QUALITY ASSURANCE PLAN

Salt Repository Project Office (SRPO)

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Salt Repository Project Rev. 0 Issued 12/04/85

TITLE

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SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
P.C. Winterhalt	11/26/85	Jerry Bruce	11/26/85

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QUALITY ASSURANCE POLICY STATEMENT

It is the policy of the Salt Repository Office to establish, maintain, and implement a Quality Assurance Program which complies with the DOE Orders and documents, Federal Regulations, Codes and Standards, and Consensus standards as identified within the QA Plan for the activities of the Salt Repository Project for the disposal of high level radioactive wastes and spent fuel in a manner that fully protects the health and safety of the public and the quality of the environment.

The QA Program shall apply to all quality-related activities as related to siting, site characterization, site selection, as well as design, construction, operation, and decommissioning of a mined geologic repository in salt. Additionally, this QA Program shall apply to all individuals and organizations which perform quality-related activities in compliance therewith. In this regard, it shall be emphasized that the implementation of Quality Assurance is an interdisciplinary function involving many organizations and is not the sole domain of a single Quality Assurance group.

The verification of quality assurance rests with the Chief, Quality Assurance who reports directly to me. The Chief, Quality Assurance has the authority and responsibility to coordinate the development and maintenance of the Quality Assurance Plan and the Quality Assurance Administrative Procedures and to verify the overall effectiveness of the QA Program. The Chief, Quality Assurance has the authority to recommend, initiate, and provide solutions to quality problems and to issue, through appropriate line management, stop work orders to cease unsatisfactory work activities. All elements of the SRPO QA Program are audited under the direction of the Chief - Quality Assurance, and the audit results and corrective actions thereto are reported to management.

The policies, requirements and responsibilities as described in the QA Program have the full endorsement and support of this Office and are mandatory for all SRPO Personnel.

11/26/85

Project Manager, SRPO — Date

TITLE GLOSSARY

SRPO MANAGER	DATE	CHIEF QUALITY ASSURANCE	DATE
	11/26/85		11/26/85

Accept (Acceptance) - The act of reviewing an activity or document and acknowledging that it may be used for the purpose intended at that time. Acceptance does not assure that future changes will not be required, and does not convey or imply approval of or assumption of responsibility for the activity or document. The originator remains fully responsible for all aspects of the activity or document, for fulfilling all specifications, and for any other obligation or liability otherwise arising under a specification, agreement, or contract.

Acceptance Criteria - Specified limits, requirements, or tolerances placed on the variation permitted in the characteristics of an item, process, or service as defined in codes, standards, drawings, specifications, procurement documents, or other requirements documents. Normally, criteria are expressed in definitive engineering terms. However, acceptance criteria may also apply to services, reports, and the like. Criteria must be definitive for decision-making purposes, but may not always be instrument or measurement related.

Activities Affecting Quality - Activities which influence or affect the achievement or verification of SRP quality objectives or requirements. These activities include, but are not limited to, the collection and analysis of data to be used for performance assessment, site selection, and site characterization for licensing and design activities. Activities related to the exploratory shaft, the waste package, the repository and to the safe and reliable operation of a high-level nuclear waste repository are also considered to be activities affecting quality.

Activity Plan - A document which provides a detailed description of the planned work, the schedule, witness or hold points for inspections, testing requirements and criteria, data requirements, review and approval requirements, and personnel responsibilities. A test plan is a specialized form of an activity plan used for test activities. An activity plan is supplemented by procedures, specific work instructions, or other documents which specify requirements or criteria.

Agreement - See Contract.

Approval - A documented act of endorsing an acceptance.

Audit (QA) - A planned and documented activity performed in accordance with written procedures or checklists to determine, by investigation and examination or evaluation of objective evidence, the adequacy of and compliance with the requirements of the QA program, established procedures, instructions, drawings, contractual requirements and other applicable documents, and the effectiveness of implementation. (An Audit is not the same as surveillance or inspection).

Audit Finding - A condition determined, as a result of an audit, to be in noncompliance with the QA Program or deficiency thereof to the QA Requirements Documents.

Auditor - An individual who performs any formal portion of an audit and who has demonstrated competence for auditor qualification in accordance with the QA Program.

Baseline - (noun) A reference point in the sequence of development at which the item or document is fully reviewed, approved for release, and change and distribution controlled as specified by approved procedures or specifications. (verb) The act of formally approving and accepting the item or document and imposing a change control system commensurate with the item or document.

Candidate Area - A geologic and hydrologic system within which a geologic repository may be located.

Certify - To determine, verify, and attest to in writing (i.e., document) the qualifications of personnel, processes, procedures, data items, or material, in accordance with stated requirements.

Certificate of Conformance - A document signed by an authorized and certified individual certifying the degree to which items or services meet specified requirements.

Certification - The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic - Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

Commercial Grade Item - An item satisfying (a), (b), or (c) below which is:

a) Not subject to design or specification requirements that are unique to nuclear or waste repository facilities;

b) Used in applications other than nuclear or waste repository facilities.

c) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

Conceptual Design - The formative stage in the design of a facility. It is prepared using operating funds for the purpose of developing and quantifying the physical construction requirements of the project, a budget quality cost estimate, and a schedule of the key design or construction activities. Conceptual design is based on user requirements established and accepted by management, and establishes the site, capacity, and functional needs of the project.

Concur - To find a document or activity in agreement with applicable requirements.

Conditions Affecting Quality - See Activities Affecting Quality and Quality-Related.

Conform - To correspond in form, manner, or character to specified standards or requirements as previously determined.

Contract - A mutually binding legal relationship obligating the seller to furnish supplies or services (including construction) and the buyer to pay for them.

Contractor - The organization legally bound by a contract.

Controlled Area - A surface location, to be marked by suitable monuments, extending horizontally no more than 10 kilometers in any direction from the outer boundary of the underground facility, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure.

Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to prevent repetition.

CRWMP - Civilian Radioactive Waste Management Program.

Data Analysis - 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.

Definitive Design (Title II) - A continuation of the development of the project based on approved preliminary design (Title I). Includes any revisions required on Title I effort; preparation of final working drawings, specifications, bidding documents, cost estimates and coordination with all parties which might affect the project; development of firm construction and procurement schedules and assistance in analyzing proposals or bids.

Design - The act of conceiving and planning the structure and parameter values of a system, device, or process, including the act of conceiving and developing design documentation and system analyses.

Design Activities - The use and integration of design information for the purpose of design development and verification. Design activities are documented as design inputs and results of verification. Design activities may include data analysis, computer runs, systems analysis (such as performance assessments), etc.

Design Bases - Information identifying specific functions to be performed by a geologic waste repository, and the specific values or ranges of values determined as references for design. These values may be: (1) constraints derived from the state of the art, generally accepted practices, engineering parameters affecting construction or operation, or requirements derived from analyses (based on calculation and/or experiments) of the effects of a postulated accident to the repository and system analyses; (2) requirements of repository operability; or (3) requirements of applicable and regulatory codes and standards.

Design Change - Any revision or alteration of the technical requirements documents which were approved and issued as design output documents.

Design Information - Data which are generated for or used for design activities. Design information includes test and experiment results, existing data, and computer codes. Data may be collected through literature searches, testing, computer runs, etc. Data acquisition includes initial data reduction and analysis.

Design Input - Those criteria, parameters, bases, or other design requirements upon which conceptual, preliminary and detailed final designs are based; e.g., site characterization study information upon which subsequent analyses or criteria are satisfied or developed, or determination of in situ permeabilities and fracture studies upon which risk assessments are based.

Design Output - Documents, such as drawings, specifications, and systems engineering documents, which define the technical requirements of structures, systems, and components.

Design Process - Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Design Review - A formally documented review of design documentation conducted at various points during the design process by individuals independent of those performing the design work, but who may be members of the organization within which the work was done. The design review compares design documentation against applicable codes, standards and other specifications to determine its adequacy and the extent to which the design conforms to stated requirements. Individuals performing a design review are completely knowledgeable in the codes, standards and other requirements forming the basis for the design.

Deviation - A departure from specified requirements. A deviation may be a characteristic outside of specifications or failure to follow accepted, documented procedures. The SRPO documents and controls deviations with a nonconformance control system; corrective action system, and stop further processing or stop work system.

Document - (noun) Written or printed information or evidence; specifically in QA, any written, printed, recorded, pictorial, or processed information describing, defining, specifying, prescribing, reporting, or certifying activities, requirements, procedures, data, or results (See QA Record). (verb) The act of creating a document; to furnish documents or documentary evidence.

Documentation - Collective body of documents.

DOE - U.S. Department of Energy.

End Item - The hardware, documented results, or deliverables of a contract or program study, test development, or activity, including recorded information and evaluations.

Final Design - Approved design output documents and approved changes thereto that forms the final basis for facility construction.

Functional Characteristic - Those attributes of a repository or its structures/systems/components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the CRWMP or other Federal regulatory documents.

Geologic Repository - A system which is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes: (1) the geologic repository operations area, and (2) the portion of the geologic setting that provides isolation of the radioactive waste.

GOCO - Government owned Contractor operated facility.

High-Level Radioactive Waste or HLW - (1) Irradiated nuclear reactor fuel, (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel, and (3) solids into which such liquid wastes have been converted.

HLW Facility - A facility subject to the licensing and related regulatory authority of the Commission pursuant to Sections 202(3) and 202(4) of the Energy Reorganization Act of 1974 (88 Stat 1244). These are DOE facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under The Atomic Energy Act and Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of long-term storage of high-level radioactive wastes generated by [DOE], which are not used for, or part of, research and development activities.

Important to Isolation - Those engineered structures, systems, and components, and those features of the geologic and hydrologic system that are essential to inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment after permanent closure will be kept within limits prescribed by 10 CFR 60 and 40 CFR 191.

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

Indoctrination and Training - Includes all of the actions necessary (e.g., classroom sessions, on-the-job training, required reading assignments, etc.) to assure that personnel assigned to manage or perform activities affecting quality on SRP projects are familiar with and understand the purpose, scope and implementation of the QA program manuals, procedures, administrative controls, and interfaces applicable to their work assignments.

Inspection - Documented examination or measurement by a qualified, independent party to verify that an item or activity conforms to specified requirements so that the resultant data or information is of known quality.

Inspector - A person who performs inspection activities to verify conformance to specific requirements.

Internal Audit - An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Item - An all-inclusive term commonly used in place of any of the following: structure, system, component, material and equipment. The term "items" may also include technical data, documents, computer codes, or samples.

Isolation - means inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

Lead Auditor - An individual trained, qualified, and certified to organize and direct an audit, report audit findings, and evaluate responses to audit findings.

May - Indicates permission.

Measuring and Test Equipment (M & TE) - Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or to acquire data to verify conformance to specified requirements.

Monitor - Overview of a process or activity to ensure that the process or activity conforms to specified requirements. (Generally not documented and does not take the place of a surveillance or inspection).

Nonconformance - A deficiency in the characteristic of an item, documentation, procedure or activity that renders the quality of an item or activity unacceptable or indeterminate. A record documenting the existence of a nonconformance is a nonconformance report (NCR).

NRC - U.S. Nuclear Regulatory Commission.

Objective Evidence - Any documented statement of fact, other information, record, or data, either quantitative or qualitative, pertaining to the quality of an item or service, based on observations, measurements, or tests which can be verified (e.g., record of site characteristics based on documented surveys, measurements, or tests).

Observation . A statement of fact regarding a weakness in a QA program which could lead to a more serious deficiency if not corrected, but which does not constitute a lack of compliance (i.e., finding) with applicable quality assurance requirements.

OCRWM - The Office of Civilian Radioactive Waste Management in DOE Headquarters.

Overview - An independent analysis and evaluation of the status and adequacy of plans and activities to assure that quality is achieved and verified in accordance with mission requirements and licensing regulations.

Peer Review - A formally documented review of technical material performed by individuals who are independent from the organization that performed the work and have technical expertise at least equal to that of the performing individuals. A peer review on a report may be conducted when underlying technical work is at the forefront of the state of the art technology or when technical conclusions are based, at least partially, on subjective judgments or application of existing theories on new ideas.

Performance Confirmation - means the program of tests, experiments, and analyses which is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

Personnel Qualifications - The characteristics or abilities gained through education, training, or experience as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

Preliminary Design (Title I) - A continuation of the design effort utilizing the conceptual design and the project design criteria as a basis for project development. Title I design develops topographical and subsurface data and determines the requirements and criteria which will govern the definitive design. Tasks include preparation of preliminary planning and engineering studies, preliminary drawings and outline specifications, lifecycle costs analysis, preliminary cost estimates, and scheduling for project completion. Preliminary design provides identification of long lead procurement items and analysis of risks associated with continued project development.

Prime Contractor - As used within the QA program, a Prime Contractor is hereby defined as an individual or organization who supplies items and services to the SRPO in accordance with a contract and/or interagency agreement or a task assignment with an integrated contractor (National Laboratory) through another DOE operations office.

Procedure - A sequence of events described in an approved document that specifies or prescribes how an activity is to be performed, and describes the methods to be employed, any special personnel, equipment, or material requirements, sequence of operations, and means of data collection, recording, reduction, interpretation, and reporting.

Procurement Document/Specification - Broadly interpreted in this Plan to mean all formal, approved, technical and administrative documents associated with requesting, specifying, contracting, and binding a procurement with a contractor, or an agreement with contractors that identifies and defines the requirements which items or services must meet in order to be considered acceptable by the purchaser; includes purchase requisitions, purchase orders, statements of work, scopes of work, drawings, specifications, work orders, instructions, contracts, and agreements. (See Contract.) This includes task agreements with integrated contractors (i.e. national laboratories) and interagency agreements with Federal agencies.

Program Plan - A written description of the activities required to achieve the goals or objectives of a program. It describes the strategy to be followed and major actions to be taken to achieve those objectives. The plan addresses program-related elements including program interfaces, schedule, major milestones, budget, technical control, quality assurance, and program control.

Purchaser - The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.

Q-List (Quality-List) - A compilation of items that are important to radiological safety of the public and those items which assure that the waste isolation objectives are met.

Qualified Procedures - An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

Quality - May be regarded, in the technical sense, as definable, controllable, measurable, and verifiable properties, features, or characteristics of a study, investigation, design, material process, or product. Quality is frequently defined in the physical sense as the fitness of a product or service for intended use. Conformance to established regulations and requirements is the definition of quality in a licensing and contractual sense.

Quality Achievement - Means the performance by line organizations of quality-related activities, such as drilling, logging, testing, designing, constructing, operating, and decommissioning, in accordance with written procedures whereby technical criteria are met.

Quality Assurance (QA) - Is defined classically in nuclear regulations, codes, and standards as comprising all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. When the product is a report of a significant study or investigation, quality assurance comprises those planned and systematic actions necessary to provide adequate confidence in the validity and integrity of the reported data, methods, procedures, conclusions, interpretations, and recommendations, and in the protection, retrievability, and possible replicability of the data. The assurance of quality encompasses multidisciplinary systems of line management controls backed by independent verification activities that demonstrate the completeness and appropriateness of achieved quality with respect to public health and safety, waste isolation, and retrievability; and reliability, maintainability, operability, performance, and other significant factors.

Quality Assurance Program - A written, documented description for an organization's total concept, requirements, and scope of effort for achieving and verifying quality. The program sets forth quality assurance policy, objectives, requirements, authority and responsibility, organization, methods and activities required to implement and assess the adequacy and effectiveness of the program. Within SRPO the QA Program consists of the QA Plan and the Quality Assurance Administrative Procedures (QAAPs).

Quality Assurance Record - A completed document that furnishes evidence of the quality and completeness of data, items, and activities affecting quality; documents prepared and maintained to provide objective evidence and demonstrate implementation of the quality assurance program.

Quality Assurance Specifications - A statement of QA requirements, including codes, standards, and specifications, with which quality-related activities and products must conform; a technical statement of QA requirements contained in the SOW section of a contract (see Procurement Document/Specification).

Quality Control (QC) - Consists of a comprehensive process of identifying and specifying technical quality criteria and requirements, controlling work performance, measuring conformance to administrative and technical methods and procedures, applying statistical quality control and measurement methods, and preventing, mitigating or correcting quality deficiencies, as appropriate, to the work specific activity.

Quality-Related - Activities related to, or which could affect, items which are important to safety, important to waste isolation, and/or which relate to the quality objectives of the SRP.

Quality Verification - Includes the activities of reviewing, inspecting, testing, checking, assessing, auditing, or otherwise verifying that items, designs, processes, data, codes, or documents conform to established criteria. Independent quality verification is performed by individuals other than those who performed or supervised the activity but who may, in some cases, be from the same organization.

Readiness Review - A QA activity which is planned and performed prior to initiation of a major work activity or event associated with facility construction, startup, operation and testing.

Regulatory Requirement - A directive having the force of law issued by a federal, state, or local government agency which is legally binding on the party(ies) and its intended purpose.

Repair - The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

Rework - The process by which an item is made to conform to original requirements.

Right of Access - The right of a Purchaser or designated representative to enter the premises of a supplier or Contractor for the purpose of inspection, surveillance, or audit.

Scope of Work (SOW) - Technical requirements and deliverables specified in a contract. (See Procurement Document/Specification.) (Same as Statement of Work.)

Service - The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, installation, program procedure development or program procedure implementation.

Shall - Denotes a mandatory requirement or action.

Should - Denotes a desired, expected, but permissible or optional requirement or action.

Significant condition adverse to quality - A condition which, if uncorrected, could have a serious effect on the quality objectives of the SRP, including the safety, operability, integrity, validity, or availability of components, systems, structures, facilities, data, or information.

Site - Means the location of the controlled area.

Site Characterization - Means the program of exploration and experiments, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of a particular site. Site characterization includes borings, surface excavations, excavation of exploratory shafts, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic repository, but does not include preliminary borings and geophysical testing needed to decide whether site characterization should be undertaken.

Special Process - A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the conformance requirements cannot be readily determined by inspection or test of the product.

SRPO Document Control Center (DCC) - The title given to the organization responsible for the receipt, preservation and retrieval of quality assurance records.

Standard Industrial Practice (Standards of the Profession) - Activities performed or products produced which conform to industrial standards (e.g., SAE, ASTM, ACI, IEEE) and are generally recognized by peers as being of high quality and integrity.

Stop Work - To discontinue all or any of the activities related to the fulfillment of Contract obligations.

Surveillance - The act of observing to verify whether an item or activity conforms to specified requirements.

Survey - An activity to evaluate an organization's capability, including its quality program, to meet the requirements specified in a request for proposal or a contract; e.g., a survey made prior to contract award; or acceptance of a QA plan, or test plan, or other critical planning activities.

Technical Data - Recorded scientific or technical information, regardless of form or characteristics. It may, for example, document research, experimental, developmental, test, demonstration, or engineering work; or be usable for characterizing an area or a site; for defining a design or process; or for procuring, producing, supporting, maintaining, or operating material. Technical data may consist of experiments and engineering data, design specifications, performance requirements, computer software and all related documents, geophysical notes and data, laboratory data, records of data reduction and analysis, and the results of peer review. The data may be in any form, such as laboratory notebooks, field notes, boring logs, geologic survey notes, graphics, engineering drawings, any photographic media, magnetic recordings, computer printouts, specification and process sheets, catalog information, referenced standards, manuals, and technical reports.

Technical Review - A formally documented review of technical material performed by individuals independent of those responsible for the work but who may be members of the organization within which the work was done. A technical reviewer has expertise at least equal to that of the individuals that prepared the material under review. A technical review is performed for material that is within the current state of the art; the review is an objective evaluation of the technical content based on well known and generally accepted standards.

Test Plan - A specialized form of an activity plan which addresses technical requirements and conditions for conducting a test or series of tests.

Testing - An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Title III Services - Those activities required to assure that the project is constructed in accordance with the plans and specifications and that the quality of materials and workmanship is consistent with the requirements of the project.

Traceability - The elements necessary to trace the history, application, or location of an item and like terms or activities by means of recorded documentation and/or physical identification.

Use-as-is - A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use without further processing.

Unusual Occurence - An unexpected or unplanned event which has a greater or potentially greater adverse effect on quality achievement than does a significant quality problem. An unusual occurrence is not an unexpected natural phenomena, such as an earthquake.

Validate - To review, inspect, test, check, compare, or otherwise determine or demonstrate that the result satisfies the original intent; e.g., a component or equipment must provide the function, performance, and reliability, within intended costs, that was stipulated by the person or documents initiating the development of the equipment; a computer program must accurately solve the problem originally posed in a timely and cost-effective manner; field data must accurately reflect existing conditions.

Verify - To review, inspect, test, check, compare, audit, or otherwise determine, confirm, substantiate, or assure that items, activities (including field and laboratory), data, data analysis and interpretation, computer programs, processes, services, and documents conform to, or have been implemented in accordance with, specified requirements, procedures, plans, etc.

Waiver - Documented authorization to depart from specified requirements.

TITLE ORGANIZATION

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

1.1 PURPOSE

This Section describes and documents the Salt Repository Project Office (SRPO) organizational structure and identifies the authorities and functional responsibilities of key individuals and groups within SRPO for managing the SRPO Quality Assurance Program. It also defines the relationships and lines of communication between individuals and groups within SRPO for the performance and implementation of activities affecting quality, as well as organizational interfaces between SRPO and the Office of Geologic Repositories (OGR) and the Chicago Operations Office.

1.2 APPLICABILITY

This Section is applicable to the SRPO organization and those organizations which interface contractually with SRPO relative to the quality-related aspects of the Salt Repository Project.

1.3 RESPONSIBILITIES

The SRPO organizational structure depicting those positions responsible for the management and implementation of the SRPO Quality Assurance Program and the lines of communication and relationships of those individuals and/or organizational elements within SRPO responsible for the siting, site characterization, site selection, design, construction, and operation of a geologic repository are shown on Attachment A. The authrities and responsibilities of external organizations, who perform quality assurance functions for assuring that the QA Program is established and implemented and for verifying that activities have been correctly performed, are described in this Section. SRPO delegates the authority for establishing and implementing major portions of this QA Program to Prime Contractors, however, SRPO retains the ultimate responsibility for implementation and effectiveness thereof.

1.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO, reports directly to the Assistant Manager for Project and Technology Management (AMPTM-CH) of the DOE Chicago Operations Office for the administrative functions

of the Salt Repository Project (SRP) day-to-day line management responsibilities. The Project Manager, SRPO, is responsible to the DOE Office of Civilian Radioactive Waste Management (OCRWM) through the Office of Geologic Repositories (OGR) for the implementation of project policy, technical, and quality assurance direction issued to SRPO. The Project Manager, SRPO, has delegated to the Chief, Quality Assurance the responsibility of developing the SRPO Quality Assurance Program and the authority to verify its implementation and effectiveness. The responsibility for implementation of the QA Program has been delegated to all SRPO personnel who perform quality-related activities as defined within the SRPO QA Program. The Project Manager, SRPO executes his QA responsibilities by approving this QA Plan and the implementing Quality Assurance Administrative Procedures (QAAPs) which set forth the requirements of the SRPO QA Program. The Project Manager, SRPO, maintains continuing involvement in QA activities by frequent meetings with the Chief, Quality Assurance, by reviewing QA audit reports and by having an independent management assessment of the SRPO Quality Assurance Program performed on an annual basis to verify its effectiveness. The Project Manager, SRPO also has the responsibility to assure timely response to corrective action reports and internal audit findings. The Project Manager, SRPO, has the authority to settle disputes which may arise between the Chief, Quality Assurance and any SRPO Chief. However, the Chief, Quality Assurance has the additional recourse of elevating disputes to the QA Manager, Chicago Operations and/or the QA Manager, OCRWM through the QA Manager, OGR. The Project Manager, SRPO, shall ensure that the SRPO Organization is in compliance with the QA Requirements as addressed in paragraph 1.4.

1.3.2 DEPUTY PROJECT MANAGER, SRPO

The Deputy Project Manager, SRPO, reports to the Project Manager, SRPO, and has the authority to act in his behalf. The Deputy Project Manager, SRPO, is responsible for coordinating activities of SRPO Chiefs and Prime Contractors which cut across SRP organizational lines and for supporting the Project Manager, SRPO in day-to-day line management responsibilities. The Deputy Project Manager, SRPO, shall assist the Project Manager, SRPO, in resolution of quality concerns such as corrective action reports and audit findings that cut across SRP organizational lines. The Deputy Project Manager, SRPO, shall maintain involvement in QA activities by frequent meetings with the Chief, Quality Assurance, and by reviewing QA audit reports.

1.3.3 CHIEF, QUALITY ASSURANCE

The Chief, Quality Assurance, reports to the Project Manager, SRPO, and is responsible for developing, maintaining, and assuring the effectiveness of the SRPO Quality Assurance Program. This organizational relationship provides the Chief, Quality Assurance, with sufficient authority, organizational freedom, and independence from undue influence or responsibilities of cost and schedules so that he may effectively administer the QA Program. The Chief, Quality Assurance, is responsible for verifying that activities affecting quality performed by SRPO and by SRPO Prime Contractors have been performed in accordance with SRPO QA Program requirements. The Chief, Quality Assurance, maintains close liaison with QA organizations of Prime Contractors. The Chief, Quality Assurance, communicates directly with the Project Manager, SRPO, and with appropriate management levels in prime contractor organizations to identify quality problems; initiate, recommend, provide or concur with solutions; and to verify implementation of solutions to quality problems. Attachment B identifies project QA lines of direction and interface coordination. The Chief, Quality Assurance, is authorized to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material within SRPO and the Prime Contractors' organizations.

1.3.3.1 Specific duties and responsibilities of the Chief, Quality Assurance, include as a minimum the following:

a) Technical direction and administrative control of SRPO Quality Assurance personnel.

b) Development and maintenance of this QA Plan and implementing Quality Assurance Administration Procedures (QAAP).

c) Performance of internal audits of the implementation and effectiveness of the SRPO QA Program.

d) Approval of Prime Contractors' QA programs and procedures.

e) Performance audits of Prime Contractor QA programs to assess their implementation effectiveness.

f) Indoctrination and training of SRPO personnel relative to this QA Plan, and assuring the accomplishment and adequacy of training for SRPO personnel in the SRPO QAAP's through the coordination of such training.

g) Interpretation of DOE Orders; regulatory codes and standards and national consensus standards as they apply to the QA Program.

h) Issuance and control of the SRPO QA Plan and the QAAPs.

i) Assuring that the SRPO QA Organization is adequately staffed to fulfill the requirements of the SRPO QA Program.

j) Coordination of the preparation and approval of QA specifications for inclusion in procurement documents.

k) Coordination of the preparation and approval of the SRPO QA Program description for incorporation into the documents required by regulations.

1.3.3.2 The Chief, Quality Assurance shall, provide Quality Specialists, as required, to support site activities. The Quality Specialist's duties and responsibilities include as a minimum the following:

a) Review site originated procurement documents.

b) Review and concur with Prime Contractors' construction, test, and installation procedures for compliance with the QA program requirements.

c) Perform surveillances of contractor site QA activities and other site activities affecting quality to verify conformance with the Prime Contractor and the SRPO QA Program.

d) Assist in the acceptance and transfer of structures, systems, activities and associated quality verification records from the Prime Contractors to SRPO.

e) Perform surveillances of and review the results of functional testing to assure compliance with specified requirements.

f) Perform surveillance of SRPO functions relative to the site collection, filing, and retention of QA records.

1.3.4 SRPO CHIEFS

The SRPO organization as depicted on Attachment A identifies SRPO Chiefs as:

a) Socioeconomics, Environmental and Institutional Relations.
b) Site Evaluation.
c) Engineering and Technology.
d) Budget and Project Control.
e) Contract Administration.
f) Quality Assurance.

These SRPO Chiefs report directly to the Project Manager, SRPO, and have management responsibility and authority for specific technical and administrative activities and to ensure that the SRPO and Prime Contractor responsibilities and requirements addressed within this QA Plan are enforced within their functional areas. Their specific responsibilities relative to implementation of the QA Program are as follows:

1.3.4.1 Identification and documentation within their areas of responsibility those activities, structures, systems or items which are quality-related and/or are to be placed on the Q-List.

1.3.4.2 Identification of the need for and coordination of the preparation of Quality Assurance Administrative Procedures (QAAPs) for quality-related activities, as identified within this QA Plan.

1.3.4.3 Evaluation and certification of the qualifications of SRPO technical personnel to perform their specific technical activities.

1.3.4.4 Provision of documented training in accordance with approved procedures for personnel within their specific organizational elements.

1.3.4.5 Implementation of, and compliance with, the requirements of this QA Plan and the Quality Assurance Administration Procedures (QAAPs) within the scope of their specific responsibilities.

1.3.4.6 Identification and documentation of the external interfaces between SRPO, OGR, and Prime Contractor organizations, and internal interfaces between SRPO Chiefs for those activities affecting quality. Ensure that delegated functions are clearly documented.

1.3.4.7 Approval of Prime Contractors' technical procedures within their specific organizational elements.

1.3.5 QUALITY ASSURANCE ORGANIZATIONAL INTERFACES

The Chief, Quality Assurance shall establish interface activities with DOE-Chicago Operations Quality Assurance Manager, OGR Quality Assurance Manager, Prime Contractors' QA organizations, and subcontractor QA organizations as indicated on Attachment B.

1.3.5.1 SRPO interface activities with DOE Chicago Operations and OGR Quality Assurance shall be established by the Chief, Quality Assurance, through:

a) Submittal of the SRPO QA Plan and procedures for review and approval.

b) Submittal of audit reports for information.

c) Attendance of periodic QA coordination meetings.

d) Compliance with the QA interface and programmatic requirements addressed with the OGR QA Program by incorporation into the SRPO QA Program.

e) Submittal of a copy of the Prime Contractors' QA program to the OGR Manager for information.

f) Responses to audits of the SRPO QA program conducted by Chicago Operations and OGR QA.

1.3.5.2 SRPO interface activities with the Prime Contractors shall be instituted by the Chief, Quality Assurance, by:

a) Incorporating required interfaces into the Prime Contractors' QA specifications.

b) Scheduling and conducting periodic audits on the Prime Contractors' QA Program.

c) Approving the Prime Contractors' quality assurance programs and implementing procedures.

d) Scheduling and conducting QA coordination meetings as deemed necessary.

1.3.5.3 SRPO interface activities with subcontractor shall be instituted by the Chief, Quality Assurance, by:

a) Participating in representative prime contractor audits of subcontractor QA program.

1.3.6 PRIME CONTRACTORS

Through SRPO QA specifications incorporated into procurement documents, the Prime Contractors shall be required to establish organizational structures and responsibilities which meet the requirements of paragraph 1.4, or as modified by the QA specification, and to pass those requirements on to their subcontractors to the degree applicable.

1.4 REQUIREMENTS

1.4.1 SRP ORGANIZATIONAL REQUIREMENTS

1.4.1.1 The organizational structure of each SRP organization shall be described within their QA Program. This description shall delineate the authority and responsibilities of persons and organizations performing (1) quality verification activities (i.e., the quality assurance/quality control personnel who verify that an activity affecting quality has been correctly performed) and (2) activities affecting quality (e.g., the personnel who do geologic investigations, design, procurement, fabrication, and construction functions). Qualified individuals or organizational elements shall be identified within the SRP organization as responsible for the quality of the delegated work prior to initiation of activities. In addition, organization charts shall show lines of responsibility and communication, and relationship of these persons and organizations to the contractors' top management. The methods to be used by personnel or organizations performing QA functions shall be described.

1.4.1.2 Personnel within SRP organizations monitoring quality assurance activities shall have sufficient authority and organizational freedom to:

a) Identify quality problems.

b) Stop unsatisfactory work or control further processing, delivery, installation or operation of a nonconforming item, deficiency, or unsatisfactory condition until proper dispositioning has occurred.

1.4.1.3 The persons or organizations assigned the responsibility for verifying the effective execution of any portion of an SRP quality assurance program at any location where activities affecting quality are being performed shall have direct access to such levels of management that are necessary to perform this function and shall have sufficient independence from cost and schedule to implement their responsibilities. Disputes arising between QA organizations and other organizational elements shall be elevated to a level of management which has authority to resolve such disputes.

1.4.1.4 The verification of conformance to established quality requirements shall be accomplished by personnel or organizations that do not have direct responsibility for the performance of an activity affecting quality. Personnel who verify conformance to requirements shall be a member of the QA organization except as specified in this QA Plan.

1.4.1.5 The responsibilities for internal and external interfaces between SRP organizational units, including change thereto, shall be defined and documented.

1.4.1.6 The individual responsible for assuring that an appropriate quality assurance program is established and verifying that activities affecting quality have been correctly performed, shall have QA knowledge and experience. This position shall have the following characteristics:

a) The same or higher organizational level as the highest line manager directly responsible for activities affecting quality, and is independent of cost and schedule.

b) Effective communication channels with other senior management positions.

c) Responsibility for QA interpretations and the approval of the QA program and revisions thereof.

d) No other duties or responsibilities which would prevent full attention to QA responsibilities.

e) Authority to initiate, recommend, provide or concur with solutions through designated channels.

f) Responsibility to verify implementation of solutions.

g) The following education and experience prior to assuming the responsibilities of the position:

(1) Bachelor degree or higher in engineering, physical sciences, industrial technology, or quality assurance from an accredited institution plus 10 years of combined experience in quality assurance, engineering, geoscience activities, construction, operation, or maintenance or;

(2) Associate degree in engineering, physical sciences, industrial technology, or quality assurance, plus 12 years of combined experience in quality assurance engineering, geoscience activities, construction, operation, or maintenance or;

(3) High School or General Equivalency Diploma plus 18 years of combined experience in quality assurance engineering, geoscience activities, construction, operation, or maintenance.

h) The experience should include four years of managerial experience in a position above the management entry level in which the candidate has demonstrated an understanding of quality concepts or principals as applied to nuclear, aerospace, DOE or geoscience activities.

1.4.2 SRP ORGANIZATIONAL RESPONSIBILITIES

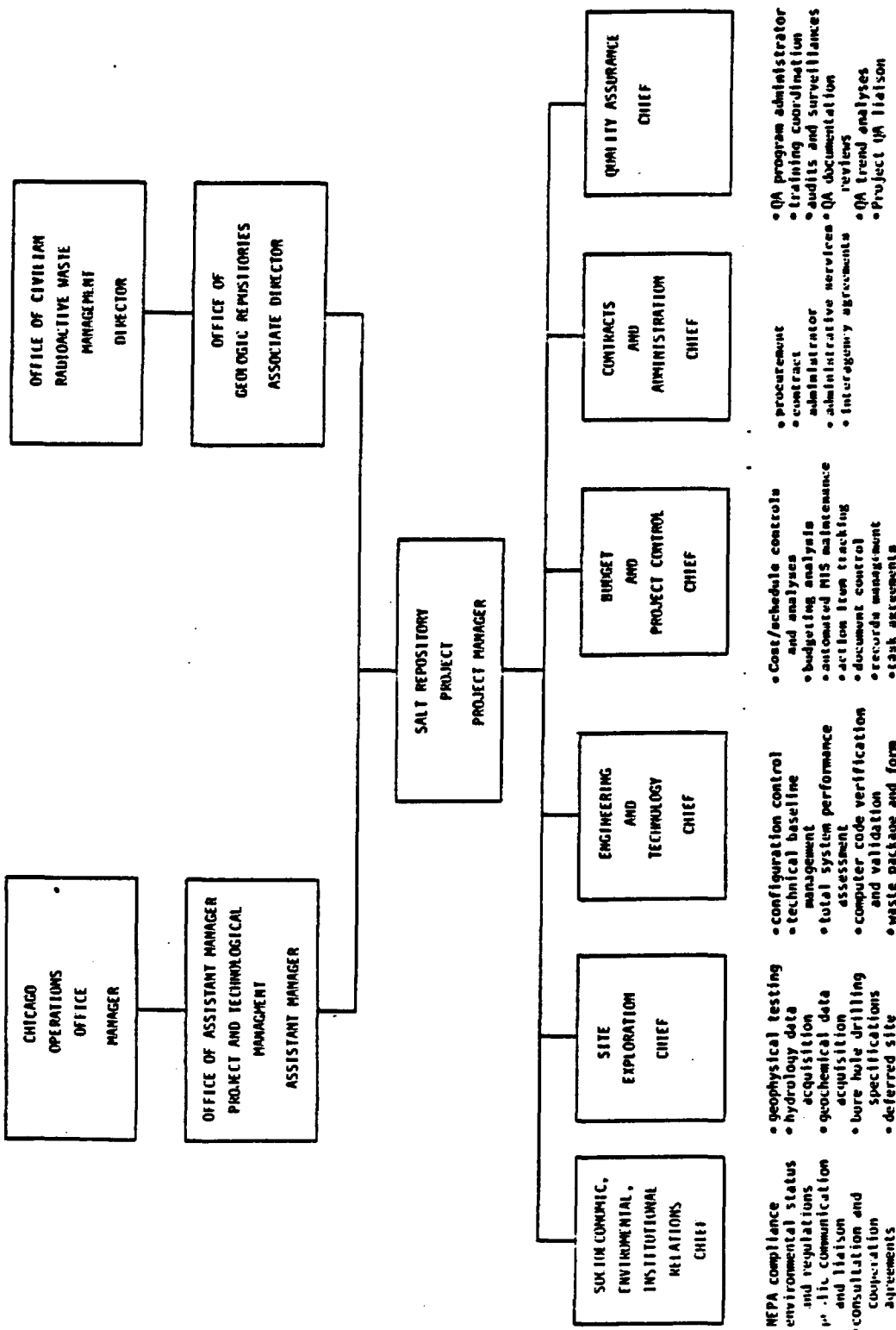
1.4.2.1 Qualification requirements imposed on SRP personnel performing quality assurance/quality control activities shall be described in procedures and/or job descriptions by the responsible SRP organization.

1.4.2.2 The SRP organization shall ensure that the achievement of quality objectives are accomplished by personnel or organizations that have been assigned the responsibility for performing an activity affecting quality. Performance of the activity may require interim examinations, reviews, or checks of the activity by the individual performing the activity; however, these review actions shall not constitute acceptance or verification of conformance of the activity, and do not relieve the person performing the activity of the responsibility for correcting any deficient conditions.

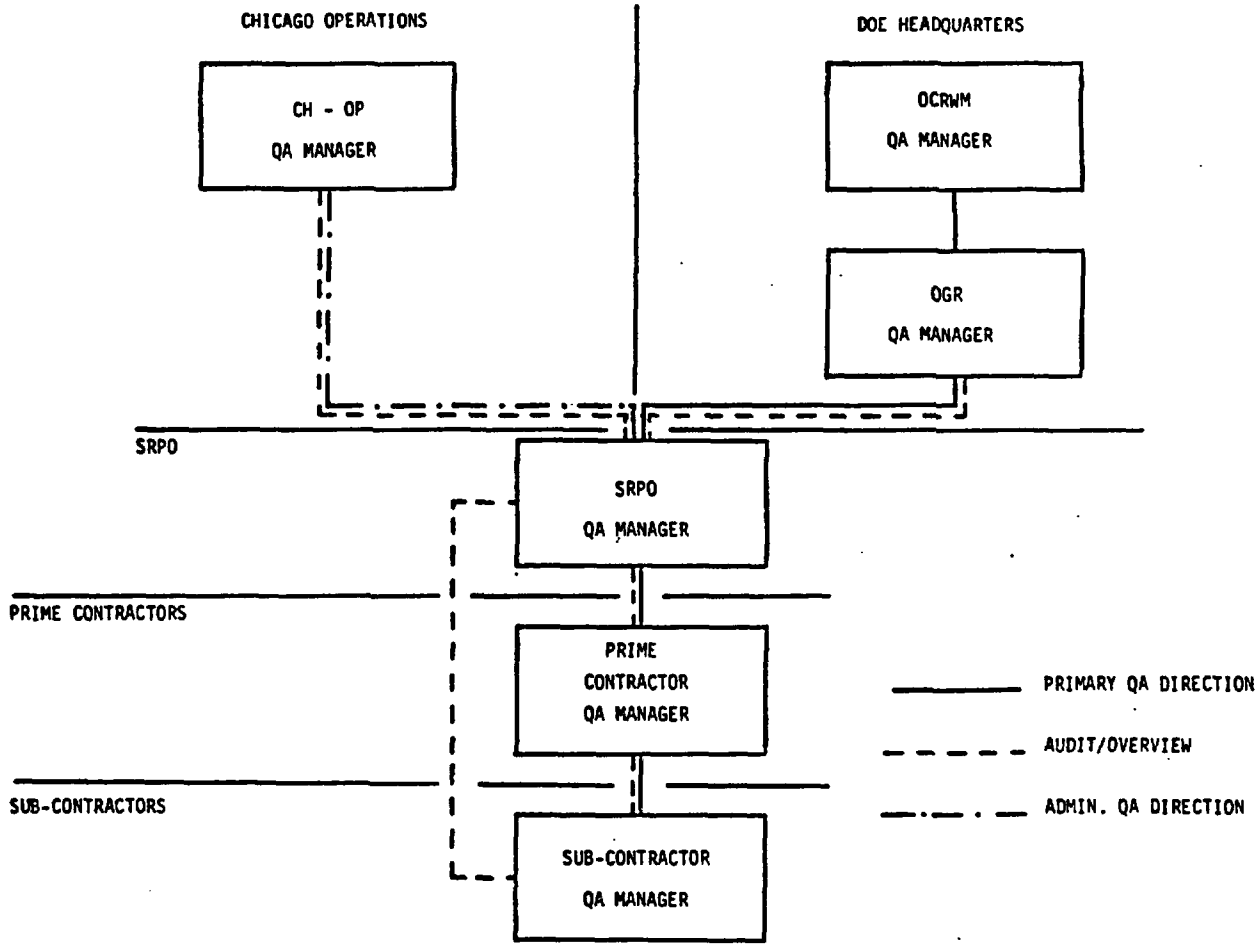
1.4.2.3 Individuals or organizations responsible for establishing and executing a quality assurance program may delegate any or all of the work but shall retain responsibility thereof.

ATTACHMENT A

SRPO ORGANIZATION STRUCTURE



ATTACHMENT B
SRP QA INTERFACES



TITLE QUALITY ASSURANCE PROGRAM

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

2.1 PURPOSE

This Section establishes the responsibilities and requirements by which the SRPO Quality Assurance Program is documented and maintained. This Section shall also address the responsibilities and requirements for indoctrination and training for those personnel performing activities affecting quality; the activities and items to which the QA Program shall apply; the management assessment methods to verify its effectiveness; and the graded approach to applying the QA requirements.

2.2 APPLICABILITY

This QA Plan is applicable to all SRPO personnel and organizational elements who are responsible for quality-related activities. This QA Plan applies to all items important to safety, important to waste isolation and/or which relate to quality objectives of the SRP. Applicable portions of this QA Plan will be applied to items and related activities in accordance with a graded approach methodology. Specific items which are important to safety will be included on a Q-List developed in accordance with methodology provided by OGR. Examples of quality-related activities include, but are not limited to the following:

a) Siting, experimental, developmental, and site characterization activities, as well as the design, procurement, construction, operation, closure and decommissioning of mined geologic repositories.

b) Receipt, handling, and storage of quality-related items, components, cores and samples.

c) Acquisition, processing, and reporting of data to be used for technological development and design basis.

d) Preparation, review, control and distribution of program and project technical plans, documents, studies, and reports.

e) Receipt, handling, storage and monitoring of high level nuclear waste and spent nuclear fuel.

2.3 SRPO RESPONSIBILITIES

Responsibilities stated in this QA Plan shall be those of the position or organization to which they refer or the designee of that position or organization. Responsibilities which are delegated shall be documented. The Project Manager, SRPO, has the overall responsibility for the implementation of the SRPO QA Program through line management. Additionally, the Project Manager, SRPO, ensures that the QA Program is developed, maintained, and monitored to verify effectiveness through the Chief, Quality Assurance. The Project Manager, SRPO, has issued a Quality Assurance Policy Statement, contained within this QA Plan.

2.3.1 QUALITY ASSURANCE POLICY

The management of the Salt Repository Project recognizes its responsibility for assuring that a salt repository is sited, characterized, engineered, designed, constructed, tested, licensed, and operated in a manner that complies with the high standards established by the project for safeguarding the health and safety of the public. To that end, this QA Plan has been developed to provide policies and procedures for implementation, consistent with NRC Regulatory Guides; codes, and standards; DOE Orders and documents; and consensus standards as identified in Section 2.3.9.

It is the policy of the SRPO that this QA Plan is mandatory. It shall be implemented and enforced by all SRPO personnel, groups, and organizational elements for accomplishing activities affecting the quality of the SRP. The QA Plan shall be verified for implementation and effectiveness, maintained and controlled by the Chief, Quality Assurance.

2.3.2 QA PROGRAM ADMINISTRATION AND REQUIREMENTS

This QA Plan establishes the programmatic requirements and controls established to assure the quality of SRPO activities and items, and defines the responsibilities for the implementation of those requirements. The procedures which are developed for the implementation of activities affecting quality are identified as Quality Assurance Administrative Procedures (QAAPs) and are prepared as interdisciplinary functions, as required, in that they address both quality assurance and technical functions. The QA Plan and the QAAPs together constitute the SRPO QA program. The SRPO QA Program along with the prime contractors' QA Programs, which are contractually imposed, reviewed and approved by the Chief, Quality Assurance, constitute the Salt Repository Project (SRP) QA Program. (See Attachment A, which depicts this QA Program hierarchy.) The applicable documents to which this QA Program shall comply are identified within paragraph 2.3.9 of this Section and the programmatic requirements of the QA Program

are identified in paragraph 2.4 of this Section. Definitions of terms used within this program are defined in the Glossary Section of this plan.

Each of the eighteen Sections of this QA Plan manual have been prepared to comply with the corresponding basic and supplemental requirements of ANSI/ASME NQA-1 and 10 CFR 50, Appendix B. Additionally, each Section delineates the QA Program requirements related to that Section and identifies the personnel/organization responsible for their implementation. The Chief, Quality Assurance, has the responsibility to ensure that the QA program requirements, as identified within each Section of this QA Plan, are properly prescribed by QAAPs within SRPO and incorporated into QA specifications which are imposed on Prime Contractors through procurement documents. The QA Specification shall be prepared by taking into consideration the Scope of Work (SOW) and the graded approach to quality assurance as identified in Section 2.3.3.

The QAAPs are numbered such that they relate to the QA Plan Section to which they apply, and are further identified in the Table of Contents within the QAAP manual. These QAAPs shall be developed and approved prior to the commencement of work to be controlled. A QAAP shall govern the re-verification of any quality-related work which may have been conducted prior to the initiation of the controls of this QA Program, to assure that the intent of this QA Program has been accomplished and documented.

2.3.3 GRADED QUALITY ASSURANCE

The SRPO Chiefs and the Chief, Quality Assurance, are to provide quality assurance controls over items important to safety or important to waste isolation as identified on a Q-List. The extent of QA controls to be applied to specific items and activities are to be identified in QAAPs and/or QA specifications. This is referred to as a graded approach to quality assurance. The graded approach requires the greatest programmatic controls to be applied to activities which affect the public health and safety, waste isolation and environmental concerns, while other activities may require lesser control, or normal industry accepted practices.

The SRPO QA Program provides for a variable extent and intensity of quality assurance via graded application of requirements to project activities, based upon the type and scope of project activities; the importance to safety/waste isolation and licensing issues; the intended application of the end items; and the importance to achieving the SRP objectives. Both Activity Plans and external procurement documents shall be evaluated to

determine the appropriate quality assurance requirements using this QA Plan, the SRPO QAAPs, and appropriate project documents as a guide to the application of ANSI/ASME NQA-1. Some factors to be considered in assigning levels of quality assurance are as follows:

a) The consequence of malfunction or failure of the item.

b) The design and fabrication complexity or uniqueness of the item.

c) The need for special controls and surveillance over processes and equipment.

d) The degree to which functional compliance can be demonstrated by inspection, test or data gathering.

e) The quality history and degree of standardization of the item or activity.

f) The difficulty of repair, replacement or requalification of an item or activity.

g) The determination of whether the activity or test could be repeated if it were found to be initially unacceptable.

h) The organizational complexity of the activity, process or performing organization.

i) The importance of the item or activity to the project and DOE Mission Plan objectives.

2.3.4 QUALITY CLASSIFICATIONS

SRPO shall develop a listing of items which are important to safety and important to waste isolation. This Q-List shall be prepared in accordance with a rationale and methodology developed by OGR and supplemented for use on the SRP.

2.3.5 INDOCTRINATION AND TRAINING

An integral part of the SRPO QA Program shall be provisions in the QAAPs for the establishment and implementation of an indoctrination and training program for SRPO personnel and Contractor personnel working at SRPO, under the SRPO QA Program in the policies, purpose, scope, and implementation of this QA Program and in the principles and techniques of the activities detailed in QAAPs. The training program shall apply to all SRPO personnel who perform project activities affecting quality in accordance with this QA Program. The training shall be accomplished through the use of any one or a combination of the following techniques:

a) Lectures.
b) Seminars.
c) Workshops.
d) Field trips.
e) On-the-job training.
f) Required reading.

Implementation of the training program is the responsibility of the Chief, Quality Assurance, and the functional SRPO Chiefs. These responsibilities include the preparation and implementation of QAAPs which require the development of program outlines, schedules, and lesson plans, as well as the designation of personnel to attend training sessions, and the maintenance of records of training. The proficiency of personnel accomplishing activities affecting quality shall be re-evaluated and maintained annually.

The Chief, Quality Assurance, has the responsibility for providing training and indoctrination to this QA Plan and those QAAPs which are primarily related to quality assurance organization activities. The Chief, Quality Assurance shall also coordinate the training to be provided on the technical QAAPs with the responsible line managers to ensure that all SRPO personnel receive the required training. It is the primary responsibility of line managers to assure that their personnel whose work may have an effect upon quality are adequately trained to the applicable QAAPs and qualified to perform their assigned responsibilities. Records of training and personnel qualifications shall be maintained.

2.3.6 SRPO PERSONNEL QUALIFICATION AND CERTIFICATION

SRPO personnel performing activities affecting quality which require specific skills shall be qualified and certified as having the necessary skills to perform those activities.

2.3.6.1 SRPO auditors and lead auditors shall be qualified and certified in accordance with requirements presented in Section 18 of this QA Plan.

2.3.6.2 SRPO personnel who perform nondestructive examinations (NDE) shall be qualified and certified in accordance with Section 9 of this QA Plan.

2.3.6.3 SRPO personnel who perform inspection and test functions shall be qualified and certified in accordance with Sections 10 and 11, of this QA Plan, respectively.

2.3.6.4 SRPO professional personnel shall be qualified and certified in accordance with approved QAAPs, prepared by the responsible line manager. The QAAPs shall specifically address:

a) Required qualification to perform specific activities (i.e., geologic evaluations, hydrology, mechanical design reviews etc.)

b) Records shall be maintained to support the required qualifications and a certification by the SRPO Chief that the qualifications are acceptable.

2.3.7 QA PROGRAM REVIEW, APPROVAL, CONTROL, AND ISSUANCE

This QA Plan and revisions hereto, shall be reviewed and approved by the Chief, Quality Assurance. It shall be issued for review in accordance with a QAAP for "Preparation of the QA Plan" and approved by the Project Manager, SRPO, and the Chief, Quality Assurance.

The QAAPs shall be developed by the Chief, Quality Assurance, and the technical SRPO Chiefs. The Chief, Quality Assurance, shall coordinate the QAAP development to assure adequate coverage of the requirements of this QA Plan by procedures.

The QA Plan and the QAAPs shall be submitted to the OGR QA Manager and the Chicago Operations Office QA manager for review and approval. All SRPO QA Program documents shall be contained in manuals which are individually serialized for identification and control purposes. A control log shall be maintained for each of the manuals which shows distribution of all copies. All holders of controlled manuals shall receive all revisions thereto.

Periodic reviews shall be made of new or revised Regulatory Guides, codes, and standards and DOE orders to create an awareness of current QA requirements which may require a revision to the SRPO QA Program. The distribution of QA Program documents shall be through the SRPO Chief, Budget and Project Control.

2.3.8 MANAGEMENT ASSESSMENT

The Project Manager, SRPO, shall conduct, or have conducted, an independent assessment of this QA Program on at least an annual basis to verify the adequacy and effectiveness of implementation. In addition, the Project Manager, SRPC, shall be cognizant of the quality assurance effort on a current basis by receiving copies of audit reports, corrective action reports, and selected correspondence dealing with SRPO quality assurance

activities. The Project Manager, SRPO, shall receive periodic reports on the status and progress of current quality assurance activities and shall hold frequent meetings with the Chiefs to discuss progress and related problem areas or concerns.

2.3.9 QA PROGRAM COMPLIANCE DOCUMENTS

The SRPO QA Program activities for the assurance of quality achievement are governed by the current edition of the following DOE orders, directives, OCRWM requirements, NRC regulations and guides, and national concensus standards;

a) DOE 5000.3, Unusual Occurrence Reporting System.

b) DOE 5700.4, Project Management Systems (DOE 4700 Draft).

c) DOE 5700.6, Quality Assurance.

d) DOE-CH 5700.6, Quality Assurance.

e) OCRWM - Quality Management Policies and Requirements.

f) OGR/B.3, OGR QA Plan for Siting and Site Characterization.

g) 10 CFR part 50 - Appendix B - Quality Assurance Criteria for Nuclear Power Plants.

h) 10 CFR part 60 - Disposal of High Level Radioactive Wastes in Geologic Repositories.

i) ANSI/ASME NQA-1 Quality Assurance Program Requirements for Nuclear Facilities.

j) NRC Review Plan - Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories.

2.3.10 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA specification as applicable to their scope of work and shall pass the applicable requirements on to their contractors. Prime Contractor QA programs shall be submitted to SRPO for approval prior to use.

2.4 REQUIREMENTS

QA Programs developed by SRPO and its Prime Contractors shall comply with the QA Program Compliance Documents as identified in Section 2.3.9

and satisfy the applicable requirements listed below, in addition to those identified within each Section of this QA Plan as determined by the Chief, Quality Assurance (see Section 2.3.2).

2.4.1 The QA Program shall include a commitment that all development, control and/or use of computer programs which affect quality-related activities 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" and as interpreted within QA Specifications.

2.4.2 Quality Assurance administrative procedures shall be established to assure that technical and quality assurance procedures required to implement the approved QA Plan are consistent with QA Program requirements and are properly documented, controlled, and maintained.

2.4.3 The QA organization management shall review and document concurrence with all quality-related procedures.

2.4.4 The QA and technical organizations shall participate early in the QA Program definition stage to determine and identify the extent to which QA controls are to be applied to specific items and activities and to assure DOE consideration is given to the technical aspects of activities affecting quality. The QA program shall be established at the earliest time consistent with accomplishing the activities. This effort involves applying a graded quality assurance approach in accordance with importance to safety or waste isolation and other factors as described in Section 2.3.3.

2.4.5 QA procedures and detailed technical procedures shall be identified and documented, to ensure that each criterion of 10 CFR Part 50, Appendix B, as appropriate to specific items and activities, will be adequately addressed.

2.4.6 Planning for accomplishing activities affecting quality shall be performed as early as practical, and no later than the start of the activities that are to be controlled, in order to assure interface compatibility and adequate implementation of quality requirements. The results of quality planning activities shall be documented.

2.4.7 Activities affecting quality shall be accomplished under suitably controlled conditions, which includes the use of specified procedures or instructions, equipment, and special conditions, and assurance that prerequisites for the given activity have been satisfied.

2.4.8 The QA Program shall provide for any special controls, processes, test equipment, tools and skills to attain the required quality and for verification of results.

2.4.9 The QA Program shall provide for identification and designation of those activities which require qualified inspection and test personnel and shall identify the minimum requirements of such personnel.

2.4.10 The QA Program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

2.4.11 A description shall be provided as to how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, compliance and effectiveness of the QA Program to 10 CFR Part 50, Appendix B. These measures shall include:

a) Maintaining an awareness of current QA Program status through reports, meetings, and/or audits.

b) Performing of an annual assessment which is preplanned and documented with corrective actions identified, implemented and tracked.

2.4.12 Indoctrination, training, and qualification programs are established and documented such that:

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 and indoctrinated to the technical objectives and requirements of applicable codes and standards.

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.

d) Appropriate management overviews the performance and proficiency 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.

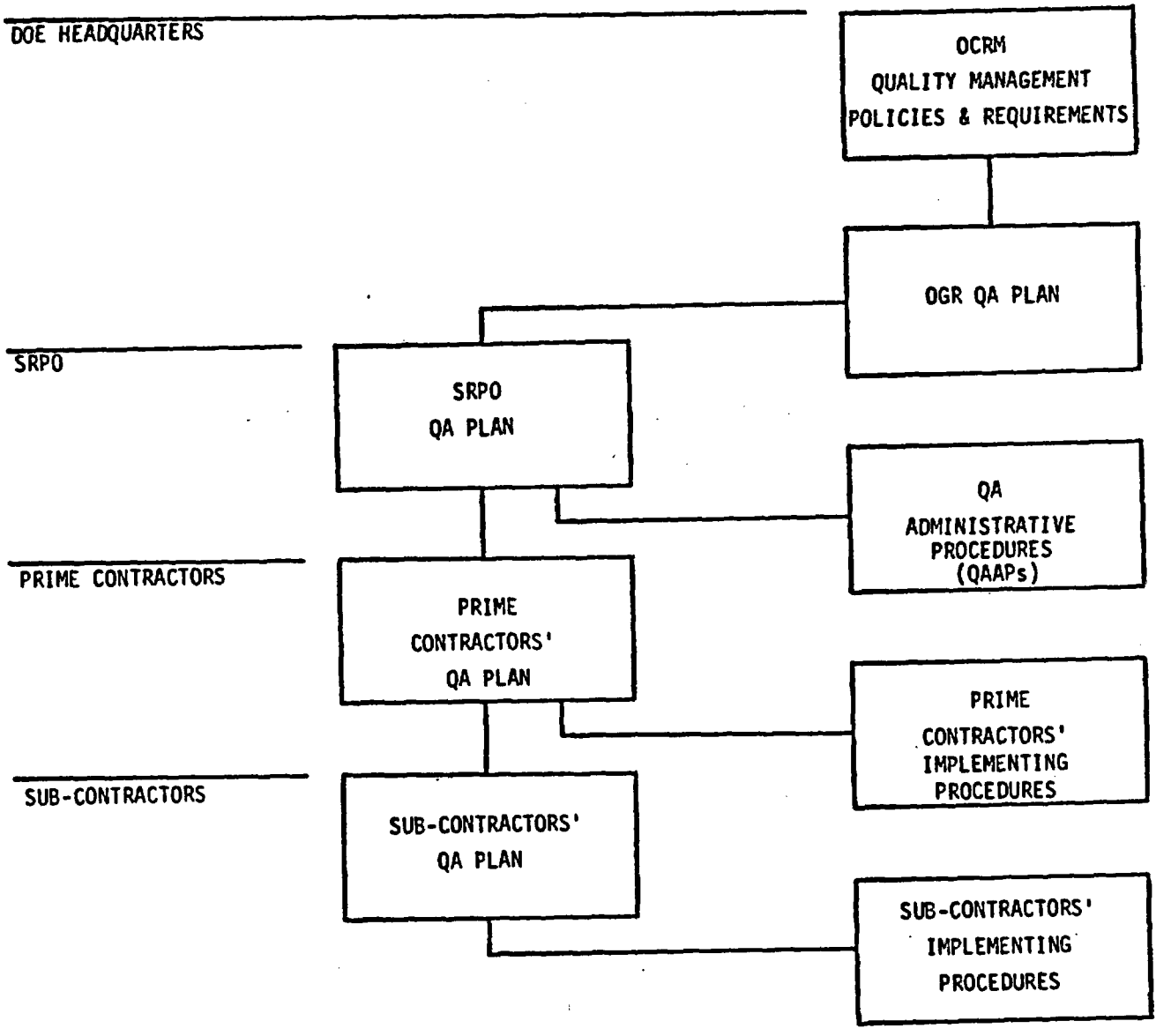
e) Qualified personnel are certified in accordance with applicable codes and standards, as applicable for nondestructive examination (NDE), inspection, test and audit functions, and other functions requiring personnel certification.

2.4.13 Written procedures shall be established to assure that only those personnel who meet the qualification requirements of the QA program are permitted to perform inspection and test activities. Personnel not meeting the qualification requirements of the QA program may be used as data recorders provided they are supervised by a qualified individual.

2.4.14 Records of personnel qualifications shall be established and maintained by the employer.

Attachment A
Document Hierarchy of QA Program

QUALITY ASSURANCE PROGRAM HIERARCHY



TITLE

PROJECT DESIGN CONTROL

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
	11/26/85		11/26/85

3.1 PURPOSE

This Section establishes the responsibilities and requirements by which the SRPO assures that design, data acquisition and design requirements are defined, controlled, and verified, and for controlling design activities, design documents and design interfaces.

3.2 APPLICABILITY

This Section applies to the control of the design of quality-related items and activities to assure adequate provisions for functional capability of those items. The requirements and responsibilities for the control of design activities shall apply to site characterization and the conceptual, preliminary and final design of repositories, exploratory shafts, test and evaluation facilities, at-depth test facilities and waste packages, and the information collection activities conducted to obtain design input data. This Section shall also apply to control of changes in design.

3.3 RESPONSIBILITIES

SRPO retains overall responsibility for assuring that data acquisition and design activities are controlled in accordance with this Section.

3.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO shall ensure the establishment of interface controls for design and data collection activities. Interfaces between SRPO Chiefs and between SRPO and the Prime Contractors shall be developed in accordance with Section 3.4.10. The Project Manager, SRPO shall have ultimate responsibility for the approval of Baseline Documents. The Project Manager, SRPO shall also preside over the SRPO Change Control Board (CCB).

3.3.2 SRPO CHIEFS

The cognizant SRPO Chiefs shall assure that preselected design input and design output documents and activities receive the

required technical, design and/or peer reviews in accordance with QAAPs. The SRPO Chiefs shall also ensure design inputs and outputs are consistent with the Baseline Documents.

The cognizant SRPO Chiefs shall document in specifications those design responsibilities delegated to Prime Contractors.

3.3.2.1 The Chief, Engineering and Technology is responsible for assuring that design control QAAPs are established and implemented for the control of design, design information, and design activities related to the repository, waste package, and exploratory shaft. The QAAPs established shall comply with and implement the requirements of Section 3.4.

3.3.2.2 The Chief, Site Exploration is responsible for assuring that geoscience data collected during site characterization, which may be used as design inputs, are obtained and controlled in accordance with approved QAAPs which implement the applicable requirements of paragraph 3.4.

3.3.2.3 The Chief, Socioeconomic, Environmental, and Institutional Relations is responsible for ensuring that all designs meet applicable federal, state, and local statutes and regulations and for assuring that all environmental and socioeconomic data collected during site characterization are obtained and controlled in accordance with approved QAAPs which implement the applicable requirements of paragraph 3.4.

3.3.2.4 The Chief, Quality Assurance, is responsible for:

a) Review of design reports prior to their approval to verify incorporation of appropriate QA provisions and compliance to QAAPs.

b) Participation in design reviews as a committee member.

c) Verification that design reviews are planned and conducted in accordance with the requirements of this Section.

d) Review and approval of deviations from applicable quality standards.

e) Verification that an independent design verification has been conducted.

f) Verification that technical, design and peer reviews for compliance with SRPO QA Program Requirements.

3.3.3 PRIME CONTRACTORS

Prime Contractors to SRPO are responsible for establishing a QA Program and implementing procedures to control data acquisition and design activities for those activities affecting quality and passing applicable requirements on to their contractors. These procedures shall meet the requirements of this Section as applicable to their scope of work and the SRPO QA Specification.

3.4 REQUIREMENTS

The requirements for design and data gathering activities shall be identified and documented in the applicable procedures, specifications, plans, drawings or other appropriate documents 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. These documents shall be controlled in accordance with the requirements of this Section.

3.4.1 DESIGN INFORMATION

Data which will be used in design activities for the development and verification of design are considered to be design information. Acquisition and protection of data shall be controlled to assure that only properly identified and traceable data are used in design activities. Data may include any related measurements or recordable observations acquired as a part of geological, geophysical, geochemical or hydrological studies and the results of any associated laboratory analyses. In general, data include any information generated for use in the technical assessment of related evaluations or experiments.

Methods of data acquisition and protection shall be reviewed in accordance with Section 3.4.6, as appropriate.

3.4.1.1 The activities related to data acquisition from literature searches, sample collection, analyses, and reporting of the analyses results shall be controlled in accordance with specific plans or procedures.

3.4.1.2 Data acquisition controls shall include the use of approved instructions and procedures, establishment of methods to provide traceability from the data to the acquisition activities; selection, calibration, control, and use of appropriate measuring and test equipment; and, procedures for data validation and the

identification and disposition of data that are erroneous, rejected, superseded or otherwise determined to be unsuited for use.

3.4.1.3 Data acquisition activities shall, where possible, be based on nationally recognized and accepted methods. The methods used for data acquisition shall be evaluated prior to use and reevaluated periodically during their use to verify their accuracy and completeness.

3.4.1.4 Data generated and/or acquired during experiments and developmental work siting, site characterization and testing of the salt repository, which will be used as design input, shall be acquired in a manner controlled to assure the accuracy, validity and integrity of the data.

3.4.1.5 Data collected through the use of monitoring systems shall be accepted only to the degree to which the accuracy and completeness of the data can be ensured through performance audits of the monitoring system.

3.4.1.6 Data reduction techniques shall be determined prior to their application and shall be documented and reviewed for adequacy. The reduction techniques shall document the manner in which non-pertinent data shall be handled.

3.4.1.7 Documentation related to the acquisition of data which could be used as design input shall be controlled in accordance with design interface procedures to assure traceability of data from its source through integration into design or other decision processes.

3.4.2 DESIGN INPUTS

Required design inputs, such as regulatory requirements, applicable DOE Orders - baseline documents, design bases, performance requirements, codes and standards, and design information shall be identified and documented. A definition shall be made of which items or features within the scope of the design are quality-related. Additionally, a determination shall be made of what quality requirements shall be applied to the various repository items and features. The selection of design inputs shall be reviewed and approved. Design inputs shall be specified and approved on a timely basis.

3.4.1.2 Design inputs shall be detailed to the level 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.

3.4.2.2 Changes from the approved design inputs, including the reason for the changes, shall be identified, approved, documented and controlled in the same manner equivalent to controls placed on the original design inputs.

3.4.3 DESIGN METHODS

Design organizations shall prescribe and document the design methods to be used in sufficient detail to allow the design process to be carried out correctly and to permit verification that the design meets requirements. Appropriate quality standards shall be identified and documented and their selection reviewed and approved prior to use.

3.4.3.1 Design methods, materials, parts, equipment and processes that are essential to the function of the final design shall be selected and reviewed for suitability of application.

3.4.3.2 Deviations from specified quality standards, including the justification for the deviations, shall be identified, approved, documented, and controlled, and reviewed by the Quality Assurance Organization.

3.4.3.3 Applicable information gained from experience and the results of related studies (e.g., data, reports, analyses, etc.) shall be made available to the cognizant design personnel.

3.4.3.4 The final design output (and all changes to the output) shall be traceable to the design input by documentation in sufficient detail to permit design verification. The design shall also identify assemblies and/or components that are part of any items being designed. If modifications are required to any assemblies and/or components, or if special testing, inspection, or handling requirements are required for the design to function, the design documents shall state what actions are necessary.

3.4.3.5 Design methods and the practices established to control design shall be documented in instructions, procedures, specifications or any other form that provides adequate control and permits reviewing, checking or verifying the results of the activity.

3.4.4 DESIGN ANALYSES

Analyses necessary for the completion of design shall be performed in a planned and controlled manner with documentation that is traceable to the specified and approved requirements.

3.4.4.1 The documentation of calculations shall be sufficiently detailed as to purpose, method, assumptions, design input, references and units that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without substantial input from the originator.

3.4.4.2 Computer programs may be utilized for design analysis without individual verification of the program for each application, provided:

a) The computer program has been verified to show that it produces correct solutions for the mathematical model within defined limits for each parameter employed.

b) The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

3.4.4.3 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 the previous applications.

3.4.4.4 Documentation of design analysis shall include:

a) Definition of the objective of the analysis.

b) Definition of design inputs and their sources.

c) Results of literature searches or other applicable background data.

d) Identification of assumptions and identification of those assumptions that must be verified as the design proceeds.

e) Identification of any computer calculations, including computer type, name or designation of the computer program utilized, revision of the program utilized, code or program inputs and

outputs, reference to code or program verification, and the bases for application to the computer program for the specific application.

f) Objective evidence of the review and approval of the analysis.

3.4.5 DESIGN VERIFICATION

Design control measures shall be established to verify the adequacy of the design by one or more of the following: the performance of design reviews; the use of alternate calculations; the performance of qualification tests; the conduct of peer reviews.

The responsibility of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of the documentation to be generated shall be identified and documented in specific instructions or procedures, prior to the performance of design verifications.

3.4.5.1 The design verification method(s) used shall be identified, the results clearly documented, and the identification of the verifier clearly indicated. The qualifications of the verifier shall be documented.

3.4.5.2 Verification shall be performed 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.

3.4.5.3 Design verification shall be performed by competent individual(s) or group(s) other than those who perform the original design. 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. Additionally, he must not have established the design inputs used in the design. Routine supervisory reviews do not satisfy the intent of this requirement, unless the supervisor is the only individual competent to perform the verification, in which case, the verification

documentation must include a justification for the supervisor performing the verification. The Chief, Quality Assurance, shall approve the supervisor performing the verification, prior to the performance.

3.4.5.4 The extent of the design verification required is a function of the importance to quality 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 previously to a verification process, 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 applications of the design.

3.4.5.5 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.

3.4.5.6 Errors and deficiencies in approved design and design information shall be documented and action taken to assure all errors and deficiencies are corrected.

3.4.5.7 Design verification may be in accordance with Sections 3.4.6, 3.4.7, and/or 3.4.8.

3.4.6 DESIGN REVIEW

Design information, design activities and designs shall be reviewed in accordance with applicable procedures. These procedures shall prescribe methods for technical review, design review, and peer review. The process for determining the applicable review shall be prescribed in procedures and the determination of applicable review shall be documented.

3.4.6.1 Design reviews are a type of technical review performed to provide assurance that the design is correct and appropriate to its application. Design reviews shall be conducted of conceptual and preliminary design documents, reports, and inputs; final design documents, drawings and reports; and design documents which are selected for baselining.

Technical reviews shall be conducted of documents related to design input and output. Where applicable, the following questions shall be addressed:

a) Were the design inputs correctly selected?

b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified or subsequent reverifications performed when the detailed design activities are completed?

c) Was an appropriate design method used?

d) Were the design inputs correctly incorporated in the design?

e) Is the design output reasonable compared with design inputs?

f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

3.4.6.2 Design reviews shall be conducted by reviewers who have technical competence in the area under consideration. The personnel assigned to design reviews shall be provided with the design input data and any other information available about the design and the requirements established. The design review shall be completely documented along with the qualifications of the review personnel.

3.4.6.3 When it is determined that the design or design activities involve the 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 shall be conducted to verify the design or design activities.

Peer reviews shall be conducted by reviewers who have equivalent technical expertise in the field subject to review, and who are not directly involved with the work to be reviewed. Reviewers shall be provided with sufficient information about the work, including purpose and objectives, for adequate evaluation of the work. The results of peer reviews shall be documented and shall include date of review; place of review;

identification of reviewers; document or activities reviewed; evaluation process used; results of evaluations; recommendations and comments resulting from review; and, the disposition of recommendations and comments.

3.4.7 ALTERNATIVE CALCULATIONS

Alternative calculations are calculations or analyses that are made with alternative methods to verify the correctness of the original calculations or analysis. The appropriateness of assumptions made, the input data, and the computer programs or other calculation methods used shall also be reviewed.

3.4.8 QUALIFICATION TESTS

Where design adequacy is to be verified by qualification tests, the tests shall be identified, and the test configuration shall be clearly defined and documented. Testing shall demonstrate the adequacy of the performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions 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 to ensure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the design reverified in accordance with requirements of this plan.

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.

3.4.9 DESIGN CHANGE

Changes to final designs shall be justified and subjected to design control measures commensurate with those applied to the original design. Details of the design control measures shall be documented prior to commencing design.

3.4.9.1 The design changes shall be approved by the same affected groups or organizations that 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 SRPO or a designee shall designate a new responsible organization. The designated organi-

zation 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.

3.4.9.2 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 in addition to correcting the specific problem presented. Corrective action, in accordance with this Plan, shall be initiated.

3.4.10 DESIGN INTERFACES

Internal and external design interfaces shall be identified and controlled, and the design efforts shall be coordinated among the participating organizations.

3.4.10.1 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 information.

3.4.10.2 Design information transmitted across interfaces shall be documented and controlled. 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.

3.4.11 DOCUMENTATION

Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this plan, shall be collected, stored, and maintained in accordance with the requirements of this plan. The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies important steps, including sources of design inputs that support the final design and design decisions.

TITLE: PROCUREMENT DOCUMENT CONTROL

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

4.1 PURPOSE

This Section establishes responsibilities and requirements to assure that design criteria, design bases, performance criteria, and technical and quality specifications that are required to assure the attainment of quality objectives are included or referenced in SRPO procurement documents for quality-related activities and items.

4.2 APPLICABILITY

This Section shall apply to the control of SRP procurement activities and documents. It includes requirements to be met by the SRPO and imposed on all Prime Contractors and their contractors to the SRPO.

4.3 RESPONSIBILITIES

The SRPO has the overall responsibility to ensure that all SRP organizational elements comply with the requirements of this Plan.

4.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO, has the authority to make purchases; enter into, extend, modify and terminate contracts; approve purchases, subcontracts and extensions, modifications and terminations of subcontracts; and settle terminations of subcontracts; all in accordance with Federal and DOE procurement regulations.

4.3.2 SRPO CHIEFS

The cognizant SRPO Chiefs are responsible for verifying that procurement documents affecting their functional activities include appropriate technical and quality assurance requirements and that Prime Contractor QA programs have been reviewed and approved.

4.3.2.1 The Chief, Budget and Project Control, has been delegated the responsibility for the administration of integrated contractors (National Laboratories) task agreements. The integrated contractor task agreements and changes thereto, shall include the applicable requirements of this Section. The Chief, Budget and Project Controls, is responsible for preparation and implementation of QAAPs to control these activities.

4.3.2.2 The Chief, Contracts and Administration, has been delegated the responsibility and authority for all contractural matters. The Chief, Contracts and Administration, shall ensure that procurement documents, interagency agreements, and changes thereto, are in accordance with the applicable requirements of Section 4.4 and that QAAPs are developed and implemented to control these activities.

4.3.2.3 The Chief, Quality Assurance, is responsible for reviewing SRPO procurement documents, prior to their release to the supplier, to assure incorporation of applicable QA requirements and compliance with this Section. This review shall be performed and documented in accordance with paragraph 4.4.2.

The Chief, Quality Assurance, shall assure, through audits and selective reviews, that Prime Contractors impose the appropriate requirements of this Section on their contractors and that the requirements are adequately and effectively implemented.

The Chief, Quality Assurance, shall coordinate the preparation of and concurrence with the QA Specification for incorporation into Prime Contractor procurement documents.

4.3.3 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification, as applicable to their scope of work, and shall pass the applicable requirements on to their contractors.

4.4 REQUIREMENTS

Procedures shall be established that assign the organizational responsibility for procurement planning; the preparation, review, approval and control of procurement documents.

These procedures shall require a review of procurement documents by QA personnel to verify that the applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; that there are adequate acceptance and rejection criteria, where appropriate; and that procurement documents have been prepared, reviewed, and approved in accordance with the established procedures.

4.4.1 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents shall include or reference applicable design bases and other requirements necessary to ensure adequate quality and to the extent necessary shall require Contractors to have a quality assurance program consistent with the applicable requirements of this QA plan. Prime Contractor QA programs, related QA Procedures, and changes thereto shall be submitted and approved by SRPO prior to initiation of activities affected by their program.

Procurement documents issued at all tiers of procurement shall include provisions for the following, to the level of detail deemed necessary by the procurement document originator and the Contracting Officer:

a) Scope of Work - The work to be performed shall be clearly stated.

b) Technical Requirements - The technical requirements for the work shall be specified. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions. The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the Contractor's performance.

c) Quality Assurance Specifications - Procurement documents shall require that the Contractor have a documented QA program approved by the purchaser which implements applicable portions of this QA Plan. The extent of the program required shall depend on the type and use of the item or service being procured. Procurement documents shall require the Contractor to incorporate appropriate QA requirements in sub-tier procurement documents.

d) Right of Access - At each tier, procurement documents shall provide for access to the contractor's facilities and records for inspection or audit by the SRPO and/or parties authorized by the SRPO.

e) Documentation Requirements - At each tier, procurement documents shall identify the documentation required to be submitted to the purchaser or retained by the contractor and whether the documentation is for information to, or for review and/or approval by, the purchaser. Submittal times shall be established. When the purchaser requires the contractor to maintain specific QA records, the retention times and disposition requirements shall be prescribed.

f) Nonconformances - Procurement documents shall include the requirements of this QA Plan for reporting and approving disposition of nonconformances. Control of nonconformances at each tier of procurement shall meet the requirements of this QA Plan. (See Section 7.0)

g) Spare and Replacement Parts - Procurement documents shall require the identification of appropriate spare and replacement parts of assemblies. Technical and quality assurance requirements for ordering these parts or assemblies shall be the same or equal to those requirements placed on the original parts.

4.4.2 PROCUREMENT DOCUMENT REVIEW

A review of procurement documents, and changes thereto, which are to be submitted to a contractor/supplier shall be made and documented prior to contract award and as early in the document preparation as practical. The review shall be performed by personnel who have access to the pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. Objective evidence of procurement document review shall include documentation of accomplishment of the following:

a) Verification that the appropriate requirements specified in paragraph 4.4.1 of this plan are incorporated.

b) Determination of any additional or modified design or data collection criteria.

c) Analysis of exceptions or changes requested or specified by the contractor, and determination of the effects such changes may have on the intent of the procurement documents, or quality of the item service, or activity to be supplied.

d) Identification of reviewer and date of review.

4.4.3 CHANGES TO PROCUREMENT DOCUMENTS

Procurement document changes shall be initiated prior to the work being conducted and shall be subject to the same degree of control as utilized in the preparation of the original documents and to the requirements of paragraph 4.4 of this Section.

TITLE INSTRUCTIONS, PROCEDURES, AND DRAWINGS

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/21/85	[signature]	11/26/85

5.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures the development and implementation of instructions, procedures, and drawings for accomplishing quality-related activities.

5.2 APPLICABILITY

This Section shall apply to SRP activities affecting quality and to those personnel and organizations performing those activities.

5.3 RESPONSIBILITY

SRPO retains overall responsibility for assuring that instructions, procedures and drawings which prescribe activities that affect quality are established and implemented by those organizations accomplishing the activity.

5.3.1 SRPO CHIEFS

The SRPO Chiefs have the primary responsibility to ensure that activities affecting quality are planned and documented to meet the requirements of this QA Plan.

5.3.1.1 The SRPO Chiefs are responsible for:

a) Ensuring that contractors have developed appropriate instructions, procedures and drawings for their quality-related activities.

b) Providing training to SRPO personnel for QAAPs within their functional scope of activities.

c) Identifying the need for new QAAPs or change in existing QAAPs.

d) The preparation of QAAPs for activities within their functional area.

5.3.1.2 The Chief, Quality Assurance, is responsible for:

a) Developing QAAPs as required for functional quality assurance activities.

b) Establishing a QAAP for controlling a standard methodology for the preparation, maintenance and control of QAAPs.

c) Coordinating, with all SRPO Chiefs, the development of QAAPs within their functional areas as required by this QA plan.

d) Approving or concurring all QAAPs indicating that the QAAPs are adequate as to content and controls and meet the requirements of this QA plan.

e) Coordinating the training for all QAAPs and providing the training for quality assurance related QAAPs.

f) Approving the distribution list of QAAPs, which is administered by the Chief, Budget and Project Control.

g) Submitting QAAPs to Chicago Cperations and OGR for approval.

h) Issuing the QAAPs to the Chief, Budget and Project Control for distribution.

5.3.2 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification as applicable to their scope of work and shall pass the applicable requirements on to their contractors.

5.4 REQUIREMENTS

Quality-related activities shall be prescribed by and performed in accordance with documented instructions, procedures and drawings or other documents appropriate to the activity.

Documents which prescribe quality-related activities shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that the prescribed activities have been satisfactorily accomplished.

QUALITY ASSURANCE PLAN

Salt Repository Project Office (SRPO)

Salt Repository Project

Rev. 0 Issued 12-4-85

TITLE PROJECT DOCUMENT CONTROL

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/21/85	[signature]	11/26/85

6.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures that project documents which prescribe and describe quality-related activities and requirements are controlled to assure that applicable documents are reviewed, approved, distributed, controlled and available at the location where they are to be used.

6.2 APPLICABILITY

This Section applies to the review, approval, distribution and control of quality-related documents for the SRP.

6.3 RESPONSIBILITIES

SRPO retains overall responsibility for assuring that documents which prescribe quality-related activities and requirements are controlled in accordance with QAAPs which satisfy the requirements of this Section.

6.3.1 SRPO CHIEFS

6.3.1.1 The Chief, Budget and Project Control, is responsible for identifying the scope of the document control program and has the authority and responsibility for document control administration. The Manager, Project Control, has the responsibility to control the issuance of the SRP Baseline Documents.

The Chief, Budget and Project Control, is responsible for developing and implementing document control QAAPs in accordance with the requirements of this Section.

The Chief, Budget and Project Control, is responsible for maintaining the distribution list for the QA Plan and the QAAPs, as well as historical copies of these documents.

6.3.1.2 The Chief, Quality Assurance, shall verify, through audits and selective reviews, that the QAAPs established to control documents are being implemented. The Chief, Quality Assurance shall also verify through audits and reviews that the correct and applicable documents are available at the location where they are being used and that obsolete and superseded documents have been removed from the work place.

The Chief, Quality Assurance, is responsible for approving the distribution list for the SRPO QA Plan and the QAAPs.

The Chief, Quality Assurance, shall approve the QA Plan and concur or approve all QAAPs.

6.3.2 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification as applicable to their scope of work and shall pass the applicable requirements on to their contractors. The QA programs and procedures and subsequent revisions thereto shall be submitted to SRPO for review and approval prior to implementation.

6.4 REQUIREMENTS

6.4.1 DOCUMENT CONTROL PROGRAM

SRPO and Prime Contractor QA programs shall include provisions for identifying and controlling certain documents which are quality-related. The programs shall include:

a) The types of documents to be controlled. Examples of types of documents are: Drawings, specifications, design criteria documents, procedures, the QA Plan and QAAPs, SRP baseline documents, procurement documents, and work instructions.

b) The specific methods and responsibilities for control include the review, approval, issuance, and revision of controlled documents to assure their technical adequacy and the inclusion of appropriate quality requirements.

c) Identification of the individuals or groups authorized to approve, release, receive and maintain documents.

d) Provisions for the review of documents for adequacy, completeness and correctness prior to approval and issuance.

e) Provisions which require that correct and applicable documents are available at the location where they are to be used.

f) Provisions which require that obsolete or superseded documents are removed and replaced by the applicable revisions at work areas in a timely manner.

g) A master list, established and maintained by the organization responsible for a document's issuance, to identify the current revision of controlled documents and the latest changes to the documents.

h) A master copy of all revisions of controlled documents.

i) A controlled distribution list to assure distribution to those requiring such documents.

6.4.2 DOCUMENT REVIEW AND APPROVAL

Documents affecting quality shall be reviewed for adequacy and approved for release by authorized personnel.

6.4.2.1 Individuals performing document reviews shall have access to pertinent background data or information upon which to base their review and approval.

6.4.2.2 Major changes to documents shall be reviewed and approved by the same organizations and level that performed the original review and approval unless other organizations are specifically designated in writing.

6.4.2.3 Minor changes to documents, such as inconsequential editorial corrections, shall not require a review and approval cycle as performed for the original document. However, the procedures controlling documents shall clearly delineate the types of changes that do not require such a review and approval and shall identify individuals who can authorize such a decision.

6.4.2.4 Individuals performing document review and approval shall be authorized to do so and that authorization shall be documented.

TITLE CONTROL OF PURCHASED ITEMS AND SERVICES

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

7.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO ensures that procured items and services conform with the procurement documents and that the qualification and approval of the Prime Contractors' QA programs are performed.

7.2 APPLICABILITY

This Section applies to all quality-related items and services procured for the Salt Repository Project.

7.3 RESPONSIBILITY

SRPO retains overall responsibility for assuring that quality-related items and services for the SRP are procured in accordance with the QA Plan and QAAPs.

7.3.1 SRPO CHIEFS

SRPO Chiefs are responsible for the preparation of QAAPs in compliance with Section 7.4 and include controls for:

a) Assuring that Prime Contractors establish procedures for the control of purchased items and services and for ensuring that the requirements of this Section are included in procurement documents, as applicable.

b) Participating in Prime Contractor selection, offer evaluation and conducting performance evaluation.

c) Reviewing and approval of Prime Contractor QA Programs, related QA procedures and nonconformance reports dispositioned as "use-as-is" or "repair".

d) Reviewing and acceptance of Prime Contractor technical procedures as required by Technical Specifications.

e) Accepting and validating delivered items. Prime Contractor technical and quality-related deliverables such as activity plans, data packages, procedures, instructions, and record turnover packages shall be reviewed and accepted or rejected in accordance with approved QAAPs.

d) Documenting and implementing the SRPO procurement planning process.

e) Ensuring that Contractor submitted documents are processed and evaluated against appropriate acceptance criteria.

7.3.1.1 The Chief, Quality Assurance, is responsible for the preparation of QAAPs for quality assurance functions as follows and in compliance with Section 7.4.

a) Review and concurrence of SRPO QAAPs for the control of purchased items and services.

b) Performance of SRPO pre-award quality assurance program evaluations and/or QA surveys prior to the award of a contract.

c) Assuring that the bid evaluations conform with the procurement QA requirements.

d) Review and recommend the appropriate Chief approval of Prime Contract QA Programs and related procedures.

e) Audit and surveillance of contractors to verify proper implementation of their QA programs and procedures for the control of purchased items and services.

f) Assistance in the evaluation of Prime Contractor performance based on surveillance, document review trends, and/or receipt inspection.

g) Review and concurrence with SRPO contractors nonconformances dispositioned as "use-as-is" or "repair."

h) Establishment of an appropriate QAAP for the procurement considerations of commercial grade items.

i) Establishment of QAAPs for conducting surveillance and inspection activities to assure QA compliance by Prime Contractors.

7.3.1.2 The Chief, Contracts and Administration, shall be responsible for preparation of QAAPs which provide the responsibilities and controls related to the selection and qualification of Prime Contractors and Interagency Agreements. These QAAPs shall incorporate the applicable requirement attributes as identified in Section 7.4.

7.3.1.3 The Chief, Budget and Project Control, shall be responsible for preparation of QAAPs which provide the responsibilities and controls related to the administration of integrated contractor (National Laboratories) task agreements.

7.3.2 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification as applicable to their scope of work and shall pass the applicable requirements on to their contractors. Prime Contractors shall submit their procedures to SRPO for review and approval.

7.4 REQUIREMENTS

The procurement of quality-related items and services shall be conducted in accordance with approved procedures to assure conformance of those items and services with specified requirements.

7.4.1 PROCUREMENT PLANNING

7.4.1.1 Procurement activities shall be planned and documented. Planning shall be accomplished prior to start of procured activities and as early as practicable.

Planning shall result in:

a) Identification of the activity to be accomplished.

b) Identification of interfaces.

c) A uniform approach to the procurement process.

d) Documented identification of methods to be used.

e) The sequence of actions and milestones indicating the completion of these activities.

f) The preparation of procedures to control the procurement activities.

g) The responsibilities for control of procurement.

7.4.1.2 Procurement planning shall consider and provide for integration of the requirements of this Section and of Section 4.0 of this QA plan. Planning shall provide for the integration of:

a) Preparation, review and change control of the procurement document.

b) Selection of procurement sources.

c) Bid evaluation and award.

d) Purchaser control of Contractor performance.

e) Verification (surveillance, inspection or audit) activities by the 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.

7.4.1.3 In developing QA requirements for data collection equipment, test equipment and other equipment, it shall be determined whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test can be detected). Where no QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing use of the equipment.

7.4.2 CONTRACTOR SELECTION

Qualification criteria shall be established as part of the solicitation process to ensure that only qualified offerers are considered for award of contract.

7.4.2.1 Procurement source evaluation and selection measures shall be implemented by the purchaser and shall provide for identification of the puchaser's organiza-

tional responsibilities for determining Prime Contractor capability.

7.4.2.2 The selection of contractors shall include the evaluation of their capability to provide items or services in accordance with the QA requirements of the procurement documents, prior to award of contract.

7.4.2.3 Contractor evaluation and selection, and the results of the evaluation, shall be documented in accordance with appropriate procedures.

7.4.2.4 Contractor QA evaluation shall include one or more of the following:

a) Evaluation of the contractor's history of providing an identical or similar product which performs satisfactorily in use. The contractor's history shall reflect current capability.

b) Evaluation of contractor's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated.

c) Evaluation of contractor's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.

7.4.3 OFFER EVALUATION

7.4.3.1 Offers shall be evaluated to determine the extent of conformance to the procurement documents. The evaluation shall be performed by individuals or organizations designated to evaluate, as applicable, the following:

a) Technical considerations.
b) Quality assurance requirements.
c) Offeror's personnel qualifications.
d) Offeror's production capability.
e) Offeror's past performance.
f) Alternatives to procurement specifications.
g) Exceptions to procurement specifications.

7.4.3.2 Evaluation of offers shall be documented.

7.4.3.3 Prior to the award of the contract, unacceptable quality conditions resulting from bid or proposal evaluation shall be resolved to the satisfaction of the purchaser's quality assurance representative.

7.4.4 CONTRACTOR PERFORMANCE EVALUATION

7.4.4.1 Interface procedures for the procurement of items and services shall be established. These procedures shall be documented and shall:

a) Assure an understanding between the purchaser and contractor of the provisions and specifications of the procurement documents.

b) Require the Contractor to identify planning techniques and processes to be utilized in complying with procurement document requirements.

c) Require a review of Contractor documents which are generated or processed during activities fulfilling procurement requirements.

d) Control identification and processing of necessary change information.

e) Establish a method to document information exchange between purchaser and Prime Contractor.

f) Establish the extent of source surveillance and inspection activities.

7.4.4.2 Procedures shall be established by which to verify the contractor's performance. Verification activities shall be accomplished by qualified personnel in accordance with approved procedures. Verification activities may include inspection, audit, surveillance, and review and shall be conducted as early as practicable.

7.4.4.3 The extent of verification activities shall be a function of the relative importance, complexity and quantity of the item or service procured and of the contractor's quality performance.

7.4.4.4 Activities performed to verify conformance to requirements of procurement documents shall be recorded.

7.4.4.5 All documentation related to quality assurance of purchased items, such as surveillance and inspection reports, audits, receiving inspection, nonconformances, dispositioned as "use-as-is" or "repair" waivers, corrective actions and certificates of conformance shall be evaluated by the purchaser to determine the contractor's QA program effectiveness.

7.4.5 CONTROL OF CONTRACTOR GENERATED DOCUMENTS

7.4.5.1 Contractor generated documents shall be controlled, handled, and approved in accordance with Section 6.0.

7.4.5.2 Contractor generated documents shall be submitted for review and acceptance in accordance with procurement specifications. Procedures shall be established which provide for acquisition, processing, and recording the evaluation of technical, inspection and test data against acceptance criteria.

7.4.5.3 Documents which are, or will become, QA records shall be controlled in accordance with records management procedures.

7.4.5.4 The organization providing items or services, shall furnish the following documentation to the purchaser:

a) Identification of the specific procurement requirements met.

b) Identification of any procurement requirements that have not been met.

c) Description of those nonconformances from the procurement documents dispositioned "accept-as-is" or "repair."

7.4.5.5 The procedure for review and acceptance of these documents shall be described in the purchaser's QA program.

7.4.6 ACCEPTANCE OF ITEM OR SERVICE

Methods shall be established for the acceptance of an item or service being furnished by the contractor.

7.4.6.1 Prior to offering the items or services for acceptance, the contractor shall verify that the item or service being furnished complies with the procurement requirements.

7.4.6.2 Where required by code, regulation, or contract, documentary evidence that items conform to procurement documents shall be available at the purchaser's site prior to installation or use.

7.4.6.3 The Purchaser's methods used to accept an item or related services may include one or more of the following:

a) Certificate of conformance.
b) Source verification.
c) Receipt inspection.
d) Post-installation test.

7.4.6.4 Methods to accept procurement of services only shall include at least one of the following:

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.

7.4.7 CONTROL OF CONTRACTOR NONCONFORMANCES

Contractors shall establish procedures for control of items and services that do not meet procurement document requirements. Nonconformances dispositioned as "repair" or "use-as-is" shall be submitted to the purchaser for approval of the recommended disposition.

TITLE IDENTIFICATION AND CONTROL OF ITEMS

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

8.1 PURPOSE

This Section establishes the responsibilities and requirements for the control of quality-related items, data and samples to assure that only correct and accepted items and data are used or installed, and that only correctly identified and traceable samples are used for generation of data.

8.2 APPLICABILITY

This Section is applicable to quality-related items, data and samples generated or used for the SRP.

8.3 RESPONSIBILITIES

SRPO retains the overall responsibility for ensuring that documents which prescribe the identification and control of items are controlled in accordance with QAAPs which satisfy the requirements of this Section.

8.3.1 SRPO CHIEFS

The SRPO Chiefs are responsible for implementing the requirements of this section within their functional areas.

8.3.1.1 The Chiefs are also responsible for:

a) Incorporating the requirements of this Section into Prime Contractors' procurement specifications, as applicable to the procurement activity.

b) Ensuring the incorporation of these requirements into contractors' procedures.

c) Establishing QAAPs to meet the requirements of this Section for any activity within SRPO requiring the identification and control of items, samples, or data.

8.3.1.2 The Chief, Quality Assurance, is responsible for the performance of audits and surveillance to ensure the implementation of the requirements of this section within SRPO, and by all SRPO Prime Contractors.

8.3.2 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification as applicable to their scope of work and shall pass the applicable requirements on to their contractors.

8.4 REQUIREMENTS

Controls shall be established to assure that only correct and accepted items are used or installed.

8.4.1 TRACEABILITY

Quality-related items shall be traceable to the appropriate technical and/or quality documentation such as drawings, specifications, purchase orders, drilling logs, field records, test records, inspection documents, and nonconformance reports.

8.4.1.1 When specified by codes, standards, or specifications specific identification or traceability shall be provided. Such requirements might include, but are not limited to, 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.

8.4.1.2 Where required, certificates of chemical and/or physical properties shall be traceable to the finished item, or to test results and analyses using such materials.

8.4.1.3 An indication of item quality status shall be provided by records traceable to the item.

8.4.2 IDENTIFICATION

8.4.2.1 Identification shall be maintained either on the items or in documents traceable to the items. Identification shall be by one or more of the following:

a) Physical identification shall be used to the maximum extent possible.

b) Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed to assure positive identification.

c) Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item.

8.4.2.2 Indication of inspection/test status of items shall be maintained throughout fabrication, assembly, storage, shipping, installation, erection and operation of the item and shall conform to Section 14 of this Plan.

8.4.2.3 Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

8.4.2.4 Markings which become obliterated shall be restored immediately.

8.4.2.5 Items of production (batch, lot, component, part) shall be identified from the initial material receipt and fabrication of the items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

a) Identification of materials, parts, and components shall be unique to the item.

b) Records traceable to the item shall include an indication of the quality status of the item and identification of the person performing the quality verification.

8.4.2.3 Engineered items and components shall have their engineering identity established either on the item, or through records traceable to the item. The identification system for fabricated items shall provide traceability to subcomponents and/or materials.

8.4.3 LIMITED LIFE ITEMS

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. Items or materials requiring control because of age or limited life cycles are identified as to cure date, date of manufacture, and expended life.

8.4.4 STORED ITEMS

Items which are stored for future use or archived for historical purposes shall be protected against physical damage or loss.

8.4.4.1 A controlled environment shall be provided for those items requiring such controls.

8.4.4.2 Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage.

8.4.4.3 Provisions shall be made for the maintenance or replacement of markings and identification records damaged due to handling or aging.

8.4.4.4 Provisions shall be made for the protection of the identifications on items subject to excessive deterioration due to environmental exposure.

8.4.4.5 Provisions shall be made for updating existing records.

8.4.5 DATA

Data that will be used as design inputs or to determine compliance with requirements shall be traceable to its source or sources. Identification and traceability of data shall be maintained throughout the prescribed retention time of the data.

8.4.6 SAMPLES

Procedures shall be established to ensure that geological or environmental samples are identified to allow traceability to the sampling location and the sampling collection activity, as well as other appropriate documentation such as drawings, specifications, purchase orders, drilling logs, field records, test records, inspection document, and nonconformance reports. These procedures shall include organizational responsibilities.

8.4.6.1 An unique identification number or symbol shall be assigned to each sample as soon as it is obtained.

8.4.6.2 Sample identification shall provide a clear association with the work activity for which the sample is being taken; traceability to such data as

sample source and description of the sample time, date, and place of sample collection; and identification of personnel obtaining the sample collection.

8.4.6.3 Sample identification shall be permanently attached or otherwise associated with the sample without affecting or contaminating the sample.

8.4.6.4 As appropriate, an identification may be placed on the sample, on the container, or on records traceable thereto.

8.4.6.5 If a sample is subdivided, each subsample shall be assigned its own identification, which retains the subsample's association with the original sample.

8.4.6.6 Field tracking and reporting forms shall be employed to establish sample status and history (i.e., chain-of-custody).

8.4.6.7 Chain-of-custody procedures shall be developed and followed, and shall apply to all samples. The procedures shall establish a chain-of-custody from sample collection until sample destruction or final disposition.

8.4.6.8 Procedures for sample preservation shall be developed and followed.

8.4.6.9 Documentation shall be made of the procedures for preparation of reagents or supplies that become an integral part of samples (e.g., preservation, filters, etc.).

8.4.6.10 Correct identification of samples shall be verified and documented prior to release for use or analysis.

TITLE CONTROL OF PROCESSES

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

9.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures that processes which affect the quality of items or services are appropriately controlled.

9.2 APPLICABILITY

The requirements of this Section are applicable to the control of processes which could affect the quality of quality-related items or services. Such processes include, but are not limited to, welding, heat treating, chemical cleaning, non-destructive examination (NDE), data collection and analysis, sample collection laboratory processes and analysis, handling of waste packages, inspection, testing, and computer processes.

9.3 RESPONSIBILITIES

SRPO retains the overall responsibility for ensuring that documents which prescribe the control of processes are controlled in accordance with QAAPs which satisfy the requirements of this Section.

9.3.1 SRPO CHIEFS

9.3.1.1 The SRPO Chiefs are responsible for assuring that the requirements of this Section are incorporated into procurement documents as required for the Prime Contractors scope of work.

The SRPO Chiefs shall assure that QAAPs are prepared and approved for any quality-related activity conducted by SRPO relative to the requirements of this Section.

9.3.1.2 The Chief, Quality Assurance, is responsible for ensuring that the requirements of this Section are incorporated into QA specifications as may be required, taking into consideration the Prime Contractors scope of work and the graded approach to QA.

The Chief, Quality Assurance, shall assure through surveillance and audit activities that process controls instituted by SRPO and/or the Prime Contractors are approved and effectively implemented.

9.3.2 PRIME CONTRACTOR

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification as applicable to their scope of work and shall pass the applicable requirements or to their contractors.

9.4 REQUIREMENTS

Processes affecting the quality of items or services shall be controlled. Special processes that control, or verify quality, shall be performed by qualified personnel using qualified procedures and equipment. The criteria for determining those processes that are controlled as special processes shall be documented in procedures.

9.4.1 PROCESS CONTROL

9.4.1.1 Processes shall be prescribed by instructions, procedures, drawings, checklists, or other appropriate means.

9.4.1.2 Process parameters shall be specified and controlled.

9.4.1.3 Environmental conditions under which the process is to be performed shall be specified and maintained.

9.4.1.4 The criteria for determining those processes that are controlled as special processes shall be prescribed in procedures.

9.4.2 SPECIAL PROCESSES

Special processes are those processes where process quality is dependent largely on the skill of the operator and on the control of process parameters and cannot be assured by the inspection of the material or items alone. These processes shall be identified. Special processes shall be performed by qualified personnel using qualified procedures and qualified equipment. Each process shall be performed in accordance with appropriate instructions.

9.4.2.1 Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements.

9.4.2.2 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.

9.4.2.3 The requirements of applicable codes and standards shall be specified or referenced in the procedures or instructions.

9.4.2.4 Acceptance criteria shall be included and referenced by the procedures or instructions.

9.4.3 QUALIFICATION OF PERSONNEL, PROCEDURES, AND EQUIPMENT

9.4.3.1 Procedures, equipment, and personnel associated with special processes shall be qualified in accordance with applicable codes, standards, QA procedures, and specifications, or when necessary, supplementary procedures.

9.4.3.2 Personnel shall be certified, and the certifications maintained through recertification, when required by governing codes or standards.

9.4.3.3 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.

9.4.3.4 The QA organization shall monitor qualification activities to verify that they are satisfactorily performed and comply with specified requirements.

9.4.3.5 Re-qualification of personnel, procedures and equipment shall be prescribed in procedures when required by governing codes and standards.

9.4.4 RECORDS

9.4.4.1 Records shall be maintained, as appropriate, for the qualified personnel, procedures, and equipment of each special process.

9.4.4.2 Special processes shall be accomplished and documented on written process sheets, shop procedures, checklists, or equivalent reports. These shall provide for recording evidence of acceptable performance of the process, verification of performance, and, if applicable, inspection and process results.

TITLE

INSPECTION

SRPO MANAGER	DATE	CHIEF, QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

10.1 PURPOSE

This Section establishes the responsibilities and requirements by which the SRPO assures verification of conformance of an item or activity to its specified requirements through inspection activities.

10.2 APPLICABILITY

This Section is applicable to inspection activities performed on items and activities affecting quality.

10.3 RESPONSIBILITIES

SRPO retains the overall responsibility for ensuring that documents which prescribe inspection activities are controlled in accordance with QAAPs which satisfy the requirements of this Section.

10.3.1 SRPO CHIEFS

10.3.1.1 The SRPO Chiefs are responsible for the development and identification of inspection characteristics, methods, acceptance and rejection criteria, and the recording of inspection results for those inspections performed by SRPO.

SRPO Chiefs shall ensure that procurement specifications incorporate inspection requirements to assure conformance with specification requirements.

10.3.1.2 The Chief, Quality Assurance, is responsible for coordinating the development of inspection QAAPs for SRPO inspection activities and approval of those QAAPs. The Chief, Quality Assurance, shall also be responsible for independent inspections of contractor activities to verify QA program implementation.

10.3.2 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA Specification as applicable to their scope of work and shall pass the applicable requirements on to their contractors.

10.4 REQUIREMENTS

Inspections shall be planned and executed to verify conformance of items and activities to their specified requirements.

The general procedures controlling inspections shall establish the criteria for the planning of inspections, conduct of inspections, qualification of personnel conducting inspections, documentation of inspections, and acceptance of the items or activities being inspected. These procedures may be supplemented by activity or item-specific instructions.

10.4.1 INSPECTION PLANNING

10.4.1.1 Planning for inspection activities shall be accomplished and documented within activity specific procedures which provide for inspection instructions, and an appropriate list of items to be inspected. The documentation shall identify:

a) Characteristics or activities to be inspected.

b) Method of inspection, including, verification of calibration and the integrity of instruments and instrument systems and verification of maintenance, as appropriate.

c) Individuals or groups responsible for performing the inspection.

d) Acceptance and rejection criteria.

e) Required procedures, drawings, and specifications and applicable revisions thereto.

f) Identification of the inspector and the objective evidence of inspection results.

g) Necessary measuring and test equipment, including the accuracy and precision requirements.

h) As applicable, mandatory inspection hold points beyond which work will not proceed without authorized consent to waive the hold point.

10.4.1.2 Controls, where required, shall be established and documented for the coordination and sequencing of hold points at established inspection points during successive stages of the activity.

10.4.1.3 The final inspection shall be planned to arrive at a conclusion regarding conformance of the item or activity to specified requirements.

10.4.2 PERFORMANCE OF INSPECTION

10.4.2.1 Inspection of quality affecting items or activities to verify conformance to the requirements established shall be performed according to the following requirements:

a) Sampling procedures used to verify acceptability of a group of items shall be based on recognized standard practices.

b) In-process inspections shall be performed for work activities when necessary to verify quality.

c) Monitoring of process methods, equipment, and personnel shall be performed when inspection is impossible, disadvantageous, or insufficient to verify quality.

d) Both inspection and process monitoring shall be performed in a systematic manner when control is inadequate without both, to assure that the specified requirements for control of the process and quality of the item are being achieved.

e) Final inspection shall include records review of the inspection results and resolution of nonconformances identified by prior inspections and their resolution. Quality records shall be examined for adequacy and completeness.

f) Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify quality and conformances of each item to specified requirements.

g) Consent to waive specified hold points shall be recorded and approved by authorized personnel prior to continuation of work beyond the designated hold point.

h) Required in-service inspection or surveillance shall be planned and performed by or for SRPO.

10.4.2.2 Procedures shall be established and implemented to verify that the characteristics of an item continue to remain within specified limits. These procedures shall include:

a) Evaluation of performance capability of essential emergency and safety systems, equipment and activities.

b) Verification of calibration and integrity of instruments and instrument systems.

c) Verification of required maintenance of the item.

10.4.3 REINSPECTION

Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate to verify acceptability. Reinspection or retest shall be performed in accordance with original requirements.

10.4.4 INSPECTION RESULTS

Inspection results shall be documented and evaluated, and their acceptability shall be determined by an authorized individual. As a minimum, records of inspection results shall identify:

a) Item inspected.

b) Date of inspection.

c) Inspector.

d) Type of observation.

e) Results of acceptability.

f) Reference to information on action taken in connection with nonconformances.

g) Traceability.

10.4.5 INSPECTION PERSONNEL

Personnel performing inspections of work activities for purposes of acceptance shall be:

a) Qualified and authorized to perform the assigned inspection task in accordance with an established qualification program for inspectors. Inspector certifications shall be documented and kept current.

b) Independent of, and shall not report directly to, the immediate supervisors who are responsible for the work being inspected.

c) Part of the QA organization except for inspection requiring special expertise in which case the independence of the inspection function from the work activity shall be maintained.

10.4.6 INSPECTION PROCEDURES

Review, approval, and control of inspection procedures shall be in accordance with Section 6.0.

10.4.7 RECORDS

All inspection and test records shall contain the following, where applicable:

a) A description of the type of observation.
b) The data 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.

TITLE TEST CONTROL

SRPO MANAGER	DATE	CHIEF QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

11.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO ensures that field and laboratory conducted development and performance tests are defined, implemented, and verified in accordance with stated requirements.

11.2 APPLICABILITY

This Section is applicable to the development of test plans by SRPO and development and implementation of contractor procedures for the conduct of development and performance testing to determine conformance to specified requirements and that items will perform satisfactorily in service.

11.3 RESPONSIBILITIES

The SRPO retains overall responsibility for ensuring that tests as required are conducted and controlled in compliance with the requirements of this Section.

11.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO, has ultimate responsibility for development of test plans and for test control related to SRPO. The SRPO chiefs have been delegated test control responsibilities as applicable to their activities.

11.3.2 SRPO CHIEFS

11.3.2.1 The Chiefs are responsible for development of test plans which will implement the overall DOE program objectives and regulatory performance requirements, and subsequent design criteria and specifications.

To ensure that SRPO test plans and contractor procedures implement the requirements of this section and the regulatory performance requirements, the Chiefs are responsible for review and approval of test plans and procedures generated by contractors in their areas of responsibility.

The Chiefs shall monitor site characterization tests as well as any other types of field and laboratory development tests conducted by contractors to verify proper implementation of the requirements of paragraph 11.4.

11.3.2.2 The Chief, Quality Assurance, is responsible for review of and concurrence with SRPO controlled test plans.

11.3.3 PRIME CONTRACTORS

Prime Contractors to SRPO shall establish and implement a QA program and procedures which satisfy the requirements of this Section, and the applicable QA Specification, as applicable to their scope of work as identified within the SRPO QA specification and shall pass those requirements on to their contractors, as applicable.

11.4 REQUIREMENTS

11.4.1 TEST PROCEDURES

11.4.1.1 Tests shall be planned and executed to verify conformance of an item to specified requirements. As such, procedures shall be established to provide the criteria for developing and implementing test plans and specific types of testing procedures. The procedures shall provide:

a) Criteria for determining when a test is required.

b) Criteria for determining how testing activities will be conducted.

c) Provisions to assure that only trained and qualified personnel perform tests.

d) Clear direction for developing test plans that assure the reliability of test results and traceability of test results to accepted standards.

11.4.1.2 The procedure controlling the planning of tests shall address the requirements related to all phases of testing, including test planning, prerequisites, conduct of testing, environmental conditions, qualifications, requirements, documentation and acceptance of test results.

11.4.1.3 Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested.

11.4.1.4 Test plans and procedures shall be reviewed in accordance with the verification requirement of Section 3.0 of this QA plan.

11.4.2 PLANNING

11.4.2.1 The planning for test activities shall be accomplished and documented. The documentation shall identify:

a) Characteristics to be tested.

b) Requirements and acceptance limits contained in applicable documents, including required precision and accuracy, potential sources of uncertainty in test procedures, plans, and parameters shall be identified.

c) Methods for performing the test. In lieu of specially prepared written test procedures appropriate sections of related documents, methods, supplier manuals, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions.

d) Mandatory inspection/monitoring 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.

i) Available personnel qualified to perform test activities.

11.4.2.2 Test procedures shall include provisions for assuring that prerequisites for a given test are met. These prerequisites include the availability and use of calibrated instrumentation and adequate test equipment and instrumentation, the completeness of item to be tested, suitable and controlled environmental conditions, that necessary monitoring is performed, and provisions for data collection and storage.

11.4.3 TEST PERSONNEL

Personnel performing tests shall possess the appropriate level of qualification, in accordance with established procedures.

11.4.4 PERFORMANCE

Tests shall be conducted to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in use. Tests shall be performed by qualified personnel in accordance with approved procedures.

11.4.5 TEST RESULTS

Test results shall be documented and evaluated by a responsible authority to determine conformance with acceptance criteria. Test records shall, as a minimum, identify:

a) Item tested (e.g., item number, part number, system number).

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.

11.4.6 DOCUMENT CONTROL

Test plans and procedures shall be reviewed and controlled in accordance with Section 6.0.

11.4.7 RECORDS

Test records shall contain requirements as addressed in Section 10. of this QA plan.

TITLE: CONTROL OF MEASURING AND TEST EQUIPMENT

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

12.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures that all measuring and test equipment used for quality-related activities are adequately controlled.

12.2 APPLICABILITY

The requirements of this Section are applicable to the control of all tools, gages, instruments, and other measuring, test and analytical equipment used for quality-related activities.

12.3 RESPONSIBILITIES

The SRPO retains overall responsibility for assuring that measuring and test equipment used for quality-related project activities are controlled.

12.3.1 SRPO CHIEFS

12.3.1.1 The SRPO Chiefs have the primary responsibility for assuring that measuring and test equipment is controlled and maintained within calibration. The SRPO Chiefs are responsible for:

a) Including in procurement documents requirements to implement this Section.

b) Preparing QAAPs to implement the requirements of this Section within SRPO, as applicable.

c) Review and approval of Prime Contractor calibration procedures developed to implement the requirements of this Section.

12.3.1.2 The Chief, Quality Assurance, shall assure through audits and surveillances that controls are established by the SRPO and the Prime Contractors to control measuring and test equipment.

The Chief, Quality Assurance, is responsible for reviewing and approving SRPO QAAPs developed to implement the requirements of this Section.

12.3.3 PRIME CONTRACTORS

Prime Contractors shall establish and implement QA programs and procedures which satisfy the requirements of this Section and the QA specifications applicable to their scope of work and shall pass the applicable requirements on to their contractors.

12.4 REQUIREMENTS

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits.

Procedures shall be established for calibration, maintenance and control of the measuring and test equipment used for measurement inspection, or monitoring quality-related activites, processes or items.

12.4.1 IDENTIFICATION OF EQUIPMENT REQUIRING CONTROL

The types of equipment requiring control shall be established. Such equipment shall include, but not be limited to, all measuring, test and analytical instruments, tools, gages, reference and transfer standards, and non-destructive test equipment used in the monitoring, measurement, inspection and analysis of quality-related items or activities.

12.4.2 SELECTION OF EQUIPMENT

The 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.

12.4.3 CALIBRATION OF EQUIPMENT

12.4.3.1 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.

12.4.3.2 If no recognized standards exist, the basis for calibration shall be documented, reviewed and accepted. The basis for acceptance shall also be documented.

12.4.3.3 Calibration procedures shall contain appropriate calibration acceptance/rejection criteria.

12.4.4 CONTROLLED EQUIPMENT

12.4.4.1 The method and interval of calibration for each item shall be defined, based on the equipment type, stability, characteristics, required accuracy, intended use, and other conditions that may affect control.

12.4.4.2 Controls shall be established to assure that controlled equipment is recalled from use as required for recalibration.

12.4.4.3 When 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 also the acceptability of items inspected or tested since the last calibration. Inspections or tests shall be repeated on those items determined to be suspect, as determined to be necessary, based on the evaluation.

12.4.4.4 Out-of-calibration devices shall be tagged, segregated and not used until recalibrated.

12.4.4.5 Equipment found to be consistently out of calibration shall be repaired and recalibrated or replaced.

12.4.4.6 Recalibration shall be performed and documented whenever the accuracy of the equipment is suspect, and before its previous calibration expires.

12.4.5 COMMERCIAL DEVICES

Calibration and control measures may not be required for rulers, tapes, levels, and other devices, if normal commercial equipment provides adequate accuracy.

12.4.6 HANDLING AND STORAGE

Measuring and test equipment shall be properly handled and stored to maintain accuracy.

12.4.7 RECORDS

Records shall be maintained and equipment shall be suitably marked to indicate calibration status.

12.4.7.1 Records shall include objective evidence that the status of all items under the calibration system are recorded and maintained.

12.4.7.2 Controlled measuring and test equipment shall be identified and traceable to the calibration test data.

12.4.7.3 Controlled equipment shall be suitably marked to indicate calibration status and date of the next calibration and to provide traceability to calibration test data.

TITLE: HANDLING, STORAGE, AND SHIPPING

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

13.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures the proper handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration.

13.2 APPLICABILITY

This procedure applies to the handling, storage, cleaning, packaging, shipping and preservation of all quality-related items and related activities.

13.3 RESPONSIBILITY

The SRPO retains overall responsibilities for assuring that adequate measures have been established and implemented for the control of handling, storage and shipping of quality-related items.

13.3.1 SRPO CHIEFS

13.3.1.1 The SRPO Chiefs are responsible for assuring that procedures are established to control the handling, shipping and storage of quality-related items, and for assuring that the requirements of this Section are included in applicable procurement documents.

13.3.1.2 The Chief, Quality Assurance, is responsible for:

a) Reviewing and concurring with SRPO procedures which control handling, shipping and storage.

b) Reviewing SRPO procurement documents to assure that the requirements of this Section are included.

c) Verifying through audits and surveillances, that contractors properly implement their handling, storage and shipping procedures.

13.3.2 PRIME CONTRACTORS

Prime Contractors to SRPO are responsible for establishing QA Programs and procedures which satisfy the requirements of this Section, and the QA Specification, as applicable to their scope of work, and shall pass the requirements on to their contractors.

13.4 REQUIREMENTS

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

Handling, storage, and shipping of items shall be 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.

13.4.1 PROCEDURES

Specific procedures for handling, storage, packaging, shipping, cleaning and preservation shall be used when required for quality-related, critical, sensitive, perishable, or high-value items.

13.4.1.1 Written procedures shall provide for 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) when required for particular items and their existence shall be verified.

13.4.1.2 Instructions and procedures for marking and labeling of items during packaging, shipment, handling, and storage shall be established to adequately identify, maintain, and preserve the item. The identification of items shall include an indication of the presence of special environments or the need for special controls.

13.4.1.3 Procedures shall provide for cleaning and preservation of all items whose quality may be affected by foreign objects and environmental conditions.

13.4.1.4 Procedures shall provide for control of the handling, storage, packaging, preservation, cleaning and shipping of geological and environmental samples to preclude damage, loss, or deterioration. The procedures shall provide for traceability of samples.

13.4.1.5 Written procedures shall provide for the handling, preservation, storage, packaging, cleaning and shipping by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.4.2 SPECIAL TOOLS

13.4.2.1 Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling.

13.4.2.2 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.

13.4.2.3 Operators of special handling tools and equipment shall be experienced or trained in the use of the specific tools or equipment.

TITLE

INSTRUCTION, TEST, AND OPERATING STATUS

SRPO MANAGER	DATE	CHIEF, QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

14.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures that quality-related items are not inadvertently used prior to performance of required tests and inspections. This Section also establishes the responsibilities and requirements by which SRPO identifies the status of required tests and inspection and the operating status of structures, systems and components.

14.2 APPLICABILITY

This Section is applicable to all SRPO quality-related items and activities for which inspection, test and operating status controls are applicable.

14.3 RESPONSIBILITIES

SRPO retains overall responsibility for assuring that adequate measures have been established and implemented for indicating the inspection, test and operating status of quality-related items.

14.3.1 SRPO CHIEFS

14.3.1.1 The SRPO Chiefs shall ensure that procedures are established for the identification and control of status indicators and for assuring that the requirements of this Section are included in applicable procurement documents.

14.3.1.2 The Chief, Quality Assurance, is responsible for:

a) Review and concurrence of SRPO QAAPs which control status indicators for quality-related items.

b) Review of SRPO procurement and QA specifications to assure that the requirements of this Section are included.

c) Audit and surveillance of contractors to verify the proper implementation of their procedures which control status indicators.

14.3.2 PRIME CONTRACTORS

Prime Contractors to SRPO are responsible for establishing QA Programs and procedures which satisfy the requirements of this Section and the QA Specification, as applicable to their scope of work, and shall pass the requirements on to their contractors.

14.4 REQUIREMENTS

14.4.1 STATUS IDENTIFICATION

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.

14.4.1.1 Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.

14.4.1.2 Procedures shall be established to indicate, by the use of markings, the status of inspections and tests on individual items.

14.4.1.3 Status indicators shall also provide for indicating the operating status of systems and components of the facility to prevent inadvertent operation.

14.4.2 AUTHORIZED PERSONNEL

The authority for application and removal of tags, markings, labels, and stamps shall be specified in procedures.

TITLE: CONTROL OF NONCONFORMING ITEMS AND ACTIVITIES

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

15.1 PURPOSE

This Section establishes the responsibilities and requirements by which the SRPO assures that all project activities and items which do not conform to the SRPO QA Program requirements are properly identified, documented and dispositioned.

15.2 APPLICABILITY

This Section applies to the control of nonconforming items and activities identified within the scope of the SRPO QA Program.

15.3 RESPONSIBILITIES

SRPO retains the overall responsibility for assuring that project activities and items that do not conform to the requirements established are identified, documented, evaluated, segregated (when practical) and dispositioned.

15.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO, shall ensure that controls are established for the identification, documentation and disposition of nonconforming items and activities and to provide management support to the timely disposition of nonconforming items or activities.

15.3.2 SRPO CHIEFS

15.3.2.1 The SRPO Chiefs are responsible for:

a) Documenting on Nonconformance Reports (NCRs) those conditions which meet the definition of nonconformance (see glossary for definition). SRPO generated Nonconformance Reports may be initiated by any SRPO individual and shall be submitted to the Chief, Quality Assurance, who shall validate, assign control numbers, process and control the NCR in accordance with the applicable QAAP. The NCR shall be evaluated and dispositioned by the responsible Chief and administered in a timely manner.

b) Assuring that all SRPO nonconformance reports, and Prime Contractor issued nonconformance reports dispositioned as "use-as-is" or "repair", are correctly dispositioned, and that the disposition will correct the nonconforming condition. NCRs shall also be evaluated to determine if the nonconforming condition may constitute a significant condition adverse to quality, per the criteria provided in Section 16.0 of this QA plan. If a significant condition adverse to quality is identified, a Corrective Action Report shall be generated in accordance with the controlling QAAP.

c) Assuring that a "stop work" condition is documented on a NCR.

15.3.2.2 The Chief, Quality Assurance, shall be responsible for the preparation of QAAPs which shall meet the requirements of this Section and shall also have the following responsibilities:

a) Administration of the nonconformance control system. This system shall include issuing and logging the NCR control numbers, maintaining the status of the NCR, including its disposition, verification of completion of the recommended disposition and close out of the NCR. Overdue responses shall be monitored and periodically reviewed with the Project Manager, SRPO.

b) Coordination and the administration of Prime Contractor NCRs issued to SRPO, which have been dispositioned "use-as-is" or "repair" to ensure that the NCR has been reviewed and approved by cognizant SRPO Chiefs in accordance with an applicable QAAP.

c) Provision of a documented system for trending NCRs by SRPO and Prime Contractors and reporting significantly adverse trends to management, using a Corrective Action Report.

d) Verification through audits and surveillances that Prime Contractors are adhering to their responsibilities and the requirements of this Section, and their QA program, relative to control of nonconforming items and activities.

15.3.3 PRIME CONTRACTOR

Prime Contractors to SRPO are responsible for establishing QA Programs and procedures which satisfy the requirements of this Section and the QA Specification, as applicable to their scope of work, and shall pass the requirements on to their contractors.

15.3.3.1 Prime Contractors shall submit all nonconformance reports dispositioned as "use-as-is" and "repair" to SRPO for review and approval of the disposition.

15.3.3.2 Prime Contractors shall submit to the SRPO Chief, Quality Assurance, semi-annual trend analysis reports of their initiated nonconformance reports.

15.4 REQUIREMENTS

15.4.1 CONTROL PROCEDURES

15.4.1.1 Items or activities that do not conform to specified requirements shall be controlled to prevent their inadvertent installation, use or continued processing. The nonconforming conditions shall be corrected or dispositioned in a timely manner.

15.4.1.2 Controls shall be provided for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items or activities, and for the notification of the NCR to the affected organizations. Procedures shall also identify individuals or organizations authorized to dispose of and close out nonconformances. Additionally, procedures shall provide for follow-up and verification of NCR closeout.

15.4.2 IDENTIFICATION

The 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. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

15.4.3 SEGREGATION

Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight,

or access limitations, other precautions shall be documented and employed to preclude inadvertent use of a nonconforming item.

15.4.4 DISPOSITION

Nonconforming conditions of the item or activity shall be reviewed and recommended dispositions shall be proposed and approved in accordance with procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation, and an approved disposition by authorized personnel. The responsibility and authority for evaluation and disposition of nonconforming items shall be defined.

15.4.4.1 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 any pertinent background information.

15.4.4.2 The final disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned "repair," or "use-as-is" shall also be documented. The as-built records, if such records are required, shall reflect the accepted deviation. 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.

15.4.7 RECORDS

Documentation shall include description and identification of the nonconformance, disposition of the nonconformance and signature approval of the disposition. Nonconformance Reports shall be periodically analyzed by the QA organizations to identify quality trends of nonconformances. The results shall be reported to upper management for review and assessment.

TITLE

CORRECTIVE ACTION

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

16.1 PURPOSE

This Section establishes the responsibilities and the requirements by which the SRPO assures that significant conditions adverse to quality are identified, documented, administered and corrected. This Section also establishes requirements for trending conditions adverse to quality and reporting these trends to management.

16.2 APPLICABILITY

This Section shall be applicable to all items and activities found to be significant conditions adverse to quality.

16.3 RESPONSIBILITIES

SRPO retains overall responsibility for assuring that significant conditions adverse to quality are identified, documented, administered and corrected.

16.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO, shall ensure that controls are established and implemented to control significant conditions adverse to quality, in accordance with this Section. Additionally, he shall assure that line management is actively identifying, documenting, processing and providing timely responses to Corrective Action Reports (CARs).

The Project Manager, SRPO, has the overall responsibility to assure that significant conditions adverse to quality are documented on a Corrective Action Report (CAR) and are communicated to DOE-Chicago Operations Office and DOE-Office of Geologic Repositories (OGR) for information.

The Project Manager, SRPO, shall evaluate Corrective Action Reports for reportability as an Unusual Occurrence Report.

16.3.2 SRPO CHIEFS

16.3.2.1 The SRPO Chiefs are responsible for:

a) Identication of those conditions which meet the documented criteria for significant conditions adverse to quality and report those conditions to the Chief, Quality Assurance, who shall initiate, control and process a Corrective Action Report (CAR) in accordance with the related QAAP.

b) Determination if the conditions adverse to quality as documented on CARs justify "stopping work", as defined with the Glossary of this QA Plan.

c) Evaluation of the CARs distributed to the SRPO from Prime Contractors and concur or reject the disposition taken and administer the CAR in accordance with the controlling QAAP.

16.3.2.2 The Chief, Quality Assurance, is responsible for the preparation of the SRPO QAAPs relative to the administration of Corrective Action Reports and trending in accordance with the requirements of this Section. The Chief, Quality Assurance, also has the following responsibilities:

a) Administration of the Corrective Action Reporting system, as documented in the appropriate QAAP. The system shall include logging, controlling, tracking for final verification of close out and documenting the status of any overdue responses, and periodically reporting to the Project Manager, SRPO, the status of overdue CAR responses.

b) Coordination of the administration (control, tracking, trending and status) of CARs issued to or received by SRPO, for review, evaluation and/or reporting to management.

c) Provision of a documented system for the trending and reporting of CARs and NCRs by SRPO and the Prime Contractors to management. Deficiency and cause trend codes shall be uniformly used by SRPO and the Prime Contractors to provide uniformity in trending data. The SRPO QA specifications shall place these trending requirements on the Prime Contractors. Deficiency information to be trended shall include nonconformances, corrective action reports, and audit/surveillance findings.

16.3.3 PRIME CONTRACTORS

Prime Contractors to SRPO are responsible for establishing QA Programs and procedures which satisfy the requirements of this Section and the QA specification, as applicable to their scope of work, and shall pass the requirements on to their contractors.

16.3.3.1 Prime Contractors shall provide the SRPO Chief, Quality Assurance, through the cognizant SRPO Chief or the responsible Technical Manager, with copies of Corrective Action Reports generated under their quality assurance program.

16.3.3.2 Prime Contractors shall submit to the SRPO Chief, Quality Assurance, through the cognizant SRPO Chief or the responsible Technical Manager, semi-annual trend analysis reports of the Corrective Action Reports generated.

16.4 REQUIREMENTS

16.4.1 IDENTIFICATION

16.4.1.1 Significant quality problems as defined by the criteria in this Section shall be identified promptly, reported to appropriate levels of management and corrected as soon as practical.

16.4.1.2 In cases where the condition adverse to quality is identified and documented as a nonconforming condition (See Section 15.0), the Nonconformance Report may be escalated to a significant condition adverse to quality, and documented on a Correction Action Report, at the discretion of the cognizant SRPO Chief or the Project Manager, SRPO.

16.4.1.3 When the results of trending activities (e.g., trending of nonconformances, trending of inspection results) indicate a significantly adverse trend, a Corrective Action Report shall be initiated.

16.4.1.4 When an audit finding is determined to constitute a significant condition adverse to quality, a Corrective Action Report shall be initiated.

16.4.1.5 When the need for a Corrective Action Report is identified, the Chief, identifying the need, shall contact the Chief, Quality Assurance, to initiate a CAR. All CARs will be initiated, administered and controlled by the quality assurance organization.

16.4.2 SIGNIFICANT QUALITY PROBLEMS

When a condition adverse to quality is determined to be a significant quality problem, the cause of the condition shall be determined and corrective action taken to preclude reoccurrence. The QA organization shall concur with the adequacy of the corrective action.

16.4.3 INITIATION OF CORRECTIVE ACTION

Following the initiation of a Corrective Action Report, the report form describing the significant condition adverse to quality shall be transmitted to the line manager responsible for the activity or item involved. The responsible line manager shall determine the cause of the condition and the corrective action necessary to prevent recurrence.

16.4.4 REPORTING TO MANAGEMENT

Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude recurrence shall be documented and reported to the upper levels of management for review and assessment.

16.4.5 FOLLOW-UP ACTION

When corrective actions have been implemented, appropriate follow-up action shall be taken by the QA organization to verify effectiveness and to close out the corrective action in a timely manner.

16.4.6 CRITERIA

A Corrective Action Report shall be initiated when any one of the following conditions are identified:

a) Trends adverse to quality, as identified by any organization within SRP, which indicates a significant quality problem. Trending procedures shall contain the criteria for identification of an adverse trend.

b) Any deficiency in an item, activity or document which, if not detected and corrected, could have an adverse effect on an item or items important to safety or important to waste isolation.

c) A design deficiency, construction or fabrication error found subsequently during construction, testing, modification or operation which, had it remained undetected, could have had an adverse effect on the performance, reliability or safety of the facility at some point in its design lifetime.

d) A significant breakdown or failure in any portion of quality assurance programs.

e) Any significant quality problem.

16.4.6 RECORDS

Documentation of corrective actions shall include:

a) Identification of the adverse condition.

b) Immediate action taken to alleviate the condition.

c) Corrective action to be taken.

d) Evaluation of corrective action.

e) Verification of implementation and effectiveness of corrective action.

f) Responsible individual and/or organization.

TITLE

QUALITY ASSURANCE RECORDS

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

17.1 PURPOSE

This Section establishes the responsibilities and requirements by which SRPO assures the identification, issuance, storage, maintenance, traceability and retrievability of quality assurance records.

17.2 APPLICABILITY

This Section applies to all SRP documents which are considered quality assurance records and to the activities which involve these records.

17.3 RESPONSIBILITIES

SRPO retains overall responsibility for assuring that adequate measures have been established and implemented for the control of quality assurance records.

17.3.1 PROJECT MANAGER, SRPO

The Project Manager, SRPO, is responsible for ensuring the establishment of controls to assure that records which furnish evidence of activities affecting quality are identified, prepared, stored and maintained.

17.3.2 SRPO CHIEFS

17.3.2.1 The SRPO Chiefs are responsible for:

a) Assuring that procedures are established and implemented by contractors to identify, collect, maintain and distribute or submit QA records.

b) Identifying documentary evidence which is or will become QA records.

c) Generating QA records for documenting quality-related activities.

d) Designating record retention periods within their areas of responsibility.

17.3.2.2 The Chief, Budget and Project Control, shall establish records transfer procedures for the Prime Contractors to assure that all quality assurance records are provided to SRPO.

17.3.2.3 The Chief, Quality Assurance, is responsible for:

a) Developing implementing SRPO procedures (QAAPs) which control the identification, collection, receipt, retention, and storage of QA records.

b) Reviewing SRPO procurement documents to assure that requirements of this Section are included.

c) Verifying through audit and surveillance that contractors develop and implement QA records control procedures.

d) Designating the retention period of Quality Assurance records.

e) Establishing or concurring with the responsibilities for controlling and maintaining record storage facilities.

f) Verifying periodically the availability of records stored for SRPO by other organizations.

17.3.3 PRIME CONTRACTORS

Prime Contractors to SRPO are responsible for establishing QA Programs and procedures which satisfy the requirements of this Section and the QA Specification, as applicable to their scope of work, and shall pass the requirements on to their contractors.

Prime Contractors to SRPO have been delegated the responsibility to provide an integrated records control system which assures control of QA records from initiation to final records storage. This system shall identify records which are retained by their contractors, and shall include provisions for records transfer. This system shall implement the requirements of this Section.

A Records Management Plan which describes this system shall be submitted to SRPO for review and concurrence.

17.4 REQUIREMENTS

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. All records shall be protected against damage, deterioration, or loss. All requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented in procedures.

17.4.1 RECORDS SYSTEM

A records system shall be established prior to site characterization by SRPO and each contractor who generates and stores QA records. The records system shall be defined and implemented in accordance with written procedures. The scope of the records program shall be defined.

17.4.2 RECORD TYPES

The applicable design specifications, procurement documents, test plans and procedures, operational procedures or other documents shall specify the quality assurance records to be generated, supplied, or maintained by or for the SRPO. All documents that are designated to become QA records shall be legible, accurate, and completed appropriate to the work accomplished.

17.4.3 AUTHENTICATION

Documents shall be considered valid QA 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. The records may be originals or reproduced copies.

17.4.4 INDEX

Records shall be indexed. The indexing system shall include, as a minimum, record retention times and location of the record within the record system.

17.4.5 DISTRIBUTION

Records shall be distributed, handled and controlled in accordance with written procedures.

17.4.6 TRACEABILITY

Records and/or the indexing system shall provide sufficient information to permit identification between the record and the item or activity to which it applies.

17.4.7 CLASSIFICATION

Records shall be classified and maintained in accordance with the following criteria for permanent or non-permanent records:

17.4.7.1 Permanent records are those that fall under one or more of the following criteria:

a) Those which would be of significant value in demonstrating capability for safe operation.

b) Those which would be of significant value in determining the cause of an accident or malfunction of an item.

c) Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.

d) Those which provide required baseline data to inservice inspections.

e) Those which provide a basis for licensing of the repository.

17.4.7.2 Non-permanent 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 permanent records. The retention period, custodian and storage location for non-permanent records shall be established in writing.

17.4.8 CORRECTION

Records may be corrected in accordance with procedures approved by SRPO. Procedures shall include a review of corrections by the originating organization. The correction shall include the date of correction and the identification of the individual authorized to issue the correction.

17.4.9 RECEIPT CONTROL

The individual or organization responsible for receiving records shall provide protection from loss or damage during the time that records are in their possession. The receipt control system shall include the following:

a) Identification of the designated organization responsible for receipt control.

b) A method for designating the required records.

c) A method for identifying records received.

d) Procedures for receipt and inspection of incoming records.

e) A method for maintaining current and accurate assessment of the status of records during the receiving process.

17.4.10 STORAGE PROCEDURE

Storage, preservation, and safekeeping of QA Records shall meet the requirements of this Section. Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. The procedure shall include:

a) A description of the storage facility, or the various storage locations when duplicate storage is used.

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.

e) The rules governing access to and control of the file.

f) A method for maintaining control of and accountability for records removed from the storage facility.

g) A method for filing supplemental and/or corrected information and disposing of superseded records.

17.4.11 STORAGE METHOD

All records maintained in hardcopy form shall be stored in a manner approved by the Purchaser.

17.4.11.1 Provisions shall be made for storage arrangement to prevent damage from moisture, temperature, and pressure.

17.4.11.2 All records maintained in hardcopy form shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.

17.4.11.3 Provisions shall be made for special processed records such as radiographs, photographs, negatives, microform, and magnetic media, to prevent damage from excessive light, pressure, electromagnetic fields, temperature, and humidity.

17.4.12 AUTHORIZED PERSONNEL

Measures shall be established to preclude the entry of unauthorized personnel into the records storage area. These measures shall guard against larceny and vandalism.

17.4.13 DAMAGED RECORDS

Measures shall be established to provide for replacement, restoration, or substitution of lost or damaged records. If replacement or restoration of lost or damaged records is not practical, action should be taken to assure the quality of items or activities affecting quality, e.g., reexamination or investigation by alternate means.

17.4.14 STORAGE FACILITIES

All records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

a) Natural disasters such as winds, flood or fires;

b) Environmental conditions such as high or low temperatures or humidity;

c) Infestation of insects, mold or rodents.

There are two acceptable methods of providing storage facilities; single or dual facilities.

17.4.14.1 Design and construction of a single record storage facility shall meet the following criteria:

a) Reinforced concrete, concrete block, masonry or equal construction.

b) Floor and roof with drainage control. If floor drain is provided, a check valve shall be included.

c) Doors, structures and frames, and hardware shall be designed to comply with the requirements of a minimum two hour 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.

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 two hour rating.

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. 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.

17.4.14.2 Alternatives to the requirements of paragraph 17.4.14.1 above are as follows:

a) Two hour fire rated vault meeting NFPA 232-1975.

b) Two hour fire rated Class B fire containers meeting the requirements of NFPA 232-1975.

c) Two hour fire rated fire room meeting the requirements of NFPA 232-1975 with the following additional provisions:

(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) Two hour fire rated dampers or doors in all boundary penetrations.

d) Microfilming the records and storing duplicate copies of the microfilm in dual facilities.

17.4.14.3 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 paragraphs 17.4.14.1 or 17.4.14.2 but shall meet the other requirements of this plan.

17.4.15 INFORMATION RETRIEVAL

Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained designating those personnel who shall have access to the file. Records maintained by a supplier to SRPO shall be accessible to SRPO or SRPO's agent.

17.4.16 DISPOSAL

The retention period, custodian and storage location for permanent records shall be established in procedures. Records shall be maintained in accordance with these procedures.

Records accumulated at various locations, prior to transfer, shall be made accessible to SRPO directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt and process these records in accordance with this standard. The most stringent requirements shall be used in determining the final disposition.

All non-permanent records shall meet one or more of the following conditions prior to disposal:

a) Regulatory requirements are satisfied.

b) Operational status permits.

c) Warranty consideration is satisfied.

d) Purchaser's requirements are satisfied.

e) Items are released for shipment; a Code Data Report is signed, or a code symbol stamp is affixed.

TITLE

AUDITS

SRPO MANAGER	DATE	CHIEF-QUALITY ASSURANCE	DATE
[signature]	11/26/85	[signature]	11/26/85

18.1 PURPOSE

This Section establishes the responsibilities and requirements for the performance of audits to verify compliance with all aspects of the SRP Quality Assurance Program and to assess program effectiveness.

18.2 APPLICABILITY

This Section is applicable to the audits of SRPO internal activities and the activities of contractors, to verify compliance of procedures and activities with the SRP Quality Assurance Program.

18.3 RESPONSIBILITIES

SRPO retains overall responsibility for assuring that audit programs are established, implemented and adequate to verify compliance with the SRPO QA Program.

18.3.1 PROJECT MANAGER, SRPO

18.3.1.1 The Project Manager, SRPO, is responsible for certifying the Chief, Quality Assurance, as a Lead Auditor.

18.3.2 SRPO CHIEFS

18.3.2.1 The SRPO Chiefs shall assure access of audit team personnel to project documentation and personnel during the conduct of internal audits.

The SRPO Chiefs shall, as appropriate, investigate internal audit findings and schedule and initiate corrective action, including measures to prevent recurrence. The SRPO Chiefs are responsible for the submittal of a formal report to the Chief, Quality Assurance, describing corrective action with regard to internal audit findings.

18.3.2.2 The Chief, Quality Assurance, is responsible for:

a) The implementation of this Section. As such, the Chief, Quality Assurance, is responsible for the development and implementation of the audit program, including the schedules and performance of audits, and the qualification and certification of auditors and lead auditors.

b) Annual issuance of a schedule of audits to be conducted, including both internal and external audits. This schedule shall be reviewed quarterly to assure that it is complete and accurate. Additional audits shall be scheduled and conducted as required to monitor project activities, or to provide additional information related to unusual events or quality problems. The schedules shall be submitted to OGR, OCRWM, and Chicago Operations Office for information.

c) Assurance that personnel assigned to audits are independent of any direct responsibility for the performance of activities being audited.

d) Establishing the program for the qualification and certification of Lead Audit personnel. The Chief shall review and approve the qualifications of auditors and technical specialists participating in an audit.

e) Reviewing and approving audit plans, checklists and reports prior to use or issue.

f) Submitting internal and external audit reports to OGR, OCRWM, and Chicago Operations Office for information.

18.3.2.3 The Lead Auditor is responsible for assuring that the audit team is prepared prior to initiation of the audit. The Lead Auditor is responsible for the development of an audit plan, direction of the audit, and preparation and issuance of the audit report. The Lead Auditor is also responsible for the review and follow-up of corrective action of resultant audit findings.

18.3.3 PRIME CONTRACTORS

Prime Contractors to SRPO are responsible for establishing QA Programs and procedures which satisfy the requirements of this Section, as applicable to their scope of work, and shall pass the requirements on to their contractors.

They shall also submit the following to SRPO for information:

a) Audit schedules.
b) Audit reports.

18.4 REQUIREMENTS

Internal and external audits shall be conducted to assure that procedures and activities comply with the overall QA program. SRPO shall perform audits of Prime Contractors and representative subcontractors, consultants, and vendors to assess the effectiveness of the Prime Contractors' audit programs.

18.4.1 PROCEDURES

Procedures shall be established for the planning, scheduling, and conduct of quality assurance audits and the resolution of findings and for the qualification of auditors. Procedures shall include provisions for:

a) Verifying that an effective QA program has been developed and documented (e.g., programmatic audits).

b) Verifying through examination and evaluation of objective evidence that quality assurance program elements conform to specified requirements (e.g., implementation audits).

c) Assessing the effectiveness of controls established and the verification activities.

d) Reporting audit findings or deficiencies to all necessary levels of management for the identification of root cause, corrective action, and the initiation of measures to prevent recurrence.

e) Verifying that corrective action has been planned, initiated, completed and is adequate.

f) Developing and maintaining a tracking and trending system for audit findings to assure that all findings are appropriately addressed in a timely manner and that audit results are incorporated into the QA organization trending program.

g) Developing and implementing a qualification and certification program for auditors in accordance with the requirements of this Section.

18.4.2 AUDIT SCHEDULE

Audits shall begin as early in the life of an activity as practical and shall continue at intervals planned according to the schedule for accomplishing the activity and the status and safety importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. The frequency of audits shall be based on:

a) Evaluation of all applicable and active elements of the quality assurance program.

b) Consideration of previous audit results and corrective actions, nonconformance reports and independent information (e.g., information from other sources such as peer organizations, regulating bodies, etc.).

c) Status and importance of the activity.

18.4.3 SUPPLEMENTAL ACTIVITIES

Regularly scheduled audits shall be supplemented by additional audits, site visits, or surveillance as necessary to provide continuing coverage or for any of the following reasons:

a) To determine the capability of a Supplier's quality assurance program prior to contract award.

b) Following contract award, to determine compliance to program requirements after sufficient time has elapsed for implementing the QA program.

c) When significant changes are made in the quality assurance program.

d) When it is suspected that the quality of an item is in jeopardy due to deficiencies in the QA program.

e) When a systematic, independent assessment of program effectiveness is desired.

f) When verifying implementation of required corrective action.

Unannounced audits may be performed, provided that prior agreement is obtained by the parties involved.

18.4.4 AUDIT PLAN

An audit plan shall be developed and documented for each audit. At a minimum, this plan shall contain:

a) Description of the audit scope.

b) Specific requirements of the program to which elements, selected for review during the audit, will be compared.

c) Proposed audit team leader.

d) Description of the activities to be audited.

e) Identification of the organization(s) to be notified.

f) Description of the schedule of activities.

g) Identification of the applicable documents.

h) Identification and description of written procedures or checklists to be used during the audit.

18.4.5 NOTIFICATION

The management of the audited organization shall be notified of the audit scope and proposed audit team personnel and audit schedule prior to the conduct of the audit.

18.4.6 CHECKLISTS

Audit checklists, to be used as guidance during the audit, shall be developed. These checklists shall be based on the applicable documents identified in the audit plan, and shall require examination of objective evidence (e.g., procedures, instructions, items, records) to assess the adequacy and effectiveness of QA program element(s) being audited.

18.4.7 AUDIT TEAM

Audits shall be conducted by an audit team. The audit team shall consist of one or more auditors, with a certified Lead Auditor appointed to serve as the team leader. Other qualified auditors, auditors-in-training, or technical specialists may be team members provided the use of such personnel has been approved by the individual or organization responsible for audits, and any necessary requirements are met. The audit team shall be identified and notified prior to the beginning of each audit.

18.4.7.1 The auditing organization shall select and assign auditors who are independent of all direct responsibility for performance of the activities which they will audit.

18.4.7.2 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.

18.4.7.3 Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful.

18.4.7.4 The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit..

18.4.8 PERFORMANCE

Audits shall be performed in accordance with the audit plan and audit checklists. Program elements selected for audit shall be evaluated against specified requirements, such as contractual requirements, specifications, approved QA plans, procedures, or instructions to determine effective and proper implementation. Objective evidence shall be examined in the depth necessary to determine if program elements are being effectively implemented. The results of these evaluations shall be documented. Results of audits shall be analyzed by the QA organization.

18.4.9 REPORT

Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. The audit report shall be signed by the audit team leader and issued to the affected management for review, assessment and initiation of appropriate action. The audit report shall, at a minimum include:

a) Description of the audit scope.

b) Identification of the auditors.

c) Identification of persons contacted during the audit.

d) Summary of audit results, including a statement regarding the effectiveness of the quality assurance program elements which were audited.

e) Description of each reported audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

Prior to the release of the audit report, the audit team leader shall obtain an agreement of the validity of findings with the audited organization.

18.4.10 AUDIT RESPONSE

The audited organization shall respond in writing to the audit findings identified in the audit report by a requested date. This response shall include a determination of root cause, and a schedule for completion of corrective action including measures to prevent recurrence. The response shall be submitted to the organization which conducted the audit. Adequacy of the response shall be evaluated by or for the auditing organization.

18.4.11 FOLLOW-UP

Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished and scheduled.

18.4.12 RECORDS

Audit records shall be maintained in accordance with Section 17 and shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

18.4.13 QUALIFICATION OF AUDIT PERSONNEL

Audit personnel shall have sufficient authority and organization freedom to make the audit process meaningful and effective.

18.4.13.1 Auditors shall be trained in the SRPO quality assurance program requirements and in the performance of audits. Auditors shall have experience or training commensurate with the scope, complexity or special nature of activities to be audited. The qualifications and certification of auditors shall be documented by the organization responsible for the audit.

18.4.13.2 Personnel designated as Lead Auditors shall be trained, qualified and certified in accordance with established procedures. The procedures shall provide for the evaluation of communication skills; training in the applicable codes, standards and

regulations; training in the general structure of the quality assurance program; auditing techniques of examining, questioning, evaluating and reporting methods of identifying and following up on corrective action and closing out audit findings; procedures; audit planning; and practical on-the-job training.

18.4.13.3 Candidates for Lead Auditor shall have participated as an auditor in a minimum of five (5) quality assurance audits within three (3) years, one of which shall be a nuclear QA audit within the year prior to qualification, and shall have passed a written examination. The procedures shall provide for the maintenance of Lead Auditor qualifications/ certifications.

United States Government | Department of Energy

memorandum

DATE: APR 18 1986

REPLY TO ATTN OF: RW-24

SUBJECT: Approval of QA Plan, NVO-196-17 (Revision 4)

TO: Don Vieth, NV-WMPO

We have reviewed the NNWSI Quality Assurance Plan, NVO-196-17 (Revision 4), and find it acceptable for use. We hereby approve the document for issuance as guidance to the NNWSI project participants. A number of editorial comments are listed in the attachment and should be considered during the next scheduled revision. All revisions to the Plan must be approved by OGR before issuance by WMPO.

We feel a better, more descriptive title for the document would be "NNWSI Quality Assurance Requirements". This retitling would would also help avoid confusing this requirements document with the WMPO QA Plan, NVO-196-18, for meeting those requirements.

It is likely that the graded approach to QA described in the Plan will have to be revised to be consistent with OGR QA Plan Supplement Number 8 when it is issued in final form. At that time we will ask that the Plan be revised and resubmitted to OGR for approval, if necessary.

William J. Purcell
Associate Director for
Geologic Repositories

Attachment: OGR Comments on NNWSI QA Plan, NVO-196-17 (Rev.4)

OGR Comments on NNWSI QA Plan, NVO-196-17, (Rev.4)

1) In the Introduction, page iii, DOE Order 5700.6 is referenced. The correct reference is 5700.6A. This is also true for NV 5700.6 (NV 5700.6A).

2) The same comment as above applies to the first and seventh paragraphs in Policy, pages v and vi respectively.

3) In Purpose and Scope, page 1, second paragraph, seventh line, the word "sealing" is used. To be consistent with 10CFR60, Subpart G 60.151, the correct term should be "closure".

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APPENDIX A

Quality Assurance Manual Evaluation

Check List

Performed by
D J Brown
3/14/86

Project Name NNWSI Revision No. 4

Manual Title NNWSI QA Plan NVO-196-17 Revision Date 1/31/86

Review Date 3/14/86

Note: ①This is the NNWSI Overall QA Plan To which WMPO, Participating Organizations and NTS Support Contractors must comply. This is a requirements document.
To be acceptable, the program must meet the applicable portions of 10 CFR 50, Appendix B; and HQ-OGR QA Plan, OGR/B-3.
②WMPO's QA Program Plan NVO-196-18 will also be reviewed via this Check list to verify compliance.

	Yes	No	N/A	LOCATION
Organization				
1. Is the responsibility for the overall program 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, does the QA organization verify the proper performance of work through implementation of appropriate QA controls?	X			1.1
	X			1.6
2. Does DOE describe major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations?	X			1.7-1.10
3. Has the DOE described how responsibility is exercised for the overall QA program? Is the extent of management responsibility and authority from DOE headquarters and from the field office addressed?	X			1.2 1.3 1.4
4. Does DOE evaluate the performance of work delegated to other organizations? Does this 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? Is the frequency and method of evaluation specified?	X			1.6 SOP-02-01
5. Are qualified individual(s) or organizational element(s) identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities?	X			1.5
6. Have clear management controls and effective lines of communication been established for QA activities between DOE and its contractor, to assure direction of the QA program?	X			1.2-1.10

Organization (Continued)

	Yes	No	N/A	Location
7. Do organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines or responsibility? Are the repositories of each major organizational element specified?	X			Figure 1 & 2
8. Is the QA organization involved in the aspects of the high level waste repository program that affect safety and waste isolation? Are the extent of QA controls determined by 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?	X			1.9 & Purpose: Scope
9. Has DOE described the QA responsibilities of each of the organizational elements noted on the organization charts?	X			1.2 - 1.10
10. Does the DOE identify a management position within its 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:	X			1.6
a) Is it at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule?	X			1.6 & Figure 2
b) Has effective communication channels with other senior management positions been established?	X			1.6
c) Has responsibility for approval of QA Manual(s), changes thereto, and interpretations there of been established?	X			1.6
d) Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters?	X			1.6
11. Is verification of conformance to established requirements 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	X			1.6
12. Do persons and organizations performing QA functions have direct access to management levels which will assure the ability to:	X			1.6 & 1.10
a) Identify quality problems?	X			1.6 & 1.10

	Yes	No	N/A	Location
Organization (Continued)				
b) Initiate, recommend, or provide solutions through designated channels?	X			1.6 & 1.1c
c) Verify implementation of solutions?	X			1.6 & 1.1
d) Stop unsatisfactory work?	X			1.6 & 1.1
13. Have the persons and organizations with the above authority been identified and is a description of how those actions are carried out provided?	X			1.6 & 1.1
14. Have provisions been established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel?	X			1.6 & 1.1
15. Are policies regarding the implementation of the QA program documented and made mandatory?	X			1.5
16. Are the persons responsible for supporting the overall QA program identified and do they have appropriate organizational position and responsibilities to exercise proper control over the QA program? Are these individuals free from non-QA duties and thus give full attention to assuring that the QA program is being effectively implemented?	X			1.6
17. Does the Plan establish line and staff organizational responsibilities for QA program implementation within the project office organizational structure and identify interfaces with HQ and contractors?	X			1.2-1.1c

QA Program

	Yes	No	N/A	Location
1. Does the QA program include all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2? Are the items and activities covered by the QA program identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2? Are these terms defined as numerical performance objectives and standards? Does the rationale include systems analyses that are used to determine what specific items and activities are covered?	X			SOP-02-0
2. Does the QA program include a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program? Is guidance for the content of documentation of computer codes provided by NUREG-0856, "Final Technical Position on Documentation of Computer codes for High-Level Waste Management?"	X			SOP-03-0
3. Have provisions been 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?	X			SOP-02-0 para. 2.0
4. Does the QA organization review and document concurrence with the quality-related procedures relative to QA requirements?	X			SOP-02.0 para. 2.0
5. Does the QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls that are to be applied to specified items and activities? Does this effort involve 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?	X			SOP-02-0 para 2.0 and SOP-02-
6. Are existing or proposed QA procedures and detailed technical procedures identified and documented, reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met?	X			2.1

QA Program (Continued)

	Yes	No	N/A	
7. Is a description 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?	X			2.3 & SOP-02-01 2.1.1
Do these measures include:				
a) Frequent contact with program status through reports, meetings, and/or audits?	X			SOP-02-01 2.1.1
b) Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked?	X			SOP-02-0 2.1.1
8. Have indoctrination, training and qualification programs been established such that:	X			2.4
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?	X			SOP-02-0! 2.2.3.1
b) Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed?	X			SOP-02-0' 2.2.3.4
c) For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance?	X			SOP-02-01 2.2.4.1
d) Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement? Does a system of annual appraisal and evaluation satisfy this criterion?	X			SOP-02-01 2.2.3.3
e) Are qualified personnel certified in accordance with applicable codes and standards?	X			SOP-02-01 2.2.3.4
9. Does the Plan describe the project office QA program and identify applicable lower tier documents, such as QA Administrative Procedures which, with the QA plan, comprise the project office overall QA program?	X			SOP-02-0 2.1.5
10. Does the Plan describe the process for the project office review and approval of the QA programs of their contractors?	X			SOP-02-0 2.1.4

QA Program (Continued)

	Yes	No	N/A	
11.	Does the Plan identify those elements of the overall field project office QA program that have been delegated to the contractors and describe the controls that are implemented by the project office to monitor the performance of the contractor in these delegated elements?	X			SOP-02-0 2.1.4
12.	Does the Plan describe the program being implemented for the indoctrination and training of the project office personnel who perform activities affecting quality? Does the Plan identify the areas of inspection and testing that will require training, qualification and certification, and describe the method for accomplishing this?	X			SOP-02-0 2.2.3

Design Control

	Yes	No	N/A	
1. Are the definitions of design, design information, and design activities used in the design control program defined in this section? (The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system).	X			SOP-02-0 3.1
2. Does it include designs at each stage of design development (i.e., from conceptual design to final design)?	X			(NVO-196-17) 3.1.3
3. Is the design control program implemented at the time of submission of the Site Characterization Plan and include design and design activities as described in 1? Does it provide for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents?	X		X	SCP not submitted Yet 3.1.1
4. Are performance requirements specified for repository system components to support:				
a) identification of which items are important to waste isolation?	X			SOP 02-02
b) establishment of a graded QA approach;?	X			
c) establishment of data gathering and analysis needs?	X			
5. Are organizational responsibilities described for preparing, reviewing, approving, verifying and validating design and design information documents?	X			SOP-02-0 3.1.2
6. Are errors and deficiencies in approved design information documents documented, and action taken to assure that all errors and deficiencies are corrected?	X			SOP-02-0 3.2.5.1
7. Are interface controls among organizations or groups involved in design development and other design activities described?	X			SOP-02-01 3.1.2 & 3.2.6
8. Do 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?	X			SOP-02-01 3.1.1
9. Have procedures been established that describe for verification of designs and design activities, the verifier who 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:	X			SOP 02-0 3.1.3

Design Control (Continued)

	Yes	No	N/A	
a) The supervisor is the only technically qualified individual?	X			SOP-02-3.2.4.4
b) The need is individually documented and approved in advance with concurrence of the quality assurance manager?	X			
10. 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, is a peer review conducted? Do the procedures define the selection process for a peer group, and the process by which the peer group conducts its review? Is a peer review a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work? Have outside consultants been retained for needed expertise, where required?	X			NVO-196-17 3.3
11. Have the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation been identified in the procedures?	X			SOP-02-0 3.2.4
12. Are design changes, including field changes, subjected to the same design controls that were applicable to the original design? Is a configuration control system in place at the earliest practicable time? Are these changes analyzed to assure that change is required? Have associated changes to procedures and training been considered, and are changes communicated to all affected groups or individuals?	X			SOP-02-0 3.2.5
13. Does the plan describe the project office process for monitoring contractors' design controls and the extent of participation of the project office in design reviews?	X			SOP-02-0 3.1.3

Procurement Document Control

	Yes	No	N/A	
1. Have procedures been established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents? Are adequate acceptance and rejection criteria, stated where appropriate? Have procurement documents been prepared, reviewed, and approved in accordance with QA program requirements? Do procurement documents require contractors, subcontractors and consultants to provide an acceptable quality assurance program?	X			SOP-02-01 4.2.1
2. Are the organizational responsibilities described for:				
a) Procurement planning?	X			NVO-196-17 4.5
b) The preparation, review, approval, and control of procurement documents?	X			SOP-02-01 4.2.2.1.3
c) Supplier selection?	X			NVO-196-1 4.5
d) Bid evaluations?	X			
e) Review and concurrence of supplier QA programs prior to initiation of activities affected by the program?	X			SOP-02-0 4.2.1.3
f) Is the involvement of the QA organization described in the procedure?	X			SOP-02-01 4.2.1.3
3. Does the plan describe the process for the project office review of procurement documents to assure that appropriate quality provisions have been specified?	X			SOP-02-0 4.2.1.3
4. Does the plan describe the controls applied by the project office over the contractors procurement activities?	X			SOP-02-0 4.2.1.3

Instructions, Procedures and Drawings

	Yes	No	N/A	
1. Are organizational responsibilities described for assuring that quality-related activities are:				
a) Specified in instructions, procedures, and drawings?	X			SOP-02-01 5.1.1
b) Accomplished through implementation of these documents?	X			
2. Have procedures been established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality-related activities have been satisfactorily accomplished?	X			SOP-02-01 5.2.1.3
3. Have these documents been verified and approved as described in Section 3, Design Control?	X			SOP-02-0 5.2.2
4. Does the plan describe the project office's program for developing, reviewing, approving, and controlling the distribution of internal procedures, instructions, and drawings that affect quality?	X			SOP-02-0 5.3
5. Does the plan identify the types of documents to be submitted by the contractors for project office review and approval and describe this review and approval process?	X			SOP-02-01 5.3

Document Control

	Yes	No	N/A	
1. Is the scope of the document control program described, and the types of controlled documents identified?	X			SOP-02-0 6.1.1 6.1.2
2. Have procedures for the review, approval, issuance, and revision of documents been established? Do these procedures assure technical adequacy and inclusion of appropriate quality requirements? Does the QA organization review and concur with these documents with respect to quality-related aspects?	X			SOP-02-0 6.2
3. Have procedures been established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work?	X			SOP-02-0 6.1.1 & 6.2.1.4
4. Are procedures established that describe how obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.?	X			SOP 02-0 6.2
5. Has a master list or equivalent document control system been established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents?	X			SOP-02-0 6.3
6. When documents which require verification are released prior to verification, are they so identified and controlled?			X	Not Address
7. Does the plan describe how the project office controls documents being transmitted to and from contractors and other project participants to assure controlled transmittal, receipt, internal distribution, and recall?	X			SOP-02-0 6.2.1.5

Control of Purchased Material, Equipment, and Services

	Yes	No	N/A	
1. Have organizational responsibilities been described for the control of purchased material, equipment, and services?	X			NVO-196-17 7.1
2. Do procedures governing procurement of items or services include appropriate QA organization participation?	X			SOP-02-0 7.0
Do these procedures provide for:				
a) Evaluation and selection of suppliers?	X			7.2.2 &
b) Verification of supplier's activities?	X			7.2.4
c) Receiving inspections?	X			7.2.7 & 2
3. Do the procedures governing procurement require that the organization providing materials, equipment, or services furnish the following records to the purchaser:				
a) Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met?	X			7.2.4
b) Documentation identifying any procurement requirements that have not been met?	X			7.2.8
c) A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair"?	X			7.2.8.1
4. Is the procedure for review and acceptance of these documents described in the purchaser's QA program?	X			7.2.8
5. Are supplier's certificates of conformance periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented?	X			7.2.7.2.
6. When developing quality assurance requirements for data collection, test equipment and other equipment, is consideration 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, are special quality/performance verification requirements established and described in procedures governing the use of the equipment?	X			7.2.4

Identification and Control of Items

	Yes	No	N/A	
1. Have controls been established that describe the methods to identify and control samples? Does the description include organizational responsibilities?	X			SOP-02-0 8.1
2. Have procedures been established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto?	X			SOP-02-0 8.2
3. Can identification of samples be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports?	X			SOP-02-0 8.1
4. Is correct identification of samples verified and documented prior to release for use or analysis, described?	X			SOP-02-01 8.2
5. Does the plan describe the methods used by the project office to monitor contractors' inspection, testing, calibration, and sample identification activities?	X			SOP-02-0 8.1

Control of Special Processes

	Yes	No	N/A	
1. Is the criteria for determining what special processes are to be controlled described? Is a complete listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, provided?	X			SOP-02-01 9.2.2
2. Are organizational responsibilities, including those for the QA organization, described for qualification of special processes, equipment, and personnel?	X			SOP-02-01 9.2.2
3. Are procedures, equipment, and personnel associated with special processes qualified and are they in conformance with applicable codes, standards, QA procedures, and specifications? Is the QA organization involved in the qualification activities to help assure they are satisfactorily performed?	X			SOP-02-01 9.2.4 3 9.2.5 4 9.2.4 5 DR
4. Have procedures been established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel?	X			SOP-02-01 9.2.6
5. Have qualifications records of procedures, equipment, and personnel associated with special processes been established and maintained?	X			SOP-02-01 9.2.6.1

Inspection

	Yes	No	N/A	
1. Does the scope of the inspection program describe an effective inspection program and has it been implemented? Do program procedures provide criteria for determining when inspections are required or define how and when inspections are performed? Does the QA organization participate in these functions?	X			SOP-02-0 10.1.
2. Are the organizational responsibilities for inspection described? Are individuals performing inspections part of the QA organization? For inspections requiring special expertise are other individuals used providing the independence of the inspection function is maintained?	X			NVO-196-17 10.1
3. Has a qualification program for inspectors been established and documented, and the qualifications and certifications of inspectors kept current?	X			SOP-02-01 10.2.6
4. Do inspection procedures, instructions, or checklists provide for the following:				
a) Identification of characteristics and activities to be inspected?	X			SOP-02-0 10.2.1
b) A description of the method of inspection?	X			10.2.1
c) Identification of the individuals or groups responsible for performing the inspection operation?	X			10.2.1
d) Acceptance and rejection criteria?	X			10.2.1
e) Identification of required procedures, drawings, and specifications and revisions?	X			10.1.1
f) Recording inspector or data recorder and the results of the inspection operation?	X			10.2.7
g) Specifying necessary measuring and test equipment including accuracy requirements?	X			10.2.1.1 10.2.5.2
5. Do procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector?	X			10.2.3
6. Are inspection results documented and evaluated, and their acceptability determined by a responsible individual?	X			10.2.4.3

Test Control

	Yes	No	N/A	SOP-02-0
1. Does the description of the scope of the test control program indicate an effective test program has been established?	X			11.1.1
Does the program's procedures provide criteria for:				
a) Determining when a test is required or how and when testing activities are performed?	X			11.1.1
b) Requiring that the test program is conducted by trained or appropriately qualified personnel?	X			11.2.2.3
c) The QA organization to audit these functions?	X			NUO-196-17 18
2. Are test plans and procedures reviewed in accordance with the verification requirements in Design Control?	X			11.2
3. Are 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, identified?	X			11.2
4. Do test procedures or instructions provide for the following:				
a) That the requirements and acceptance limits are contained in applicable documents, including precision and accuracy?	X			11.2.1
b) Instructions for performing the test?	X			11.2.2
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?	X			11.2.2
d) Mandatory inspection hold points (as required)?	X			11.2.2
e) Acceptance and rejection criteria, including required levels of precision and accuracy?	X			11.2.1
f) Methods of data analysis?	X			11.2.3
g) Methods of documenting or recording test data and results?	X			11.2.4
h) Provisions for assuring test prerequisites have been met?	X			11.2.2
5. Are test results documented, evaluated, and their acceptability determined by a responsible individual or group as described in Design Control?	X			11.2.3

Control of Measuring and Test Equipment

	Yes	No	N/A	SOP-02-01
1. Has the scope of the program for the control of measuring and test equipment been described and are the types of equipment to be controlled established?	X			12.1
2. Are QA and other organizations' responsibilities described for establishing, implementing, and assuring effectiveness of the calibration program?	X			12.1
3. Have procedures been established and do they describe 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? Is the review and documented concurrence of these functions identified?	X			12.1
4. Is measuring and test equipment labeled, tagged or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data?	X			12.1.2
5. Is measuring and test equipment calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability, characteristics, and other conditions which could affect measurement?	X			12.1.3 & 4
6. Are calibration standards traceable to nationally recognized standards? Where national standards do not exist, have provisions been established to document acceptability of the calibration standard used?	X			12.1.3
7. When measuring and test equipment is found to be out of calibration, are evaluations made and documented to determine the validity and acceptability of measurements performed since the last calibration? Are inspections or tests repeated on items determined to be suspect?	X			12.1.4

Handling Storage and Shipping

	Yes	No	N/A	SOP-02-01
1.	X			13.1
2.	X			13.1

1. Are sampling, handling, preservation, storage packaging, and shipping requirements established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions?

2. Have procedures been established that describe 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?

Inspection, Test and Operating Status

	Yes	No	N/A	NVO-1%-1 + SOJ -- 1
1.	X			14.1
2.	X			14.1

1. Have procedures been established which describe the use of label, tags or other markings to indicate the status of inspections or tests on an item?

2. When this function is delegated to others, does the program describe the controls imposed on the contractors to determine that the work is accomplished to the requirements of NQA-1 and/or Appendix B?

Nonconformances

	Yes	No	N/A	
1. Have procedures been established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities? Do the procedures identify individuals authorized to dispose of and close out nonconformances?	X			NVO-196-17 15.2
2. Is the QA responsibilities related to nonconformance control described in the procedure?	X			SOP-15-0 5.0
3. Does documentation identify and describe the nonconformance, disposition the nonconformance, and include signature approval of the disposition?	X			NVO-196-17 15.2
4. Do the procedures require that nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances?	X			SOP02-0 16.1
5. Does it also require that significant results be reported to upper management for review and assessment?	X			SOP02.01 16.1
6. Does the plan describe the field project offices' procedures for identifying and reporting unusual occurrences which are encountered during their own surveillance and review activities?	X			NVO-196-17 15.5
7. Does the plan include provisions for analyzing both the project office and contractor-identified non-conformances to permit early detection of quality trends?	X			NVO-196-17 15.4
8. Does the plan develop the criteria and describe the method for reporting, evaluating, and follow-up of unusual occurrences?	X			NVO-196-17 15.5

SOP-15.01 should have provisions for revising NCRs during processing.

Corrective Action

	Yes	No	N/A	
1.	X			SOP-02-0 16.1 5.3
2.	X			NPO-16- 16.1
3.	X			NPO-16-1 16.2
4.	X			SOP-02-0 16.1

Note: SOP-17-01 Records Management Plan not issued yet

Quality Assurance Records

	Yes	No	N/A	
1. Is the scope of the records program described in a written procedure? Do 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?	X			NVO-196-1 17.1
2. Are QA and other organizations identified and their responsibilities described for the definition and implementation of activities related to QA records?	X			17.6
3. Do inspection and test records contain the following (where applicable):	X			SOP02-0 Parts 12 & 1
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?				↓
4. Are records classified as Lifetime or Nonpermanent in accordance with written instructions? Assumed to be more defined in SOP-17-01 when issued	X			SOP02-0 17.2.5
5. Does the record and/or record indexing system provide sufficient information to permit identification between the record and the item or activity to which it applies?	X			17.2.5
6. Does the record indexing system include as a minimum:				17.2
a) Record retention time?				
b) Location of the record in the system?				
7. Does the record procedure include, as a minimum, the following:	X			17.2.6
a) A description of the storage facility?				
b) The filing system to be used?				

	Yes	No	N/A	
Quality Assurance Records (Continued)				
c) A method for verifying that the records received are in agreement with the transmittal document and that the records are legible?				17.2.6
d) A method of verifying that records are the designated ones?				
e) The rules governing access to and control of the files?				
f) A method of maintaining control of and accountability for records removed from the storage facility?				
g) A method for filing supplemental information and disposal of superseded records?				
8. Does the record storage facility meet the requirements of a:				17.2.9
a) Single Facility				
1. Reinforced concrete, concrete block, masonry or equal construction?				
2. Forced air circulation with filter system?				
3. Fire protection system?				
4. Sealant applied to walls as a moisture or condensate barrier?				
b) Dual Facility				
1. Sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard?				
2. Meet the other requirements of limited access, record index, etc.?				
9. If this function is delegated, does the plan describe how the requirements are transmitted to the contractor?				17.2.1.3

Audits

	Yes	No	N/A	
				SOP 02-01
1. Does the plan describe internal and external audits to assure that procedures and activities comply with the overall QA program to be performed by DOE and its contractors? Does it describe DOE performed audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program?	X			18.2
2. Is an audit plan prepared identifying audits to be performed, their frequencies, and schedules? Are audits regularly scheduled based upon the status and safety importance of the activities being performed and are they initiated early enough to assure effective QA?				18.2.2.1
3. Do audits include an objective evaluation of the quality-related practices, procedures, instructions, activities; and items and the review of documents and records to ensure that the QA program is effective and properly implemented?	X			18.2.3
4. Is audit data analyzed by the QA organization and the results reported to responsible management for review, assessment, and appropriate action?	X			18.2.3
5. Are audits performed in accordance with pre-established written procedures or check lists?	X			18.2.3
6. Is a tracking system for audit findings established to help assure that all findings are appropriately addressed and to trend audit findings?	X			18.3
7. Does the audited organization describe in a formal report the corrective action to be taken to address findings? Is this report submitted to the auditing organization and/or responsible management?	X			18.2.5
8. In the resolution of findings, is the root cause of each finding identified and corrective action for it described?	X			18.2.5
9. Are audits conducted by properly trained and certified personnel having no direct responsibilities in the areas being audited?	X			18.2.2.3 + App. D
10. Are auditors trained and certified to a written procedure?	X			App. D
11. Are records maintained of auditors training, qualification and certifications?	X			App. D