacy and validity of site characterizations results and design bases. Plans and strategies, acquisitions, reduction and analysis of data during site characterization, and subsequent system analyses, which are construed as activities important to safety and/or waste isolation and are governed by controls described herein.

The project offices may delegate the design control program development and implementation to project participants but they retain responsibility for the overall design for each potential repository site.

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

3.2 COMPUTER SOFTWARE

Computer software for technical computer codes used for the collection and/or manipulation of data which are important to safety and/or waste isolation is to be controlled by participants procedures consistent with guidelines established in NUREG 0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management". These controls will be applied throughout all phases of the project beginning with site characterization.

3.3 APPLICATION OF DESIGN CONTROLS TO DATA ACQUISITION

3.3.1 Design Control Measures for Test Control

The processes of identifying data needs, planning data acquisition work and sequence, and experiment design such as preparation of the necessary test procedures for the geologic repository projects are associated with (a) establishing how much of the "as-built design" of each site must be determined, (b) how and in what sequence the "as-built" characterization is to be done, and (c) what processes of data acquisition best assure the validity of such exploration and measurement. Therefore, the activities of data acquisition (test) planning and data acquisition (test) procedure generation require the

same design control measures that are applied to conventional systems, structures and components for the repository design.

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

3.3.2 Existing Data

The project offices have accumulated a considerable body of data relevant to site characterization (e.g., geotechnical, climatological, seismology, etc.) including literature searches, data developed outside the repository projects such as by mining and oil companies, utilities, national laboratories, universities, or data published in technical or scientific publications, and/or data gathered without qualified management controls in effect.

The use of such data in the site characterization process which will be used to support the licensing process will require qualification. There are four alternative methods or combination of methods that may be used as follows: (a) Peer Review as described in Section 3.7; (b) Use of corroborating data; (c) Use of confirmatory testing; and (d) Demonstrating that appropriate QA program controls equivalent to 10CFR60 Subpart G had been used. Methods (b), (c) and (d) should include a documented technical review to determine the acceptability of the data (additional confidence/credibility could be achieved by using a combination of methods). Note: The definition of existing data does not include information which is accepted by the scientific and engineering communities as established facts (e.g. engineering handbooks, density tables, gravitational laws, etc), and requires no qualification for use.

The project offices shall issue a QA administrative procedure prescribing their roles and responsibilities in the qualification of existing data.

3.3.3 Current Data

Reduction and analysis of data collected during Project site characterization, or of prior data that has since been qualified, will be performed under controls specified in

approved participant procedures. Such procedures will provide, as appropriate to the nature of the data reduction and/or analysis at issue, for:

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

3.4 THRESHOLDS FOR APPLICATION OF QA PROGRAM CONTROLS TO DESIGN AND TEST ACTIVITY

Development of approaches, techniques, models, etc., for performance of site characterization analysis, data acquisition planning, and design may be viewed as analogous to development of special processes which is treated as a creative activity whose results are determined acceptable or unacceptable during qualification of the process.

The threshold for application of formal QA program controls should be defined as that point in time at which the particular approach, technique, model, etc., is applied in data acquisition or analysis that evaluates or supports evaluation of natural site waste isolation characteristics, or in design of items that are or could become Q-listed. (See Figure 3-1.)

Controls applied to activities that have not reached the above threshold should consist of guidelines for keeping sufficient notes for preparation of any required report or reports describing the technical basis, logic, limitations, applications, etc., of the approach, technique, model, etc., under development. Application of any such approach, technique, model, etc., should be permitted only if (a) the "process" has been "qualified" (i.e., verified and validated, peer reviewed, etc., as appropriate to its nature), or (b) results of the application are clearly flagged as conditioned on "qualification" of the "process".

3.5 DESIGN CONTROLS FOR SITE CHARACTERIZATION STUDIES AND DESIGN OF EQUIPMENT, FACILITIES, WASTE FORM AND WASTE PACKAGING

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

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

3.5.1 Design Verification by Formal Design Review

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

3.5.2 Design Verification by Testing

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

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

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

3.5.3 Design Verification by Alternate Calculations

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

3.5.4 Design Verification by Similarity

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

3.5.5 Design Verification by Peer Review

See Section 3.7.

3.6 DESIGN CHANGES

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

3.7 PEER REVIEW

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

Procedures implementing Peer Review shall define the peer group selection process and describe the conduct and documentation of peer reviews. The peer reviewers should consider the validity of assumptions, alternate interpretations, uncertainty of results, appropriations of methodology, adequacy of applications, validity of conclusions and adequacy of requirements and criteria.

Peer reviewers shall be individuals who have qualifications at least equivalent to those required for performance of the original work 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.

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

Project offices shall prepare and implement a QA Administrative procedure describing how they participate in or perform peer reviews. The cognizant QA organization shall conduct surveillance and audits of peer review activities.

3.8 DESIGN INTERFACES

Significant design interfaces exist between the project offices and between the participants who are assigned responsibility for portions of the design, development and other design activities. The interfaces shall be identified and controlled within each organization. The procedures shall define interface controls, responsibilities, lines of communication, and documentation of internal and external interface activities.

3.9 REVIEW PLAN

The project participants shall develop a general plan and schedule which will be continually updated to reflect technical and readiness reviews as described in Section 2.5, that are to be accomplished for site characterization and design activities. The project offices are responsible to have this information obtained and integrated on a project-wide basis and to have completion verified.

3.10 PROJECT OFFICE COGNIZANCE

3.10.1 Project Offices

Project office personnel shall exercise regular and frequent surveillance within their areas of expertise over technical work being performed by project participants. Technical surveillance includes:

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

3.10.2 Document Review

Project technical personnel review technical documents (such as test reports, analyses, reports of study results, etc.) for appropriateness of approach, reasonableness of conclusions, clarity and evidence of necessary supporting inputs. 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 for draft documents.

3.10.3 Project Office QA Audit and Surveillance of Design Controls

The project office QA organization shall perform audits and surveillance of project design controls, as described in Section 18.0 of this QA Plan.

3.11 HQ-OGR IMPLEMENTATION

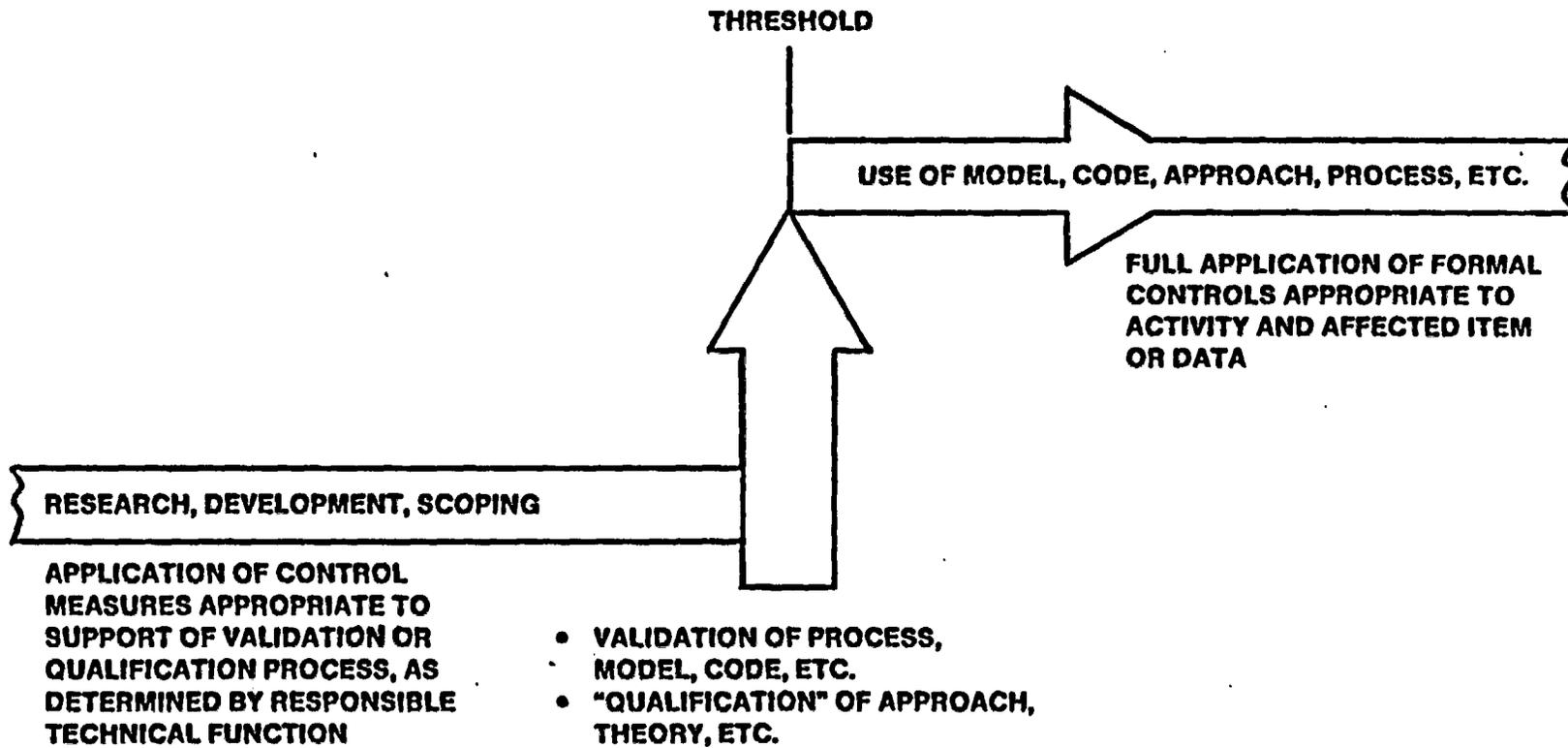
3.11.1 Project Offices Design Control Procedures

Design control administrative procedures developed by the project offices shall be reviewed and approved as prescribed in Section 2.0 of this QA Plan.

3.11.2 HQ-OGR Technical Reviews

HQ-OGR will perform technical reviews, as appropriate, of design-related technical plans and scientific/technical reports submitted by project offices. These reviews will be performed in accordance with established procedures.

FIGURE 3-1 THRESHOLDS FOR APPLICATION OF QA PROGRAM CONTROLS TO DESIGN AND TEST ACTIVITIES



4.0 PROCUREMENT DOCUMENT CONTROLS**4.1 HQ-OGR, PROJECT OFFICES AND PARTICIPANTS**

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

- a. Procurement planning
- b. Preparation, review, approval and control of procurement documents
- c. Review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases (where applicable), and other requirements are referenced or included in the procurement documents; that adequate accept/reject criteria and plans for acceptance are included where appropriate; that an appropriate supplier QA program has been specified or provision for work to be done to appropriate portions of the purchasers QA program; and that the procurement documents have been prepared in accordance with the applicable procedure(s),
- d. Supplier selection,
- e. Bid evaluation, with participation by the initiator and/or QA (as applicable) for bids that restate or interpret technical and/or quality assurance requirements,
- f. Review of, and concurrence with, the supplier QA program prior to initiation of supplier work subject to program requirements,
- g. Procurement documents shall require project participants subcontractors and consultants to provide or perform work to an acceptable quality assurance program.
- h. Changes to procurement documents require the same controls as the originals.

4.1.1 HQ-OGR IMPLEMENTATION

HQ-OGR shall implement these requirements through procedure QIP 4.0; "Procurement Document Control".

4.2 HQ-OGR EVALUATION ROLE

The HQ-OGR shall review selected procurement document packages prepared by or for the Project Offices during QA audits and/or surveillance activities.

5.0 INSTRUCTIONS, PROCEDURES & DRAWINGS

5.1 HQ-OGR, PROJECT OFFICES AND PARTICIPANTS

Program and project activities are prescribed by, and performed in accordance with, written instructions, procedures and/or drawings appropriate to the work. Such procedures, instruction and drawings shall be reviewed for accuracy and adequacy by personnel who are competent in the subject matter addressed; and QA, for program compliance. Section 3.0 defines requirements for reviewers of design documents and Section 6.0 covers review of procedures and instructions.

5.2 ADMINISTRATIVE PROCEDURES

Administrative procedures are documents that define management controls and control systems, establish responsibilities and authorities for exercising them, and specify the approved overall methodology. The Program is governed by two basic categories of administrative procedures: (1) Procedures that define and direct operation of the Project management system, covering such areas as the work breakdown system, the various project baselines, etc., are reviewed as stated in 5.1, and (2) procedures that define and direct controls and control systems making up the Program and Project quality assurance programs. Requirements of this section, relative to administrative procedures, apply to the second category, which are designated "QA administrative procedures".

5.3 TECHNICAL PROCEDURES

Project technical work is prescribed by, and performed in accordance with, detailed procedures (e.g., laboratory procedures, special process procedures, test procedures, etc.). Project offices shall be 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 shall be reviewed by the participants QA personnel prior to use to verify that the necessary control features have been included.

5.4 INSTRUCTIONS

Written instruction shall be detailed sequences of steps, descriptive material specifying how an activity is to be performed, such as: statements of actions necessary to carry out a nonconformance; disposition, or inspection checklists, etc. (Instructions may not change or mitigate procedural requirements.)

5.5 DRAWINGS

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

5.6 ACCEPTANCE CRITERIA

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

5.7 USE AND AVAILABILITY

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

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

5.8 HQ-OGR IMPLEMENTATION

HQ-OGR shall implement these requirements through procedure QIP 5.0, "Preparation and Control of OGR Quality Implementing Procedures."

5.9 HQ-OGR EVALUATION ROLE

The HQ-OGR shall review and approve quality assurance administrative procedures prepared by the project offices.

6.0 DOCUMENT CONTROL

6.1 CONTROL ELEMENTS FOR HQ-OGR AND PROJECT OFFICES

HC-OGR and Project Offices shall maintain or have maintained a document control system for documents that direct or affect work within the scope of the Program and Project QA programs. These document control systems shall provide for:

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

6.2 INTERORGANIZATION DOCUMENT REVIEW AND APPROVAL

6.2.1 Project QA Documents

The Project QA Plans and implementing Project Office QA administrative procedures shall be submitted to HQ-QGR for review and approval as specified in Section 2.6.

6.2.2 Project Participants QA Program Documents

QA program descriptions and implementing QA administrative procedures prepared by the major direct funded Project Participants shall be submitted to the project offices for review and approval.

6.2.3 Other Participants' Documents

Other participating organizations shall submit their 'QA Plans and implementing QA administrative procedures for review and approval by the next higher participant in the project hierarchy. Project offices shall review and approve QA program descriptions, QA administrative procedures and any major or substantive changes thereto for other government agencies performing Project work under Memoranda of Understanding (MOU) with the DOE, and for public institutions performing Project work on direct contract with the DOE.

6.2.4 Technical Documents

Technical reports prepared by project participants as a basis for, or as part of, site characterization, waste form, waste package design, or repository design, shall be reviewed and approved by Project Offices (Ref. specific Project Management Plan and Systems Engineering Management Plan).

6.3 REVIEW AND APPROVAL PROCESS

Document review shall be accomplished by competent, independent reviewers. Reviewer comments and the resolutions of comments shall be documented for the record, and document approval requires determination by the approver(s) that all comments have been resolved satisfactorily. Documents shall be reviewed by the cognizant QA organization for concurrence with quality-related aspects.

6.4 DOCUMENT TRANSMITTAL AND RECEIPT CONTROLS

Controlled documents distributed by HQ-OGR, the project offices, or project participants shall be controlled in accordance with approved procedures. Controls shall include logging, updating of distribution lists and document indices, and a formal receipt acknowledgement system to assure superseded documents are replaced in a timely manner.

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

6.5 HQ-OGR DOCUMENT CONTROL

HQ-OGR shall implement these requirements through procedure QIP 6.0, "Document Control." In addition HQ-OGR will perform surveillance and audits of the projects' document control programs.

6.6 CONFIGURATION MANAGEMENT

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

Configuration Management uses the applicable document control requirements when changes are made to baseline documentation, since each project configuration is defined in written documents. The project offices and project participants execute Configuration Management through compliance with plans and implementing procedures. The project offices approve the Configuration Management Plans.

6.7 PROJECT OFFICE QA CONTROLS

The project offices QA organizations shall perform audits and surveillances of their configuration management program to verify control effectiveness.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 HQ-OGR AND PROJECT OFFICE IMPLEMENTATION

The HQ-OGR and project offices shall institute measures to ensure that purchased items and services conform to the requirements specified in applicable procurement documents. Controls include evaluation and selection of suppliers with a demonstrated capability of providing the required item(s) or service(s), verification that applicable controls are exercised during item processing or performance of the contracted services, and verification that completed items or services conform to procurement acceptance criteria. The cognizant QA organization is required to ensure that these controls are adequate and appropriate to the procurement. HQ-OGR and the project offices shall require the same controls specified herein to be implemented by their participants.

7.2 SUPPLIER QA PROGRAMS

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

7.3 SUPPLIER SELECTION AND EVALUATION

HQ-OGR, project offices and participants shall recognize that some of the research and analysis required for site characterization requires the services of specialists, or of institutions or agencies whose work does not ordinarily involve formal QA activities. In these instances, selection is based on technical capability, and establishment of QA measures appropriate to the services to be performed shall be required at the outset of their work by the procuring organization.

Except where technical requirements dictate selection on the basis of unique capabilities, as indicated above, procurement of items or services within the scope of the program or project

QA program shall be made from suppliers who are pre-approved by the responsible QA organization in the project.

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

Where project offices contract directly (via DOE Procurement Division) for items or services within the scope of the Project QA program, supplier selection and evaluation is accomplished in accordance with approved procedures for supplier evaluation, selection and verification.

7.4 VERIFICATION

7.4.1 Verification of Work in Progress

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

7.4.2 Acceptance

Acceptance of completed items or services is accomplished as follows:

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

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

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

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

The procuring project office's or participants' QA organization shall verify or have verified that required

documentation is received and complies with procurement QA requirements. Acceptability of results of technical services (such as studies, analyses, etc.) will be determined by the organization initiating the procurement.

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

7.5 SUPPLIER-FURNISHED DOCUMENTATION

HQ-OGR, project offices and participants shall include provision in procurements within the scope of the project QA program for the following supplier furnished documentation:

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

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

7.6 PROJECT OFFICE CONTROL OF PURCHASED ITEMS AND SERVICES

DOE occupies the role of owner on the OGR Projects. Project work is accomplished on contracts between DOE and participant contractors, inter-department agreements between DOE and other Federal government agencies, various contractual arrangements with non-Federal public agencies and institutions, and subcontracts issued by participating contractors. Each Project, therefore, comprises a DOE procurement network.

The project offices are responsible for administering the entire procurement network, for specifying the necessary technical and QA program requirements, and for ensuring that delivered items, materials and services comply with applicable quality assurance requirements. Compliance with applicable provisions of the QA program described in this QA plan is a condition of all OGR

Project procurement contracts. Direct procurements within the scope of OGR project QA program initiated by the project offices are managed in accordance with approved procedures. Nonconforming items or services proposed to be dispositioned "accept as is" or "repair" (or to disposition in a way that fits the definition of either of those two dispositions) shall be reviewed and approved or disapproved by the office in accordance with approved procedures.

7.7 HQ-OGR PROCUREMENTS

HQ-OGR shall implement these requirements in accordance with procedure QIP 7.0, "Control of Purchased Items and Services."

7.8 HQ-OGR EVALUATION ROLE

The OGR shall review selected procurement document packages or supplier records prepared by or for the Project Offices during QA audits and/or surveillance activities.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS, AND SAMPLES**8.1 HQ-OGR AND PROJECT OFFICES**

Items, materials, and samples shall be identified and controlled on the Repository projects in order to assure:

- a) That the history of items and materials is fully known and documented from the time of receipt to the point of use.
- b) That samples have traceable documentation from the point of collection through consumption (test/analysis) and into long-term storage.

8.1.1 Provisions shall be made for documenting in project records the installation, consumption, or other use, of any Q-listed item or material (including samples) in such a manner that it will be possible to determine the identity (and therefore history) of any Q-listed item/material or sample used on the projects. (Note: Continued traceability of samples in storage are included in Records Management, Section 17.0.)

8.2 PARTICIPATING CONTRACTORS RESPONSIBILITIES**8.2.1 Responsibilities**

Each project participant is responsible for identification and control of items, materials, and/or samples in their custody. The project offices provide overall project direction for identification and control of 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, test records, inspection documents and nonconformance reports as applicable.

8.2.2 Procedures

Procedures shall provide for verification and documentation of correct sample identification prior to the release of samples for use or analysis, and preclude assignment of a single identifier to multiple discrete samples.

8.2.3 Sample Subdivision

In situations involving subdivision of a sample, identification of the individual items resulting from the subdivision shall be readily traceable to the original sample.

8.3 HQ-OGR CONTROLS

Responsibility for ensuring compliance to these requirements is delegated to the project offices. HQ-OGR will monitor control effectiveness by surveillances and audits.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SPECIAL PROCESS -- DEFINITION

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

9.2 IDENTIFICATION AND QUALIFICATION

Special processes used on the Repository projects shall be explicitly identified in appropriate QA program documents (QAP or QA-related administrative procedures), and each participant shall develop and maintain a list of those processes that are considered to fall within the scope defined by Section 9.1, above. Participants are responsible for maintenance and distribution a controlled listing of special processes used on their project. The procedures that specify how individual special processes are to be performed shall be qualified by demonstration that, when performed as specified, the process yields required results. Special process personnel shall be qualified by training (where appropriate) and demonstration that they can perform the process(es) with the desired results. Where equipment affects the outcome of a special process, the equipment shall be similarly qualified. The responsible participant's QA Plan shall describe the function the QA organization performs in qualification of special process procedures, personnel and/or equipment.

9.3 DOCUMENTATION OF PERFORMANCE OF SPECIAL PROCESSES

Where validity of site characterization depends on precise control of processes, procedures shall 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 shall be maintained.

9.4 STANDARD PROCESSES

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

9.5 HQ-OGR CONTROLS

HQ-OGR has delegated responsibility for special processes to the project offices, and will monitor control effectiveness during overview activities.

10.0 INSPECTION

10.1 INSPECTION ACTIVITIES

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

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

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

10.2 INSPECTOR QUALIFICATION

Inspections to verify conformance of items or activities to specified requirements shall be performed by inspectors reporting to a participants' QA organization who did not perform or directly supervise the work being accepted. Where appropriate, personnel possessing particular expertise who are independent of the activity being inspected, may perform inspections for acceptance. QA personnel performing inspection functions will be qualified in accordance with ANSI/ASME NQA-1-1986 Supplement 2S-1 and Appendix 2A-1, NONMANDATORY GUIDANCE ON THE QUALIFICATIONS OF INSPECTION AND TEST PERSONNEL (The use of SNT-TC-1A-1980 Qualified Level I NDE inspectors for inspection acceptance is not allowed).

Where experts are required for special inspections, QA in concert with the technical organization determines the inspection requirements and (when appropriate) QA evaluates individual qualifications and provides the necessary QA training to ensure the individual can perform the inspections, use the inspection equipment, and document the inspection results. The qualification records of inspection personnel are reviewed by the participant QA organization. Participants may have inspection personnel or they may contract for inspection services.

10.3 RESPONSIBILITIES

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

Project Offices shall verify that project inspection activities are achieving intended results through audits and surveillances.

10.4 INSPECTION PROCEDURES

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

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

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

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

10.5 INSPECTION RESULTS

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

10.6 DOCUMENTATION AND RECORDS

Verification that activities have been accomplished in accordance with, and that their results conform to, established requirements shall be documented as performed within a reasonable time and shall be retained as part of the formal project records.

10.7 HQ-OGR CONTROLS

HQ-OGR has delegated responsibility for inspections to the project offices, and will monitor control effectiveness during overview activities.

11.0 TEST CONTROL

11.1 TEST ACTIVITIES

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

11.2 TEST PLANS AND PROCEDURES REVIEW

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

This activity is driven from the project management system manual (DOE/RW-0043) to the site specific project management plans, and system engineering management plans and their annexes and the study plans which are upstream of the threshold of design control measures covered by Section 3.0 DESIGN CONTROL.

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

11.3 UNCERTAINTIES AND ERRORS

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

11.4 SPECIAL CONSIDERATIONS FOR SOME TEST EQUIPMENT AND INSTRUMENTATION

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

11.5 PERSONNEL QUALIFICATION

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

11.6 TEST PROCEDURES

11.6.1 Test Procedure Content

Test procedures shall include as appropriate the following elements:

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

- b. Test prerequisites such as calibrated instrumentation, presence of specified test equipment and instrumentation, completeness and/or acceptability of item or condition to be tested, specified environmental conditions, and provision for data collection and storage. For tests of long duration, specific provisions will be made for cases in which instrumentation whose calibration interval is shorter than expected test duration. Such provisions are to be designed to ensure validity of data throughout the test.
- c. Instructions for performing the test.
- d. Mandatory inspection and/or witness points (as required).
- e. Acceptance and/or rejection criteria, including required levels of precision and accuracy. (Note: "Accept/reject criteria" means that those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output which, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)
- f. Methods of data analysis (which may, however, appear in data analysis procedures other than the procedures used for performing the testing).
- g. Methods of documenting or otherwise recording test data and results.
- h. Provisions for assuring and documenting the fact that test prerequisites were met.

11.6.2 Test Procedure Considerations

Other factors to be evaluated for inclusion by the technical organizations in preparing test procedures for research and experimental are as follows:

- a. Title of the experiment or research testing.

- b. Name of the individual(s) performing the experiment or research and any additional witnesses to the experiment or research.
- c. Qualifications of the individual(s) performing or witnessing the experiment or research or references to such qualification records if required.
- d. Description of experiment's objective.
- e. Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- f. Record retention time, if longer than three (3) years from the date of the last entry.
- g. A description of the procedures, or sequence of steps in the conduct of the experiment or research.
- h. Acceptance and/or rejection criteria, including required levels of precision and accuracy. (Note: "Accept/reject criteria" means that those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output which, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner.. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure or in the design of the experiment.)
- i. Methods of data analysis (which may, however, appear in data analysis procedures other than the procedures used for performing the testing).
- j. Methods of documenting or otherwise recording test data and results.
- k. Provisions for assuring and documenting the fact that test prerequisites were met.

11.7 TEST RESULTS EVALUATION AND ACCEPTANCE

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

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

11.8 EXPERIMENTS AND RESEARCH TEST CONTROLS

Experimental and research tests are performed to determine how subsequent data acquisition, design or construction tests will be performed. These may lie upstream of the threshold of design control as described in Section 3.0. Required controls shall be determined by the responsible technical organization on the basis of the nature of the experiment. Normal controls of Section 3.0 and 11.0 do not automatically apply.

11.8.1 Experiments and Research Requirements

Documentation of experiments and research performed should be prepared using logbooks or other suitable means to provide a written record of the activity. The entries in 11.6.2 should be considered on the basis of their merits by the technical personnel for use prior to the initiation of the experiment or research.

11.8.2 Record Keeping Requirements

Record entries should be made during the experiment or research and should be sufficiently detailed that another competent experimenter/researcher could repeat the activity. Typical entries as appropriate would include:

- a. Date and name of individual making the entry.

- b. Description of the experiment or research attempted, including detailed step-by-step process followed.
- c. Description of any conditions which may adversely affect the results of the experiment or research.
- d. Identification of samples used and any additional equipment and materials not previously described.
- e. Data taken and a brief description of the results to include notation of any unaccepted results.
- f. Any deviations from the planned experiment or research.
- g. Any interim conclusions reached, as appropriate.
- h. Any final results and a summary of the outcome of the experiment or research.

11.8.3 Final Record Entries

The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

11.9 PROJECT OFFICE TEST CONTROL RESPONSIBILITIES

Project offices will verify by technical surveillance, QA surveillance and QA audit that the participants' direction and management is producing effective test controls throughout the projects.

11.10 HQ-OGR OVERVIEW

HQ-OGR has delegated responsibility for test control to the project offices. The OGR will verify the control effectiveness during technical and QA surveillances and participating in project office QA audits.

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

12.1 CALIBRATION PROGRAM

HQ-OGR has delegated the responsibility for control of Measuring and Test Equipment (M&TE) to the project offices.

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

When a nationally recognized standard does not exist, (i.e. helium standard leaks) the basis for calibration is documented and reviewed. Where beyond-the-state-of-the-art or untried methods are being employed for calibration, an evaluation should be made to determine if a peer review of the proposed method is required by the organization that established the calibration requirement. Participants who use M&TE shall describe in their QA administrative procedures the types of M&TE that are subject to their calibration program. Calibration programs do not normally apply to devices where normal commercial practice provides adequate accuracy.

12.2 QA INVOLVEMENT

Participants on the projects shall make provision for their QA organizations to verify that the calibration controls are established, implemented, and effective; by concurrence with calibration program procedures, and with audits and surveillance of calibration activities. The project office QA organizations are to verify effectiveness of the management of the calibration programs on their projects.

12.3 HQ-OGR OVERVIEW

During HQ-OGR project overviews reviews and/or participation in project QA audits of major participants, OGR will evaluate the effectiveness of the project office controls.

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

13.1 CONTROLS

HQ-OGR has delegated the responsibility for control of handling, storage and shipping of items, materials, and samples to the project offices.

Project office participants whose tasks include receipt, processing or storage of items, materials, or samples within the scope of the OGR QA Plan are required to establish and implement controls that protect them from loss, damage, or deterioration. Project participants QA organizations shall monitor these programs to assure controls are in place.

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

13.2 Project Office Responsibilities

The project office QA organizations shall verify effectiveness of controls by their projects participants by surveillance and audit.

13.3 HQ-OGR Overview

During HQ-OGR project overviews, reviews and/or participation in project office QA audits of major participants, OGR will evaluate the effectiveness of the project office controls.

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 CONTROLS

HQ-OGR has delegated the responsibility for controls for maintaining inspection, tests, and operating status to the project offices.

Controls for maintaining and indicating the status of project inspections, test and operations are established and implemented for the purpose of ensuring that required inspections or test, or required inspection or test steps, are not inadvertently bypassed. Project participants are required to establish and implement procedures that provide for use of status indicators (such as tags, markings, area postings, etc., as appropriate) to show inspection, test and/or operating status. In addition, logs, status boards or other suitable administrative controls are required where knowledge of status required at locations remote from the actual inspection, test or operation activity.

The project participant's QA organization shall monitor and periodically verify that appropriate controls are in place.

14.2 PROJECT OFFICE RESPONSIBILITIES

The project office QA organization shall periodically audit and perform surveillances to verify control effectiveness of their project participants.

14.3 HQ-OGR OVERVIEW

During HQ-OGR project overviews, reviews and/or participation in project office QA audits of major participants, OGR will evaluate the effectiveness of the project office controls.

15.0 CONTROL OF NONCONFORMING ITEMS OR SAMPLES

15.1 IDENTIFICATION AND CONTROL

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

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

15.2 EVALUATION AND DISPOSITION

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

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

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

Standard repair procedures may be prequalified and utilized for repairs after initial technical review and approval at the next higher level of project participation, and used in dispositioning subsequent nonconformances.

15.3 ACCOMPLISHMENT OF DISPOSITION

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

15.4 TRENDS

The participants shall establish systems for monitoring and analyzing nonconformance reports for trends to help to determine root cause and to initiate appropriate action when the need is indicated. Those nonconformances submitted to the project offices for technical disposition acceptance shall be processed to their approved QA administrative procedures. The project office QA Directors shall evaluate trend reports and notify their Project Managers of significant nonconformance trend information.

15.5 HQ-OGR RESPONSIBILITIES

HQ-OGR has delegated the responsibility for the control of nonconforming items, materials and samples to the project offices. OGR personnel will perform overviews of nonconformance controls implemented by the participants during joint audits and technical reviews with the project offices.

16.0 CORRECTIVE ACTION**16.1 POLICY**

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

16.2 CORRECTIVE ACTION PROGRAM

The project offices are responsible to direct establishment and ensuring implementation of project-wide programs for formal corrective action to prevent recurrence of significant problems. The program shall provide for the following:

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

16.3 HQ-OGR RESPONSIBILITIES

HQ-OGR QA personnel shall monitor and verify that corrective actions implemented within the divisions are effective and prevent further recurrence. HQ-OGR Procedure QIP 16.0 prescribes how corrective actions are accomplished within OGR.

16.4 UNUSUAL OCCURRENCE REPORTING

Project offices and their participants shall implement procedures for evaluating significant events which results in any deviation from the planned or expected behaviour of an activity, operation or

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course of events, which has or could have significant programmatic, (reliability, cost or schedule), safety, health events are to be reported in accordance with DOE Order 5000.3.

Information copies of these reports are to be forwarded to the OCRWM QA Manager by the Project Offices.

16.5 HQ-OGR OVERVIEW

HQ-OGR personnel shall monitor the project corrective action programs during surveillances and participation in project office audits of participants.

17.0 QUALITY ASSURANCE RECORDS**17.1 POLICY**

The collection, storage and maintenance of Quality Assurance Records generated or purchased during all phases of the geologic repository program shall be governed by a documented records management program, to ensure that sufficient records are maintained in an identifiable and retrievable form, and to furnish objective evidence of the items and the performance of activities affecting quality.

17.2 RECORDS MANAGEMENT SYSTEM

The project offices shall develop an information resource management plan incorporating the requirements for a records program which includes those records important to safety and/or waste isolation and which are required for site characterization, subsequent licensing or in operation of a repository including items (such as core samples, etc.) that become a part of the record. The records programs for QA records shall comply with the provisions of ANSI/ASME NQA-1 and Supplement 17S-1 except as exempted herein.

The project offices may delegate responsibility for records management to their participating contractors, and in the interests of promoting economy and uniformity may elect to designate a single participant to establish a project-wide program and records center with other participants forwarding completed records to a common facility.

The records management program shall include records administration; receipt and processing of records; storage preservation and safekeeping of records; records retrieval; and disposition of records received from other participants, contractors and subcontractors. Written procedures shall implement the established requirements, including control of the distribution and classifying the records as post closure, lifetime, or nonpermanent; and the methods used for correcting or supplementing Quality Records.

Completed records shall be transferred to permanent storage in a timely manner. Interim storage pending transfer shall be in (a) one hour fire rated cabinets, (b) in dual storage or (c) in metal files protected by an automatic electronic monitored dry fire protection system in a room or building. Interim storage of QA records pending transfer to an approved facility may be downgraded to controls utilized for in-process records before completion, providing the record can be reconstructed from other files or simple inspections or tests without unreasonable costs or project delays. Record storage facilities maintained by the project offices and their participants shall be accessible by DOE and their authorized agents upon reasonable request, as allowed by THE ACT.

Geotechnical samples though considered quality records, do not require storage in accordance with the requirements of ANSI/ASME NQA-1, Supplement 17S-1, Section 4.4.1. Samples shall be afforded archival controls and protection in a building for the period during which additional examination or analysis by DOE or the NRC may be needed. Provisions in the storage system do not have to prevent or mitigate the natural time-dependent deterioration processes, inherent to the sample materials, that will destroy or substantially change sample properties so they may not lend credibility to previous test results or analysis. (Note: Samples including rock, cores, water and gas may be changed by exposure to normal ambient atmospheric conditions and would no longer be representative of the in-situ materials).

17.3 REPOSITORY RECORDS DEFINITIONS

17.3.1 Record Types

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

- a. **Documents** - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results, some of which may be one-of-a-kind.
- b. **Items** - Physical samples, magnetic media, and other materials that retain or support data, and other one-of-a-kind items that cannot be reproduced.

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

17.3.2 Quality Assurance Record Definition

A Quality Assurance Record is an individual document that has been executed, completed, and approved and that evidence of the quality and completeness of data (including raw data), items, and activities affecting quality; documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); procurement documents; other documents such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; and items such as magnetic media, physical samples (such as rock, core, and water); and other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document or item (and documentation) which will

receive no more entries, whose revisions would normally consist of a reissue of the document (or documentation) or corrections, and that is signed and dated by the originator and, as applicable, by approval personnel (an item would generally not require any additional testing or evaluation).

17.4 PARTICIPANTS RECORDS PLANS

Organizations participating in any phase of the geologic repository program shall prepare records management plans and/or procedures and shall submit these documents to the organization that approves their QA Plans. These plans and/or procedures shall:

- a. Identify the types of records to be generated, purchased, and/or maintained, including all records referenced in pertinent final reports and other documents.
- b. Identify the methods to be used to comply with all applicable records requirements including those to be used to control in-process records.
- c. Identify and define the responsibilities of pertinent organizations including the QA organization.
- d. Specify the methods for periodic purges of nonpermanent records if required.
- e. Define the scope of the QA Records Program which includes such items as geotechnical samples and data; results of reviews; inspection results, test results; audits and surveillance reports material analyses, results of monitoring and overviews of work performance; qualification of personnel procedures and equipment; drawings; specifications procurement documents; calibrations procedures on reports design review reports; peer review reports; readiness review reports; nonconformance reports; corrective action reports; stop work action and related correspondence.

17.4.1 Record Indexing

Plans and/or procedures governing records administration shall require that quality assurance records be indexed with sufficient information to permit correlation between the record and the item/activity to which it applies. The index shall be established prior to receipt of records, and shall indicate retention time if applicable and record location within the records system.

17.4.2 Records Receipt Control

The requirements regarding receipt of records shall define conditions for acceptance of records from internal organizations and/or other contractors and subcontractors. All such records shall be legible, complete, and identifiable to the item or activity involved. The records receipt requirements shall specify prerequisites to be met for submittals, and that responsibility be assigned for implementing a system for controlling records receipt. The receipt control system should permit the statusing of records during the receiving process.

The requirements regarding record retrieval shall stipulate that the records storage system permit an accurate retrieval of information without undue delay. Those records maintained by an outside organization shall be required to be accessible to the project office or its designated contractor.

The requirements regarding records disposition shall establish control of the transfer of records from others to the project office or its designated contractor. Upon final transfer, records shall be inventoried against transmittal documents and processed in accordance with written procedures. Nonpermanent records shall be retained for the specified retention period and subsequently are no longer required to be maintained as records. A process shall be established for identification and disposal of outdated records where feasible and desirable.

17.5 PROJECT OFFICE IMPLEMENTATION

The project offices QA organizations shall monitor effectiveness of the records management program controls by surveillance and audit.

17.6 HQ-OGR IMPLEMENTATION

17.6.1 HQ-OGR Records

HQ-OGR will make provision for QA records generated by OGR to be processed in accordance with procedure QIP 17.0, to the OGR Licensing Support System (LSS).

17.6.2 HQ-OGR Record Storage

Since the OGR Licensing Support System (LSS) is designed to capture, retain and control a set of records that is both more comprehensive than and inclusive of the set of records required in this QA Plan, the Office of Geologic Repositories will not establish a separate quality records system. Instead, the LSS will be used as the repository for and custodian of all OGR Quality records. Accordingly, the LSS is required to be operated in a manner that satisfies the requirements for records management as specified in this QA Plan, as a minimum.

17.6.3 HQ-OGR Overview

HQ-OGR will evaluate the effectiveness of the project office records program controls by overview, surveillances and participating in project office audits of their participants.

18.0 AUDIT & SURVEILLANCE

18.1 HQ-OGR & PROJECT OFFICES

HQ-OGR, Project Offices and project participants shall establish and maintain a formal internal Quality Assurance Audit program.

Audits performed by the Project Offices shall include participation by appropriate technical advisors, who will verify adequacy of technical processes employed to assure the validity and correctness of technical work.

Annual Project Office audits of project activities shall include:

- a. Activities within the scope of this Quality Assurance program performed by the Project Office
- b. Implementation of the Project Quality Assurance program as established if managed by participants, and
- c. Selected activities throughout the project, with emphasis on performance of major contractors in their implementation of the Project Quality Assurance program and on the effectiveness of contractor audit programs.

In addition, project office auditors shall accompany audit teams of major contractors on selected audits to observe audit performance and evaluate effectiveness of contractor audit processes.

18.1.1 Participants Subcontractors

Participants who award subcontracts for project work shall be required to conduct external audits of the Quality programs established by the subtier contractors for whom they are responsible.

18.2 AUDIT PROGRAM CONTENT

Quality Assurance audits within the project field offices shall address the following questions:

- a. Is the audited participant implementing the approved QA program?
- b. Are the controls and/or control systems defined in the approved QA program working effectively?
- c. Does the record provide convincing objective evidence that

the controls and/or control systems have been, and are being rigorously applied?

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

18.3 AUDIT SCHEDULING

18.3.1 Project Participants

Project participants who conduct a Quality Assurance audit program shall develop, maintain and implement an approved audit schedule.

18.3.2 Schedule Basis

Audit schedules are based on planned and ongoing Project work and the safety importance of the activities being performed. Schedules shall provide for:

- a. Verification early in the life of a discrete task or work phase that approved controls are in place and are being applied, and
- b. Verification at appropriate later points in the life of the task or work phase that comprehensive credible evidence exists to demonstrate control effectiveness, and
- c. Judicious use of technical participants on audit teams to verify the appropriateness and adequacy of technical approaches being employed on samples of activities being performed in their areas of expertise.

Audits of QL-1 and QL-2 work or activities are performed at least once annually or once within the duration of the activity if shorter.

18.3.3 Scheduling Factors

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

18.3.4 Special Audits

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

18.3.5 Audit Schedule Submittals

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

18.4 AUDITOR QUALIFICATION

18.4.1 Lead Auditor Use

The use of a certified lead auditor as team leader for every QA audit is a formal program requirement. Lead auditor qualifications shall comply with the requirements of ANSI/ASME NQA-1-1986, Supplement 2S-3 and Appendix 2A-3 as specified in Section 3.

18.4.2 Lead Auditor Responsibilities

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

18.4.3 Technical Participation

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

18.5 AUDIT PREPARATION

18.5.1 Background Evaluation

Preparation for individual audits shall include study of audited 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, if any, and review of the current status of the work.

18.6 AUDIT PERFORMANCE

18.6.1 Conduct of Audit

Audits shall be performed to check lists or procedures prepared or identified during audit preparation and shall include compliance and product oriented auditing as well as Effectiveness Audits. 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.

18.6.2 Audit Documentation

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

18.7 AUDIT FINDINGS

An Audit Finding results from a review of objective evidence associated with an activity/product such as:

- o Drawings
- o Documents
- o Calculations
- o Circumstances
- o Facts
- o Conditions

Evaluation results must establish the existence of a significant condition adverse to quality as defined in ANSI/ASME NQA-1 Supplement S-1, or a failure of a control system to achieve the intended purpose, which is a violation of an established policy/procedure/instruction requirement that would reasonably be expected to result in a reduced quality of the specified end product.

An Audit Finding may summarize numerous small anomalies of the same or similar type in the same or different areas which collectively create a significant condition adverse to quality.

Audit Findings require a response from the audited organization and shall include: Identification of the root cause, corrective action to be taken, action to prevent recurrence and the impact on completed work.

18.8 AUDIT CONCERNS

An audit concern results from a review of objective evidence associated with an activity/product such as:

- o Drawings
- o Documents
- o Calculations
- o Facts
- o Circumstances
- o Conditions

An audit concern shall represent a technical or programmatic noncompliance, related to an established policy/procedure/instruction requirement, that would not reasonably be expected to result in a reduced quality of the specified end product.

If specific corrective action is required for an audit concern, it shall be documented in the response to the concern; if no response is required, the audit concern only requires inclusion in the audit report.

Typical audit concern examples are:

- Initials used rather than a full signature.
- Missing entry on a training record where training can be verified in another way.
- Response overdue relative to a procedurally specified time.
- Placing a "copy" of a document into the project file rather than the "original" as required by a procedure (Procedure should probably be evaluated for change as being obsolete).
- Omitting verification initials on grammatical RCR comments, etc.

18.9 AUDIT OBSERVATIONS

An audit observation is a written expression of an auditor's opinion regarding a perceived quality-affecting condition relating to a control system which might be improved.

An audit observation may, for example, reflect the fact that only a limited investigation of a particular situation was conducted, the results of which would not substantiate the preparation of either an audit finding or an audit concern.

An audit observation need not be responded to by the audited organization.

18.10 AUDIT REPORTS

18.10.1 Audit Reporting

Audit results shall be reported to the audited activity, upper management of the audited organization(s), and upper management of the auditing organization. Copies of audit reports shall be forwarded to higher level organizations in accordance with distribution instructions issued by HQ-OGR or project office.

18.10.2 Effective Element Reporting

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

18.10.3 Audit Results Responsibilities

The Lead Auditor is responsible for evaluation of the audit results in conjunction with the appropriate audit team members and audited organization personnel to determine that the proper classification of each of the results, (Finding, Observation, Concerns), has been made and that they properly relate to the program element being audited.

18.11 EXEMPTIONS FROM INTERNAL AUDIT REQUIREMENTS**18.11.1 Policy**

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

Typical situations justifying this approach include the following:

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

18.12 SURVEILLANCE - GENERAL**18.12.1 Surveillance Plans**

Project participants who are required to conduct audit programs shall also develop and implement an approved surveillance plan, which shall be updated and reissued at periodic intervals.

18.12.2 Surveillance Results

Surveillance is documented observation and/or examination of work that is in-progress, and surveillance results constitute a part of the formal project record. Surveillance shall include one or more of the following:

- a. Actual observation of the physical performance of work,
- b. Observation of the work place for presence of suitable conditions and adequate housekeeping and safety measures,

- c. Observation of related access control, fire prevention provisions, etc.,
- d. Review or spot checks of documents in preparation,
- e. Review or spot checks of procedures or instructions governing the work,
- f. Evaluation or verification of the presence and effectiveness of applicable controls, and
- g. Discussion with personnel performing or supervising the work.

18.13 QUALIFICATION FOR SURVEILLANCE

Surveillance of the HQ-OGR and projects shall be 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 should bear a clear relationship to the field under surveillance. QA personnel performing surveillance of controls applied to technical activities are not required to be qualified in the technical discipline(s) involved.

18.14 HQ-OGR AND PROJECT OFFICES AND PARTICIPANTS

QA surveillances performed shall be by approved Procedure. Technical personnel shall participate in the planning of, and in surveillance activities as appropriate within their areas of expertise.

18.15 AUDIT AND SURVEILLANCE FOLLOW-UP ACTIVITIES

18.15.1 By Audited or Surveilled Activity

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

18.15.2 By Auditing or Surveilling Organization

The auditing or surveilling organization shall:

- a. Evaluate responses to significant deficiencies identified during audit or surveillance for evidence that the reported cause appears capable of having produced the observed condition(s) and that the

proposed course of corrective action addresses the alleged cause in such a way as to have a high likelihood of long-term prevention of recurrence.

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

18.15.3 Participants Responsibility

Project participants shall maintain tracking and trending systems that will provide visibility of significant problems so that any recurrence can be immediately recognized. Project offices trending of audit findings, concerns and surveillances results shall be performed in accordance with approved procedures.

18.16 HQ-OGR AUDIT PROGRAM

HQ-OGR will implement the requirements of this criteria in accordance with procedures QIP 18.0, "External Audits"; QIP 18.1, "HQ Participation in Project Audits of Contractors"; QIP 18.2, "HQ Review of Project Submitted Audit Reports"; QIP 18.3, "Auditor Training, Qualification, and Certification" and QIP 18.4, "Internal Audits".

SECTION 3

REQUIREMENTS SECTION

The purpose of this section is to list in a tabular format the principal QA requirements for the HQ-OGR and project offices for the mined geologic repository program.

The basis for the tabulation are 1) the requirements of 10 CFR 60, Subpart G which specifies compliance with 10 CFR Part 50, Appendix B; 2) implementation of an acceptable QA program to ANSI/ASME NQA-1 as required by DOE Order 5700.6; and 3) compliance with the NRC Review Plan for High-Level Waste Repositories. Compliance with all three is mandatory for QL-1. For QL-2 only compliance with ANSI/ASME NQA-1 is mandated, unless items or activities are planned for upgrading to QL-1 or further consideration is needed to satisfy subsequent licensing issues.

The tabular format and order has been established to make direct comparisons between ANSI/ASME NQA-1 and the NRC Review Plan more useable.

The user of this document should evaluate the program description in Section 2 to assure that additional HQ-OGR programmatic requirements and constraints specified in the QAMPR beyond the listings does not exist. Section 2 also describes the roles of HQ-OGR, the project offices, and project participants in performing work on the repository programs and other requirements documents such as DOE Orders 5000.3 and 4700.1.

For convenience, the sections have been numbered in a manner to make evaluations easier (i.e., Program Description, Section 2, page 2-2-1 "Quality Assurance Program" implements the requirements of Requirements Section 3, page 3-2-1, "Quality Assurance Program").

10 CFR 50, Appendix B	ANSI/ASME NQA-1 - 1986 Edition	NRC Review Plan
<p>1.0 Organization</p> <p>1.1 The applicant shall be responsible for the establishment and execution of the quality assurance program.</p> <p>1.2 The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility therefor.</p>	<p>2.2 Delegation of Work</p> <p>The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefor.</p> <p>3.1 Responsibility</p> <p>Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.</p>	<p>1.1 The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.</p> <p>Clarification: Responsibility for overall QA program policy and direction is exercised by DOE Headquarters and the Office of Geologic Repositories. Within the DOE Field Offices, Project Management is exercised by technical staff monitoring (surveillance) and review. Surveillance includes evaluation of participants technical performance and of the effectiveness of controls under which the work is performed. The project offices technical staff and/or support contractors are normally not involved in direct project work, but exercise technically oriented management functions with participant line organizations performing quality affecting activities. Thus verification of proper performance of work is not limited to the HQ-OGR and Project Office QA organizations, as the technical staffs also perform verification of technical adequacy in their technical management role.</p> <p>1.2 DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</p> <p>1.3 DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.</p>

10 CFR 50, Appendix B	ANSI/ASME NQA-1 - 1986 Edition	NRC Review Plan
<p>1.3 The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing.</p>	<p>1. ORGANIZATION</p> <p>The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.</p> <p>3.1 Responsibility</p> <p>Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.</p>	<p>1.4 DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.</p> <p>1.5 Qualified individual(s) or organization element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.</p> <p>1.6 Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</p> <p>1.7 Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.</p> <p>1.9 DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.</p> <p>1.10 DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:</p> <ul style="list-style-type: none"> a. Is at the same or higher organizational level as the highest line manager directly responsible for performing activities affecting quality (such as design engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

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		<p>b. Has effective communication channels with other senior management positions.</p> <p>c. Has responsibility for approval of QA manual(s), changes thereto, and interpretations thereof.</p> <p>d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.</p> <p>1.15 The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.</p>
<p>1.4 These activities include both the performing functions of attaining quality objectives and the quality assurance functions.</p>	<p>2.1 Purpose</p> <p>The organizational structure and the responsibility assignments shall be such that:</p> <p>(a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and</p> <p>(b) quality achievement is verified by persons or organizations not directly responsible for performing the work.</p>	<p>1.8 The QA organization is involved in the aspects of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.</p>
<p>1.5 The quality assurance functions are those of (a) assuring that an appropriate Quality Assurance program is established and effectively executed and (b) verifying such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed.</p>		<p>1.11 Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for: design, item 3.7; inspections, item 10.2; and test data evaluation, item 11.3 are outlined in these sections.</p>

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<p>1.6 The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.</p> <p>1.7 Such persons and organizations performing quality assurance functions shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.</p>	<p>Persons or organizations responsible for assuring that an appropriate quality assurance program is established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.</p> <p>2.3 Nonconforming Items</p> <p>Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing.</p> <p>Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.</p>	<p>1.12 Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:</p> <ul style="list-style-type: none"> a. Identify quality problems. b. Initiate, recommend, or provide solutions through designated channels. c. Verify implementation of solutions. d. Stop unsatisfactory work. <p>The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.</p> <p>1.13 Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.</p> <p>1.14 Policies regarding the implementation of the QA program are documented and made mandatory.</p>

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<p>1.8 Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom.</p> <p>1.9 Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function.</p>	<p>3 MULTIPLE ORGANIZATIONS</p> <p>3.1 Responsibility</p> <p>Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.</p> <p>3.2 Interface Control</p> <p>3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.</p> <p>3.2.2 Interface responsibilities shall be defined and documented.</p> <p>Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.</p>	<p>1.7 Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.</p> <p>1.9 DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.</p> <p>1.12 Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:</p> <ul style="list-style-type: none"> a. Identify quality problems. b. Initiate, recommend, or provide solutions through designated channels. c. Verify implementation of solutions. d. Stop unsatisfactory work. <p>The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.</p>

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<p>2.0 <u>Quality Assurance Program</u></p> <p>2.1 The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a Quality Assurance program which complies with the requirements of this appendix.</p> <p>2.2 This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions.</p> <p>2.3 The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations.</p>	<p>A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof.</p> <p>The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.</p> <p>The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality.</p>	<p>2.5 The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific terms and activities. This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR Part 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.</p> <p>2.6 Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met.</p> <p>2.3 Provisions are established to assure that technical and quality assurance procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official.</p> <p>2.4 The QA organization reviews and documents concurrence with the quality-related^a procedures relative to QA requirements.</p> <p>2.1 The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR Part 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.</p>

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<p>2.4 The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.</p> <p>2.5 Activities affecting quality shall be accomplished under suitably controlled conditions.</p> <p>2.6 Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.</p> <p>2.7 The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.</p> <p>2.8 The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.</p>	<p>The program shall provide control over activities affecting quality to an extent consistent with their importance.</p> <p>The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.</p> <p>The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.</p> <p>The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.</p>	<p>2.2 The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."</p> <p>2.8 Indoctrination, training, and qualification programs are established such that:</p> <ul style="list-style-type: none"> a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures. b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed. c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

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		<p>d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.</p> <p>e. Qualified personnel are certified in accordance with applicable codes and standards.</p>

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	<p>1 GENERAL</p> <p>This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination.</p> <p>2 CERTIFICATION</p> <p>2.1 Qualification Requirements</p> <p>The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities.</p> <p>When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Standard may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.</p> <p>2.2 Personnel Selection</p> <p>Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.</p> <p>2.3 Indoctrination</p> <p>Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed.</p>	

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	<p>2.4 Training</p> <p>The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests.</p> <p>2.5 Determination of Initial Capability</p> <p>The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration.</p> <p>2.6 Evaluation of Performance</p> <p>The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of 2.5 above. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of one year shall be reevaluated by a redetermination of required capability in accordance with the requirements of 2.5 above.</p>	

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	<p>2.7 Certificate of Qualification</p> <p>The qualification of personnel shall be certified in writing in an appropriate form, including the following information:</p> <ul style="list-style-type: none"> (a) employer's name; (b) identification of person being certified; (c) activities certified to perform; (d) basis used for certification, which includes such factors as: <ul style="list-style-type: none"> (1) education, experience, <u>indoctrination</u>, and training (2) test results, where applicable (3) results of capability demonstration (e) results of periodic evaluation; (f) results of physical examinations, when required; (g) signature of employer's designated representative who is responsible for such certification; (h) date of certification and date of certification expiration. <p>2.8 Physical</p> <p>The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.</p> <p>3 RECORDS</p> <p>3.1 Record Files</p> <p>Records of personnel qualification shall be established and maintained by the employer. <u>These records shall include the information required by 2.7 above.</u></p>	

10 CFR 50, Appendix B	ANSI/ASME NQA-1 - 1986 Edition	NRC Review Plan
	<p>1 GENERAL</p> <p>This Supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak testing (LT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.</p> <p>2 CERTIFICATION</p> <p>2.1 Applicable Documents</p> <p>The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement.</p> <p>2.2 Program</p> <p>The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.</p> <p>2.3 Records</p> <p>Records of personnel qualification shall be established and maintained by the employer.</p>	

10 CFR 50, Appendix B	ANSI/ASME NQA-1 - 1986 Edition	NRC Review Plan
	<p>1 GENERAL</p> <p>This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a <i>Lead Auditor</i>, who organizes and directs audits, reports audit findings, and evaluates corrective action. This supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as <i>Auditors</i>, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training. It supplements the requirements of Basic Requirements 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.</p> <p>2 QUALIFICATION OF AUDITORS</p> <p>2.1 Responsibility of Auditing Organization</p> <p>The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below:</p> <p>(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results;</p> <p>(b) training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.</p> <p>(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.</p>	

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	<p>3 QUALIFICATION OF LEAD AUDITORS</p> <p>An individual shall meet the requirements of 3.1 through 3.4 below prior to being designated a Lead Auditor.</p> <p>3.1 Communication Skills</p> <p>The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.</p> <p>3.2 Training</p> <p>Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.</p> <p>3.2.1 Knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.</p> <p>3.2.2 General structure of quality assurance programs as a whole and applicable elements as defined in this Standard.</p> <p>3.2.3 Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.</p> <p>3.2.4 Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.</p> <p>3.2.5 On-the-job training to include applicable elements of the audit program.</p>	

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	<p>3.3 Audit Participation</p> <p>The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.</p> <p>3.4 Examination</p> <p>The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in 3.2 above. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement.</p>	
	<p>4 MAINTENANCE OF QUALIFICATION</p> <p>4.1 Maintenance of Proficiency</p> <p>Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s). Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.</p> <p>4.2 Requalification</p> <p>Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of 3.2 above, reexamination in accordance with 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit.</p>	

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	<p>5 ADMINISTRATION</p> <p>5.1 Organizational Responsibility</p> <p>Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.</p> <p>5.2 Qualification Examination</p> <p>The development and administration of the examination for a Lead Auditor required by 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to this Standard. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of Section 6 below.</p>	

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	<p>6 RECORDS</p> <p>6.1 General</p> <p>Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer.</p> <p>6.2 Certification of Qualification</p> <p>Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following:</p> <ul style="list-style-type: none"> (a) employer's name; (b) Lead Auditor's name; (c) date of certification or recertification; (d) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.); (e) signature of employer's designated representative who is responsible for such certification. <p>6.3 Updating of Lead Auditors' Records</p> <p>Records for each Lead Auditor shall be maintained and updated annually.</p> <p>1 GENERAL</p> <p>This Supplement provides amplified requirements for the indoctrination and training of personnel performing or managing activities affecting quality. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that basic requirement when and to the extent specified by the organization invoking this Standard.</p>	

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	<p>2 APPLICABILITY</p> <p>This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained shall be identified. The extent of indoctrination and training shall be commensurate with the following:</p> <ul style="list-style-type: none"> (a) the scope, complexity, and nature of the activity; and (b) the education, experience, and proficiency of the person. <p>Activities affecting quality include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.</p> <p>3 INDOCTRINATION</p> <p>Personnel shall be indoctrinated in the following subjects as they relate to a particular function:</p> <ul style="list-style-type: none"> (a) general criteria, including applicable codes, standards, and company procedures; (b) applicable quality assurance program elements; and (c) job responsibilities and authority. <p>4 TRAINING</p> <p>Training shall be provided, if needed, to:</p> <ul style="list-style-type: none"> (a) achieve initial proficiency; (b) maintain proficiency; and (c) adapt to changes in technology, methods, or job responsibilities. <p>5 RECORDS</p> <p>Records of the implementation of indoctrination and training may take the form of:</p> <ul style="list-style-type: none"> (a) attendance sheets; (b) training logs; or (c) personnel training records. 	

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<p>2.9 The applicant shall regularly review the status and adequacy of the quality assurance program.</p> <p>2.10 Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.</p>	<p>Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.</p>	<p>2.7 A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:</p> <ul style="list-style-type: none"> a. Frequent contact with program status through reports, meetings, and/or audits. b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.
	<p>1 GENERAL</p> <p>This requirement provides the education and experience for the qualification of Lead Auditors.</p> <p>2 EDUCATION AND EXPERIENCE</p> <p>The prospective Lead Auditor shall have verifiable evidence that a minimum of ten (10) credits under the following score system have been accumulated.</p> <p>2.1 Education (4 Credits Maximum)</p> <p>Associate degree from an accredited institution: score one (1) credit, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) credits; or</p> <p>A bachelor's degree from an accredited institution: score two (2) credits, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) credits; in addition, score one (1) credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.</p>	

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	<p>2.2 Experience (9 Credits Maximum)</p> <p>Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) credit for each full year with a maximum of five (5) credits for this aspect of experience.</p> <p>If two (2) years of this experience have been in the nuclear field, score one (1) additional credit; or</p> <p>If two (2) years of this experience have been in quality assurance, score two (2) additional credits; or</p> <p>If two (2) years of this experience have been in auditing, score three (3) additional credits; or</p> <p>If two (2) years of this experience have been in nuclear quality assurance, score three (3) additional credits; or</p> <p>If two (2) years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.</p> <p>2.3 Other Credentials of Professional Competence (2 Credits Maximum)</p> <p>For certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency or National Professional or Technical Society: score two (2) credits.</p> <p>2.4 Rights of Management (2 Credits Maximum)</p> <p>The Lead Auditor's employer may grant up to two (2) credits for other performance factors applicable to auditing which may not be explicitly called out in the Appendix. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.</p>	

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<p>3.0 <u>Design Control</u></p> <p>3.1 Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in paragraph 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions.</p>	<p>3 DESIGN CONTROL</p> <p>The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents.</p> <p>2 DESIGN INPUT</p> <p>Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.</p> <p>3 DESIGN PROCESS</p> <p>The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. <u>Design documents shall be adequate to support facility design, construction, and operation.</u></p> <p>Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall:</p> <p>(a) be relatable to the design input by documentation in sufficient detail to permit design verification; and</p>	<p>3.1 The definitions of <u>design</u>, <u>design information</u>, and <u>design activities</u> used in the design control program are as defined in this section. The term <u>design</u> 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). <u>Design information</u> and <u>design activities</u> refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954.</p> <p>3.2 The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities as described in section 3.1. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.</p>

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	<p>3 DESIGN PROCESS (cont.)</p> <p>(b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.</p> <p>3.1 Design Analyses</p> <p>Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.</p> <p>(a) Computer programs may be utilized for design analysis without individual verification of the program for each application provided:</p> <ul style="list-style-type: none"> (1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and (2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application. 	

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	<p>3 DESIGN PROCESS (cont.)</p> <p>Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.</p> <p>(b) Documentation of design analyses shall include (1) through (6) below:</p> <p>(1) definition of the objective of the analyses;</p> <p>(2) definition of design inputs and their sources;</p> <p>(3) results of literature searches or other applicable background data;</p> <p>(4) identification of assumptions and indication of those that must be verified as the design proceeds;</p> <p>(5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem;</p> <p>(6) review and approval.</p> <p>4 DESIGN VERIFICATION</p> <p>Verification shall be formed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.</p>	

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	<p>4.1 Extent of Design Verification</p> <p>The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.</p> <p>Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.</p> <p>4.2 Methods</p> <p>Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.</p> <p>4.2.1 Design Reviews. These are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable, (a) through (f) below shall be addressed.</p> <p>(a) Were the design inputs correctly selected?</p> <p>(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed?</p>	

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	<p>4.2 Methods (cont.)</p> <p>(c) Was an appropriate design method used?</p> <p>(d) Were the design inputs correctly incorporated into the design?</p> <p>(e) Is the design output reasonable compared to design inputs?</p> <p>(f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?</p> <p>4.2.2 Alternate Calculations. These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.</p>	
	<p>7 DOCUMENTATION AND RECORDS</p> <p>Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Standard, shall be collected, stored, and maintained in accordance with documented procedures.</p> <p>The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.</p>	

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<p>3.2 These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled.</p> <p>3.3 Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components.</p> <p>3.4 Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations.</p> <p>3.5 These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.</p>	<p>Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.</p> <p>Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.</p> <p>Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled.</p> <p>Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application.</p> <p>6 INTERFACE CONTROL</p> <p>Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall 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.</p>	<p>3.3 Organizational responsibilities are described for preparing, reviewing, approving, verifying and validating design and design information documents.</p> <p>3.6 Procedures require that design drawings specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.</p> <p>Clarification: Participants design control procedures require that design drawings, specifications, criteria and analysis be reviewed by their QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements (HQ-OGR and Project Offices do not perform design or approve design documents).</p> <p>3.5 Interface controls among organizations or groups involved in design development and other design activities are described.</p>

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<p>3.6 The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.</p>	<p>Design information transmitted across interfaces shall be documented and controlled. <u>Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval.</u> Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document. Design interfaces shall be identified and controlled.</p> <p>4 DESIGN VERIFICATION</p> <p>Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated.</p> <p>Design adequacy shall be verified by persons other than those who designed the item.</p>	<p>3.4 Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.</p> <p>3.8 For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.</p>

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<p>3.7 The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization.</p> <p>3.8 Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse design conditions.</p>	<p>Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. cursory supervisory reviews do not satisfy the intent of this Standard.</p> <p>4.2.3 Qualification Tests. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met.</p>	<p>3.7 Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design, (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification, provided:</p> <ul style="list-style-type: none"> a. The supervisor is the only technically qualified individual. b. The need is individually documented and approved in advance with concurrence of the Quality Assurance manager. <p>It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.</p> <p>3.9 The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.</p>

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<p>3.9 Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in-service inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.</p>	<p>If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.</p> <p>6 DESIGN VERIFICATION</p> <p>Design verification for some designs or specific design features may be achieved by suitable qualification testing of a prototype or initial production unit. Qualification testing may be used in combination with other verification methods. For example, it may be most effective to verify that an instrumentation cabinet is designed to withstand the maximum earthquake-caused vibratory motions by actually subjecting the cabinet and its associated components to shaker tests which correspond to these vibratory motions. The shaker tests will not, however, verify that the circuitry is designed correctly or that the component in the cabinet will perform its intended function. Other tests or verification means are required to confirm that remaining design functions are adequately performed by the instrumentation and that those components perform the intended functions for the varying conditions to which they are subjected.</p>	

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<p>3.10 Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.</p>	<p>5 CHANGE CONTROL</p> <p>Changes to final designs, field changes, <u>modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair</u> shall be justified and subject to design control measures commensurate with those applied to the original design. <u>These measures shall include assurance that the design analyzes for the structure, system, or component are still valid.</u> Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization which could be the Owner's engineering organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.</p> <p>Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.</p> <p>Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.</p>	<p>3.10 Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.</p>

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<p>4.0 Procurement Document Control</p> <p>4.1 Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors.</p> <p>4.2 To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.</p>	<p>4 PROCUREMENT DOCUMENT CONTROL</p> <p>Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.</p> <p>1 GENERAL</p> <p>This Supplement provides amplified requirements for procurement document control. It supplements the requirements of Basic Requirement 4 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.</p> <p>2 CONTENT OF THE PROCUREMENT DOCUMENTS</p> <p>Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.</p> <p>2.1 Scope of Work</p> <p>A statement of the scope of the work to be performed by the Supplier shall be in the procurement documents.</p> <p>2.2 Technical Requirements</p> <p>Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the Purchaser for monitoring and evaluating the Supplier's performance.</p>	<p>4.2 Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.</p> <p>4.1 Procedures are established for the review of procurement documents by QA personnel to determine the applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants to provide an acceptable Quality Assurance program.</p>

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	<p>2.3 Quality Assurance Program Requirements</p> <p>Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard. The extent of the program required shall depend upon the type and use of the Item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtler procurement documents.</p> <p>2.4 Right of Access</p> <p>At each tier of a procurement, the procurement documents shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser.</p> <p>2.5 Documentation Requirements</p> <p>The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.</p> <p>2.6 Nonconformances</p> <p>The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.</p> <p>2.7 Spare and Replacement Parts</p> <p>The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies.</p>	

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	<p>3 PROCUREMENT DOCUMENT REVIEW</p> <p>A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.</p> <p>Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award.</p> <p>Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations:</p> <ul style="list-style-type: none"> (a) appropriate requirements specified in Section 2 of this Supplement; (b) determination of any additional or modified design criteria; (c) analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished. <p>Reviews required by this Section shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.</p> <p>4 PROCUREMENT DOCUMENT CHANGES</p> <p>Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.</p>	

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<p>Instructions, Procedures, and Drawings</p> <p>5.1 Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.</p> <p>5.2 Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.</p>	<p>5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS</p> <p>Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.</p>	<p>5.1 Organizational responsibilities are described for assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described in Section 3.</p> <p>5.2 Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality-related activities have been satisfactorily accomplished.</p>

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<p>6.0 DOCUMENT CONTROL</p> <p>6.1 Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality</p>	<p>6 DOCUMENT CONTROL</p> <p>The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.</p> <p>1 GENERAL</p> <p>This Supplement provides amplified requirements for a document control system. It supplements the requirements of Basic Requirement 6 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.</p> <p>The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings.</p> <p>The term <u>document control</u> used throughout this Supplement is defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.</p> <p>2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE</p> <p>The control system shall be documented and shall provide for (1) through (c) below:</p> <p>(a) identification of documents to be controlled and their specified distribution</p> <p>(b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents</p> <p>(c) review of documents for adequacy, completeness, and correctness prior to approval and issuance</p>	<p>6.1 The scope of the document control program is described, and the types of controlled documents are identified.</p> <p>6.2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these document with respect to quality-related aspects.</p> <p>6.5 A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.</p> <p>6.6 When documents which require verification are released prior to verification, they are so identified and controlled.</p>

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<p>6.2 These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed.</p> <p>6.3 Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.</p>	<p>3 DOCUMENT CHANGES</p> <p>3.1 Major Changes</p> <p>Changes to documents, other than those defined as minor changes in 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.</p> <p>3.2 Minor Changes</p> <p>Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.</p>	<p>6.3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.</p> <p>6.4 Procedures are established to describe to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.</p>

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<p><u>Control of Purchased Material, Equipment, and Services</u></p> <p>7.1 Measures shall be established to assure that purchased material, equipment, and services whether purchased directly or through contractors and subcontractors, conform to the procurement documents.</p>	<p>7 CONTROL OF PURCHASED ITEMS AND SERVICES</p> <p>The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.</p> <p>1 GENERAL</p> <p>This Supplement provides amplified requirements for control of purchased items and services. It supplements the requirements of Basic Requirement 7 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. This Supplement includes requirements for source selection, bid evaluation, Supplier performance evaluation, and verification of conformance.</p> <p>2 PROCUREMENT PLANNING</p> <p>Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities.</p> <p>Planning shall determine the following:</p> <ul style="list-style-type: none"> (a) what is to be accomplished; (b) who is to accomplish it; (c) how it is to be accomplished; (d) when it is to be accomplished. <p>Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.</p>	<p>7.1 Organizational responsibilities are described for the control of purchased material, equipment, and services.</p>

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	<p>Planning shall result in the documented identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning shall provide for the integration of (a) through (i) below:</p> <ul style="list-style-type: none"> (a) procurement document preparation, review and change control; (b) selection of procurement sources; (c) bid evaluation and award; (d) Purchaser control of Supplier performance; (e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points; (f) control of nonconformances; (g) corrective action; (h) acceptance of item or service; (i) quality assurance records. 	

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<p>7.2 These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.</p>	<p>3 SUPPLIER SELECTION</p> <p>3.1 Source Evaluation and Selection</p> <p>The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.</p> <p>Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability.</p> <p>Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more of (a) through (c) below:</p> <p>(a) evaluation of the Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The Supplier's history shall reflect current capability.</p> <p>(b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated;</p> <p>(c) Supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.</p> <p>4 BID EVALUATION</p> <p>Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:</p> <p>(a) technical considerations (b) quality assurance requirements (c) Supplier's personnel (d) Supplier's production capability (e) Supplier's past performance (f) alternates (g) exceptions</p> <p>Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation.</p>	<p>7.2 Procedures governing procurement of items or services, including appropriate QA organization participation, provide for:</p> <p>(a) evaluation and selection of suppliers; (b) verification of supplier's activities; and (c) receiving inspections.</p>

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	<p>5 SUPPLIER PERFORMANCE EVALUATION</p> <p>The Purchaser of items and services shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f) below:</p> <ul style="list-style-type: none"> (a) establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents; (b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements; (c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements; (d) identifying and processing necessary change information; (e) establishing method of document information exchange between Purchaser and Supplier; (f) establishing the extent of source surveillance and inspection activities. <p>These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for verification of quality achievement.</p> <p>5.1 Extent of Activities</p> <p>The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of Suppliers.</p> <p>5.2 Records</p> <p>Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented.</p> <p>The Purchaser shall assure that this documentation is evaluated to determine the Supplier's quality assurance program effectiveness.</p>	

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	<p>8 ACCEPTANCE OF ITEM OR SERVICE</p> <p>8.1 General</p> <p>Methods shall be established for the acceptance of an item or service being furnished by the Supplier. Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use.</p> <p>8.2 Methods of Acceptance</p> <p>Purchaser methods used to accept an item or related service from a Supplier shall be Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site, or a combination thereof.</p> <p>8.2.1 Certificate of Conformance. When a Certificate of Conformance is used, the minimum criteria of (a) through (f) below shall be met.</p> <p>(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.</p> <p>(b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.</p> <p>(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.</p> <p>(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.</p>	

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	<p>(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.</p> <p>(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.</p> <p>8.2.2 Source Verification. When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.</p> <p>8.2.3 Receiving Inspection. When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall be performed in accordance with established procedures and inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.</p> <p>8.2.4 Post-Installation Testing. When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.</p>	

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	<p>8.3 Acceptance of Services Only</p> <p>In certain cases involving procurement of services only, such as third party inspection; engineering and consulting services; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:</p> <ul style="list-style-type: none"> (a) technical verification of data produced; (b) surveillance and/or audit of the activity; (c) review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc. <p>10 COMMERCIAL GRADE ITEMS</p> <p>Where the design utilizes commercial grade items, the following requirements are an acceptable alternate to other requirements of this Supplement, except as noted in (b) below and the requirements of Supplement 45-1.</p> <ul style="list-style-type: none"> (a) The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application. (b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with paragraph 3.1 of this Supplement. (c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number). (d) After receipt of a commercial grade item, the Purchaser shall determine that: <ul style="list-style-type: none"> (1) damage was not sustained during shipment; (2) the item received was the item ordered; (3) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements; (4) documentation, as applicable to the item, was received and is acceptable. 	

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<p>7.3 Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment.</p>	<p>6 CONTROL OF SUPPLIER GENERATED DOCUMENTS</p> <p>Supplier generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to assure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.</p>	
	<p>7 CONTROL OF CHANGES IN ITEMS OR SERVICES</p> <p>The Purchaser and Supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented and are in accordance with this Standard.</p> <p>Methods shall be established for the acceptance of an item or service being furnished by the Supplier. Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use.</p>	
<p>7.4 This documentary evidence shall be retained at the nuclear powerplant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.</p>		<p>7.3 The organization providing materials, equipment, or services furnishes the following records to the purchaser:</p> <ul style="list-style-type: none"> a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met. b. Documentation identifying any procurement requirements that have not been met. c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair." <p>The procedure for review and acceptance of these documents should be described in the purchaser's QA program.</p>

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7.5 The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.	<p>Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented.</p> <p>The Purchaser shall assure that this documentation is evaluated to determine the Supplier's quality assurance program effectiveness.</p>	7.4 Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

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	<p>9 CONTROL OF SUPPLIER NONCONFORMANCES</p> <p>The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement document requirements.</p> <p>These methods shall contain provision for (a) through (3) below:</p> <p>(a) evaluation of nonconforming items;</p> <p>(b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition;</p> <p>(1) technical or material requirement is violated;</p> <p>(2) requirement in Supplier documents, which has been approved by the Purchaser, is violated;</p> <p>(3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework;</p> <p>(4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired;</p> <p>(c) Purchaser disposition of supplier recommendation;</p> <p>(d) verification of the implementation of the disposition;</p> <p>(e) maintenance of records of Supplier-submitted nonconformances.</p>	<p>7.5 In developing quality assurance requirements for data collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment.</p>

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<p>8.3 These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.</p>	<p>3 SPECIFIC REQUIREMENTS</p> <p>3.1 Identification and Traceability of Items</p> <p>When specified by codes, standards, or specifications that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records) the program shall be designed to provide such identification and traceability control.</p> <p>3.2 Limited Life Items</p> <p>Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.</p> <p>3.3 Maintaining Identification of Stored Items</p> <p>Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identifications on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing plant records.</p>	<p>8.4 Correct identification of samples is verified and documented prior to release for use or analysis.</p>

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<p>9.0 Control of Special Processes</p> <p>9.1 Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.</p>	<p>9 CONTROL OF PROCESSES</p> <p>Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.</p> <p>1 GENERAL</p> <p>This Supplement provides amplified requirements for control of processes. It supplements the requirements of Basic Requirement 9 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.</p> <p>2 PROCESS CONTROL</p> <p>Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained.</p> <p>3 SPECIAL PROCESSES</p> <p>Each special process shall be performed in accordance with appropriate instructions which include or reference procedure, personnel, and equipment qualification requirements.</p> <p>3.1 Responsibility</p> <p>It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.</p> <p>3.1.1 Qualification of personnel, procedures, and equipment shall comply with specified requirements.</p> <p>3.1.2 Conditions necessary for accomplishment of the process shall be included in procedures or instructions. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements.</p>	<p>9.1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.</p> <p>9.2 Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.</p> <p>9.3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.</p> <p>9.4 Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.</p> <p>9.5 Qualifications records of procedures, equipment, and personnel associated with special processes are established and maintained.</p>

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	<p>3.2 Acceptance Criteria</p> <p>The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions.</p> <p>3.3 Records</p> <p>Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.</p> <p>3.4 Special Requirements</p> <p>For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.</p>	

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<p>10.0 Inspection</p> <p>10.1 A program for inspection of activities affecting quality shall be established and executed by or for the organizations performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity.</p> <p>10.2 Such inspection shall be performed by individuals other than those who performed the activity being inspected.</p>	<p>10 INSPECTION</p> <p>Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.</p> <p>4 INSPECTION PLANNING</p> <p>4.1 Planning</p> <p>Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.</p> <p>4.2 Sampling</p> <p>Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.</p> <p>2.1 Reporting Independence</p> <p>Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.</p> <p>2.2 Qualification</p> <p>Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.</p> <p>Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.</p>	<p>10.1 The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.</p> <p>10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.</p>

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<p>10.3 Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to as</p> <p>10.4 If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided.</p> <p>10.5 Both inspection and process monitoring shall be provided when control is inadequate without both sure quality.</p>	<p>7.1 Planning and Performance</p> <p>Required inservice inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.</p> <p>7.2 Methods</p> <p>Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.</p> <p>5 IN-PROCESS INSPECTION</p> <p>5.1 Inspection</p> <p>Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.</p> <p>Both inspection and process monitoring shall be provided when control is inadequate without both.</p>	<p>10.3 A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.</p> <p>10.6 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.</p> <p>10.4 Inspection procedures, instructions, or check lists provide for the following:</p> <ul style="list-style-type: none"> a. Identification of characteristics and activities to be inspected. b. A description of the method of inspection. c. Identification of the individuals or groups responsible for performing the inspection operation. d. Acceptance and rejection criteria. e. Identification of required procedures, drawings, and specifications and revisions. f. Recording inspector or data recorder and the results of the inspection operation. g. Specifying necessary measuring and test equipment including accuracy requirements.

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	<p>5.2 Combined Inspection and Monitoring</p> <p>5.2.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.</p> <p>5.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.</p> <p>6 FINAL INSPECTIONS</p> <p>6.1 Resolution of Nonconformances</p> <p>Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.</p> <p>6.2 Inspection Requirements</p> <p>Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformances of the item to specified requirements. Quality records shall be examined for adequacy and completeness if not previously so examined.</p> <p>6.3 Acceptance</p> <p>The acceptance of the item shall be documented and approved by authorized personnel.</p> <p>6.4 Modifications, Repairs, or Replacements</p> <p>Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.</p>	

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<p>10.6 If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.</p>	<p>3 INSPECTION HOLD POINTS</p> <p>If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.</p> <p>B RECORDS</p> <p>Records shall, as a minimum, identify (a) through (f) below:</p> <ul style="list-style-type: none"> (a) item inspected (b) date of inspection (c) inspector (d) type of observation (e) results or acceptability (f) reference to information on action taken in connection with nonconformances 	<p>10.5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.</p>

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<p>11.0 Test Control</p> <p>11.1 A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.</p> <p>11.2 The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear powerplant or fuel reprocessing plant operation, of structures, systems, and components.</p>	<p>11. TEST CONTROL</p> <p>Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated.</p> <p>Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.</p> <p>2 TEST REQUIREMENTS</p> <p>Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents.</p>	<p>11.1 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed; and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.</p> <p>11.2 Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.</p> <p>11.3 The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.</p>

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<p>11.3 Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.</p>	<p>3 TEST PROCEDURES</p> <p>Tests procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.</p> <p>In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.</p>	<p>11.4 Test procedures or instructions provide for the following:</p> <ul style="list-style-type: none"> a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy. b. Instructions for performing the test. c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage. d. Mandatory inspection hold points (as required). e. Acceptance and rejection criteria, including required levels of precision and accuracy. f. Methods of data analysis. g. Methods of documenting or recording test data and results. H. Provisions for assuring test prerequisites have been met.
<p>11.4 Test results shall be documented and evaluated to assure that test requirements have been satisfied.</p>	<p>4 TEST RESULTS</p> <p>Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied.</p> <p>5 TEST RECORDS</p> <p>Test records shall, as a minimum, identify (a) through (g) below:</p> <ul style="list-style-type: none"> (a) item tested (b) date of test (c) tester or data recorder (d) type of observation (e) results and acceptability (f) action taken in connection with any deviations noted (g) person evaluating test results 	<p>11.5 Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.</p>

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<p>12.0 Control of Measuring and Test Equipment</p> <p>12.1 Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.</p>	<p>12 CONTROL OF MEASURING AND TEST EQUIPMENT</p> <p>Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.</p> <p>2 SELECTION</p> <p>Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.</p> <p>3 CALIBRATION AND CONTROL</p> <p>3.1 Calibration</p> <p>Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.</p> <p>3.2 Control</p> <p>The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspected.</p>	<p>12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.</p> <p>12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.</p> <p>12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring: The review and documented concurrence of these functions is identified.</p> <p>12.4 Measuring and test equipment is labeled, tagged or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.</p> <p>12.5 Measuring and test equipment is calibrated as specified intervals based upon required accuracy, precision, purpose, degree of usage, stability, characteristics, and other conditions which could affect the measurement.</p> <p>12.6 Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.</p> <p>12.7 When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.</p>

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	<p>3.3 Commercial Devices</p> <p>Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.</p> <p>4 HANDLING AND STORAGE</p> <p>Measuring and test equipment shall be properly handled and stored to maintain accuracy.</p> <p>5 RECORDS</p> <p>Records shall be maintained and equipment shall be suitably marked to indicate calibration status.</p>	

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<p>13.0 Handling, Storage, and Shipping</p> <p>13.1 Measures shall be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration.</p>	<p>13 HANDLING, STORAGE, AND SHIPPING</p> <p>Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.</p> <p>2 INSTRUCTION</p> <p>Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.</p> <p>3 REQUIREMENTS</p> <p>3.1 General</p> <p>When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.</p> <p>3.2 Procedures</p> <p>When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.</p> <p>3.3 Tools and Equipment</p> <p>Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.</p>	<p>13.1 Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.</p>

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<p>13.2 When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.</p>	<p>3.4 Operators</p> <p>Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment.</p> <p>4 MARKING</p> <p>Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.</p>	<p>13.2 Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.</p>

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<p>14.0 Inspection, Test, and Operating Status</p> <p>14.1 Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear powerplant or fuel reprocessing plant.</p> <p>14.2 These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests.</p> <p>14.3 Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear powerplant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.</p>	<p>14 INSPECTION, TEST, AND OPERATING STATUS</p> <p>The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.</p>	<p>14.1 Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.</p> <p>Clarification: Procedures will be established to assure that inspection, test and operating status is clearly indicated by means of marking, tagging, boundary markers, etc., as appropriate to the nature of the equipment or natural region affected and of the inspection, test or operation involved.</p>

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<p>15.0 Nonconforming Materials, Parts, or Components</p> <p>15.1 Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.</p> <p>15.2 These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.</p>	<p>15 CONTROL OF NONCONFORMING ITEMS</p> <p>Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.</p> <p>2 IDENTIFICATION</p> <p>(a) Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item. The identification shall be legible and easily recognizable.</p> <p>(b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.</p> <p>3 SEGREGATION</p> <p>(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.</p> <p>(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.</p>	<p>15.2 QA responsibilities related to nonconformance control are described.</p> <p>5.1 Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. The procedures identify individuals authorized to dispose of and close out nonconformances.</p>

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<p>15.3 Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.</p>	<p>4 DISPOSITION</p> <p>4.1 Control</p> <p>Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.</p> <p>4.2 Responsibility and Authority</p> <p>The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.</p> <p>4.3 Personnel</p> <p>Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.</p> <p>4.4 Disposition</p> <p>The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.</p> <p>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. The as-built records, if such records are required, shall reflect the accepted deviation.</p> <p>4.5 Repaired or Reworked Items</p> <p>Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.</p>	<p>15.3 Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.</p> <p>15.4 Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.</p>

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<p>16.0 Corrective Action</p> <p>16.1 Measures shall be established to assure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.</p> <p>16.2 In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.</p> <p>16.3 The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.</p>	<p>16 CORRECTIVE ACTION</p> <p>Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.</p>	<p>16.1 Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.</p> <p>Clarification: Corrective action taken to prevent recurrence of nonconformances shall be documented. Nonconformances will be evaluated by trend analysis for additional corrective action as appropriate. Evaluation will involve consideration of such factors as cost of remedial action for repetitive occurrence, issuance, value of repetitions, potential impact of repeated occurrences on more significant aspects of the work, potential for repeated occurrences to produce a negative perception of overall control effectiveness and cost to isolate cause(s) and implement preventive action(s).</p> <p>16.2 Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.</p> <p>16.3 Follow up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.</p> <p>16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.</p> <p>Clarification: Significant conditions adverse to quality, the cause of the conditions, and the corrective actions taken to preclude repetition will be documented and reported to immediate management and upper levels of management for review and assessment. Conditions adverse to quality will be considered significant if they are determined to have a potential adverse impact on safety and/or waste isolation, or on the integrity of the record relative to safety or waste isolation.</p>

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<p>17.0 Quality Assurance Records</p> <p>17.1 Sufficient records shall be maintained to furnish evidence of activities affecting quality.</p> <p>17.2 The records shall include at least the following: operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.</p> <p>17.3 The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment.</p>	<p>17 QUALITY ASSURANCE RECORDS</p> <p>Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.</p> <p>2.1 Records System</p> <p>A records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.</p> <p>2.2 Generation of Records</p> <p>The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the Owner. Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished.</p>	<p>17.1 The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspections; tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; design review reports; peer review reports; nonconformance reports; and corrective action reports.</p> <p>17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.</p>

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	<p>2.3 Record Validation</p> <p>Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies.</p> <p>2.4 Index</p> <p>The records shall be indexed. The indexing system(s) shall include, as a minimum, record retention times and the location of the record within the record system.</p> <p>2.5 Distribution</p> <p>The records shall be distributed, handled, and controlled in accordance with written procedures.</p> <p>2.6 Identification</p> <p>Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.</p> <p>2.7 Classification</p> <p>Records shall be classified as <i>Lifetime</i> or <i>Nonpermanent</i> by the Owner, or his agent when authorized, in accordance with the criteria given in 2.7.1 and 2.7.2 below.</p> <p>2.7.1 Lifetime Records. Lifetime records are those that meet one or more of the following criteria:</p> <ul style="list-style-type: none"> (a) those which would be of significant value in demonstrating capability for safe operation; (b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; (c) those which would be of significant value in determining the cause of an accident or malfunction of an item; (d) those which provide required baseline data for in-service inspections. 	

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	<p>Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.</p> <p>2.7.2 Nonpermanent Records. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.</p> <p>2.8 Retention of Records</p> <p>Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing.</p> <p>2.9 Corrected Information in Records</p> <p>Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.</p> <p>3 RECEIPT</p> <p>3.1 Responsibility</p> <p>The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.</p> <p>3.2 Receipt Control</p> <p>Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.</p>	

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<p>17.4 Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.</p> <p>17.5 Records shall be identifiable and retrievable.</p>	<p>As a minimum, a receipt control system shall include the following:</p> <ul style="list-style-type: none"> (a) a method for designating the required records; (b) a method for identifying records received; (c) procedures for receipt and inspection of incoming records; (d) a method for submittal of completed records to the storage facility without unnecessary delay. <p>3.3 Status</p> <p>Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.</p> <p>8 RECORDS</p> <p>Records shall, as a minimum, identify (a) through (f) below:</p> <ul style="list-style-type: none"> (a) item inspected (b) date of inspection (c) inspector (d) type of observation (e) results or acceptability (f) reference to information on action taken in connection with nonconformances <p>5 RETRIEVAL</p> <p>Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type.</p> <p>A list shall be maintained designating those personnel who shall have access to the files.</p> <p>Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner.</p>	<p>17.3 Inspection and test records contain the following where applicable:</p> <ul style="list-style-type: none"> a. A description of the type of observation. b. The date and results of the inspection or test. c. Information related to conditions adverse to quality. d. Inspector or data recorder identification. e. Evidence as to the acceptability of the results. f. Action taken to resolve any discrepancies noted.

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<p>17.6 Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.</p>	<p>4 STORAGE, PRESERVATION, AND SAFEKEEPING</p> <p>4.1 Storage</p> <p>The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.</p> <p>Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum, (a) through (g) below:</p> <ul style="list-style-type: none"> (a) a description of the storage facility; (b) the filing system to be used; (c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible; (d) a method of verifying that the records are those designated (see 3.2 above); (e) the rules governing access to and control of the files; (f) a method for maintaining control of and accountability for records removed from the storage facility; (g) a method for filing supplemental information (see 2.9 above) and disposing of superseded records. <p>4.2 Preservation</p> <p>Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records the requirements of (a) through (c) below shall apply.</p> <ul style="list-style-type: none"> (a) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure. (b) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. (c) Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. 	<p>17.4 Suitable facilities for the storage of records are described and utilized.</p>

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	<p>4.3 Safekeeping</p> <p>Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.</p> <p>Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.</p> <p>4.4 Facility</p> <p>Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:</p> <ul style="list-style-type: none"> (a) natural disasters such as winds, floods, or fires; (b) environmental conditions such as high and low temperatures and humidity; (c) infestation of insects, mold, or rodents. <p>There are two satisfactory methods of providing storage facilities, single or dual.</p> <p>4.4.1 Single Facility. Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below:</p> <ul style="list-style-type: none"> (a) reinforced concrete, concrete block, masonry, or equal construction; (b) floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included. (c) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating; (d) sealant applied over walls as a moisture or condensation barrier; (e) surface sealant on floor providing a hard wear surface to minimize concrete dusting; (f) foundation sealant and provisions for drainage; (g) forced air circulation with filter system; (h) fire protection system; (i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating. 	

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	<p>The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.</p> <p>If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.</p> <p>4.4.2 Alternate Single Facilities. The following are acceptable alternatives to the criteria of 4.4.1 above for a single facility:</p> <ul style="list-style-type: none"> (a) 2 hr fire rated vault meeting NFPA 232-1975¹; (b) 2 hr fire rated Class B file containers meeting the requirement of NFPA 232-1975¹; or (c) 2 hr fire rated file room meeting the requirements of NFPA 232-1975¹ with the following additional provisions: <ul style="list-style-type: none"> (1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station; (2) records storage in fully enclosed metal cabinets; (3) adequate access and aisle ways; (4) prohibition in the room of work not directly associated with record storage or retrieval; (5) prohibition in the room of smoking, eating, or drinking; (6) 2 hr fire rated dampers or doors in all boundary penetrations. <p>4.4.3 Dual Facilities. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either 4.4.1 or 4.4.2 above, but shall meet the other requirements of this Standard.</p>	

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	<p>6 DISPOSITION</p> <p>Records accumulated at various locations, prior to transfer, shall be made accessible to the Owner directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Standard.</p> <p>Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition.</p> <p>The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied:</p> <ul style="list-style-type: none"> (a) items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed; (b) regulatory requirements are satisfied; (c) operational status permits; (d) warranty consideration is satisfied; (e) Purchaser's requirements are satisfied. 	

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	<p>3.2 Personnel</p> <p>The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.</p> <p>3.3 Selection of Audit Team</p> <p>An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit.</p> <p>4 PERFORMANCE</p> <p>Audits shall be performed in accordance with written procedures or check lists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.</p>	

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<p>18.3 Audit results shall be documented and reviewed by management having responsibility in the area audited.</p> <p>18.4 Followup action, including reaudit of deficient areas, shall be taken where indicated.</p>	<p>5 REPORTING</p> <p>The audit report shall be signed by the audit team leader and issued and shall include the following information, as appropriate:</p> <ul style="list-style-type: none"> (a) description of the audit scope (b) identification of the auditors (c) identification of persons contacted during audit activities (d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited (e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization. <p>6 RESPONSE</p> <p>Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.</p> <p>7 FOLLOW-UP ACTION</p> <p>Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.</p> <p>8 RECORDS</p> <p>Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.</p>	<p>18.4 Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.</p> <p>18.7 The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.</p> <p>18.8 In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.</p>