



**NYE COUNTY NUCLEAR WASTE  
REPOSITORY PROJECT OFFICE**

**QUALITY ASSURANCE PROGRAM  
PLAN**

<b>APPLICABILITY</b>	<b>SUPERSEDES</b>	<b>Revision: 2</b>
ALL NWRPO ACTIVITIES	Revision, 06-30-98	<b>Date: 11-11-98</b>
<b>DRAFT</b>		<b>Page: Page 1 of 36</b>
<b>APPROVED</b>		
Project Manager	Date	Project Quality Assurance Officer Date

**POLICY STATEMENT**

It is the policy of Nye County that the NWRPO establish and maintain a documented Quality Assurance Program. The purpose is to assure that NWRPO will continually achieve quality of performance in all areas of its responsibilities through the application of effective management systems, in conformance with its mission. This Program is designed to meet the requirements<sup>1</sup> of ANSI/ASME NQA-1, 1986 Edition<sup>2</sup> and the criteria of 10CRF50 Appendix B.

All NWRPO personnel and its contractors/subcontractors who perform or manage quality-affecting functions shall work to the procedures that implement the Quality Assurance Program. The NWRPO Project Manager is responsible to assure that all quality-affecting work performed under his cognizance complies with the requirements of the Quality Assurance Program. The Project Quality Assurance Officer is responsible for the establishment, implementation, and verification of the Quality Assurance Program's compliance with this policy. The Project Quality Assurance Officer is also responsible for keeping the Project Manager regularly informed as to the status of the QA Program.

The intent of the QA Program is not merely to produce documentation, but more importantly, to provide assurance that the data derived from NWRPO's oversight and investigation program are of the highest quality. Furthermore, it is intended to assure that the NWRPO's scientific activities are conducted in a systematic manner using documented instructions and procedures that will ensure the validity, integrity, preservation, and retrievability of the data generated.

<sup>1</sup> Basic Requirements, Supplementary Requirements, and Nonmandatory Requirements as applicable and as incorporated in NWRPO implementing procedures.

<sup>2</sup> All following references to NQA-1 refer to the 1986 Edition

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**TABLE 1**  
**QUALITY ASSURANCE PROGRAM**  
**REQUIREMENTS MATRIX**

	ANSI/ASME NQA-1 Basic Requirement	10CFR50 APPENDIX B Criterion
Organization	1	I
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Procurement Document Control	4	IV
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Document Control	6	VI
Control of Purchased Material, Equipment, and Services	7	VII
Identification and control of Materials, Parts, and Components	8	VIII
Control of Processes	Not applicable	Not applicable
Inspection	10	XI
Test Control	11	XI
Control of Measuring and Test Equipment	12	XII
Handling, Storage, and Shipping	13	XIII
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## INTRODUCTION

The Nuclear Waste Policy Act of 1982 (NWPAct) defined a process whereby the Nation would site, construct, operate, and decommission a geologic repository for 1) spent fuel from the nation's commercial nuclear power plants, and 2) high-level radioactive waste from federal weapons plants. In its 1987 amendments to the Act, Congress designated Yucca Mountain, located in Nye County, Nevada, as the sole candidate site for a repository.

The NWPAct assigned three roles to separate agencies of the executive branch. The Environmental Protection Agency is directed to promulgate generally applicable standards for protection of the general environment from off-site releases from radioactive material in repositories; the Department of Energy (DOE) is directed to characterize Yucca Mountain for its suitability for a repository, as well construct, operate and decommission the facility, if licensed; and the Nuclear Regulatory Commission (NRC) was charged with the role of promulgating technical requirements and criteria for licensing, first the construction, then the operation, and ultimately, the closure and decommissioning, of a repository. The NRC is also responsible for evaluating DOE's license application and awarding a license, if appropriate.

DOE's site characterization program includes surface-based testing and the construction of an exploratory studies facility (ESF) to facilitate the study of underground site features. DOE's primary mission is to collect sufficient data to determine site suitability and to support a license application.

### **NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE**

Nye County has responded to Yucca Mountain being designated the Nation's candidate site for disposal of spent nuclear fuel and high-level nuclear waste by organizing the Nuclear Waste Repository Project Office (NWRPO). NWRPO's purpose is to investigate the potential impact a repository at Yucca Mountain might have on the health, safety, environment and overall well being of the residents of Nye County.

To achieve this purpose, NWRPO administers a program of monitoring, oversight, independent scientific investigations, impact assessment and impact mitigation. In particular, NWRPO and its contractors/subcontractors (1) monitor DOE activities, (2) critically review and analyze plans, reports, data, and analysis from DOE and other sources, (3) conduct such independent investigations as may be needed to (a) evaluate and validate DOE data, assumptions, conclusions, and designs and (b) establish NWRPO's own database and analysis for potential licensing and impact mitigation proceedings.

The policies followed by NWRPO are established by the Board of County Commissioners, upon the advice of the County Manager and the NWRPO Project Manager, and with the counsel of the District Attorney.

This Quality Assurance Program Plan is based upon the NWRPO's interpretation of Federal requirements (that is, ANSI/ASME NQA-1, 10CFR50, Appendix B) for nuclear power plants adapted for waste repository research and is designed to establish procedures for controlling activities that ultimately affect the final product of NWRPO oversight and investigation. The extent to which this Quality Assurance Program deals with QA and the responsibilities among the various NWRPO activities is consistent with their individual importance.

## **1.0 ORGANIZATION**

### **1.1 PURPOSE**

This section defines the detailed organizational structure, functional responsibilities, levels of authority, and lines of communication for the direction and execution of the NWRPO Quality Assurance Program.

The purpose of the Nuclear Waste Repository Project Office is to investigate the potential impact a repository at Yucca Mountain might have on the health, safety, environment and overall well-being of the residents of Nye County. NWRPO's quality assurance (QA) purpose is to ensure that its program of monitoring, oversight, independent scientific investigations, impact assessment and impact mitigation are performed properly and are verified, using appropriate QA controls. This is achieved through the development, implementation, and monitoring of the QA Program. This section describes NWRPO's organizational structure, functional responsibilities, levels of authority, and lines of communication.

### **1.2 SCOPE**

This section applies to all NWRPO activities and personnel participating in quality-related activities.

### **1.3 RESPONSIBILITIES**

NWRPO's organizational structure and responsibility shall be such that:

- Quality is achieved and maintained by line organization personnel who are assigned the responsibility of performing work.
- Quality achievement is verified by a person(s) who is not directly responsible for performing the work.

The NWRPO organization chart (Figure 1-1) illustrates the lines of authority, and QA responsibilities, communications and advisory links between the project personnel. Project

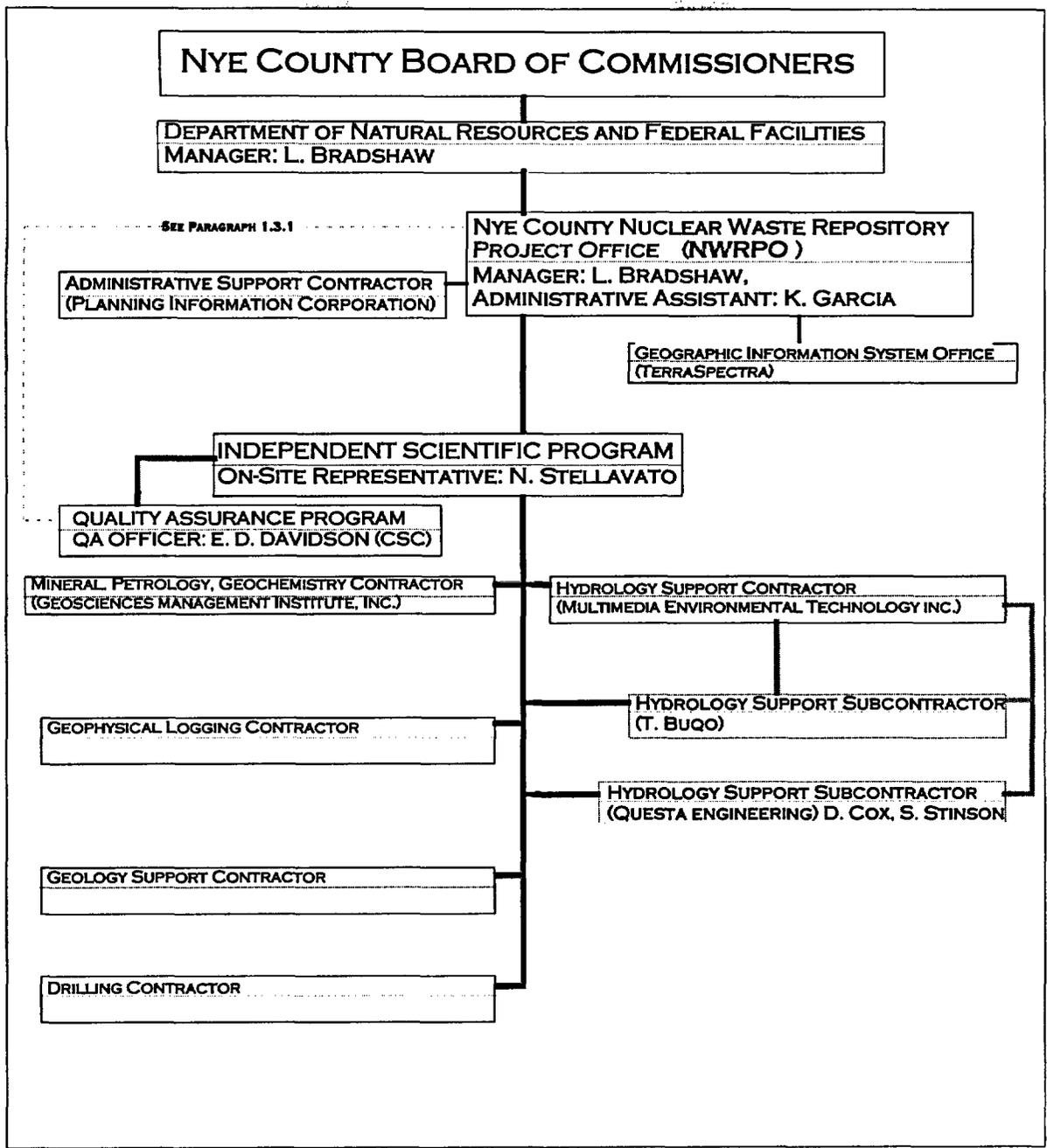


Figure 1-1. Nye County Waste Repository Project Office Organization Chart

personnel carrying out QA responsibilities shall have sufficient authority, access to work areas and organizational freedom to:

- Identify quality problems;
- Initiate, recommend, or provide solutions to quality problems;
- Verify implementation of solutions;
- Assure that further activities are controlled until proper disposition of a nonconforming condition has occurred;
- Assure that an appropriate quality program is established;
- Verify that activities affecting quality have been performed in accordance with specified procedures;
- Maintain a method of coordinating, preparing, approving, distributing, storing and retrieving quality-related documents such as Project QA Program Document, Quality Administrative Procedures, Work Plans, Technical Procedures, and other controlled documents;
- Regularly assess the adequacy of the Program to assure its effective implementation;
- Provide for the planning and accomplishment of activities affecting quality by the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that the prerequisites for the given activity have been satisfied.

Organizations other than NWRPO, such as contractors and subcontractors, are involved in the execution of activities covered by the requirements of the QA Program. The responsibility and authority of each contractor and subcontractor shall be clearly established and documented, and subsequent activities monitored by the Project QA Officer for QA compliance. Contractors and subcontractors may perform their work under their own QA Program upon the review and recommendation of the QA Officer and the approval of the Project Manager.

**1.3.1 Project Quality Assurance Officer** The Project QA Officer reports to the On-site Geotechnical Representative. However, in those instances where the On-Site Geotechnical Representative conducts quality-affecting technical work the QA Officer will report directly to the Project Manager.

The QA Officer conducts, or delegates the conduct of, periodic audits to verify that project activities are being performed in accordance with the QA Program. The Project QA Officer has the authority and responsibility to issue nonconformances, verify implementation of corrective action, and stop work, if necessary. Responsibilities also include review and approval of work packages, technical procedures, and any other documents that contain QA directives and are issued to the NWRPO project personnel. The QA Officer is charged

with the development, maintenance, and safekeeping of the project administrative and technical files. The QA Officer is also responsible for ensuring that peer reviews are conducted as required, job descriptions and qualifications of project personnel are on file, and controlled documents are appropriately distributed. Additionally, the QA Officer assesses the effectiveness of the QA Program, and initiates and/or reviews appropriate revisions of the QA Program document or related documents. The QA Officer also reviews contractor and subcontractor QA programs and recommends their acceptance to the Project Manager.

**1.3.2 Project Manager** The Project Manager is responsible ensuring that the NWRPO technical program is supported by and carried out under a program of quality assurance. The Project Manager reviews and makes a decision on the QA Officer's recommendation regarding the acceptance of contractor and subcontractor QA programs. The Project Manager resolves any disputes that may arise between the QA Officer and the On-Site Geotechnical Representative.

**1.3.3 On-Site Geotechnical Representative** The On-Site Geotechnical Representative is responsible for the technical performance and staffing of the project. The On-Site Geotechnical Representative verifies that peer reviews are conducted as required, nonconformances are adequately addressed, and job descriptions and qualifications of project personnel are on file. The On-Site Geotechnical Representative also assures that the QA Officer periodically audits project activities and verifies that they are being conducted in accordance with established project procedures. The On-Site Geotechnical Representative resolves any disputes that may arise between the QA Officer and other participants

**1.3.4 Principal Investigator** Principal Investigators are under the direction of the On-Site Geotechnical Representative and are responsible for planning, coordinating, performing, and documenting NWRPO work requirements. Principal Investigators also have the responsibility of applying the NWRPO QA Program to their assigned activities and the development of work packages. Work packages include a description of the work to be performed, a plan for completing the work, and technical procedures required to control the work. Principal Investigators must also develop and maintain a technical file and datasets, and ensure that personnel are trained in the use of these procedures and other procedures applicable to the performance of the work.

**1.3.5 Task Manager** Task Managers are under the direction of the Principal Investigator, are responsible for completing the assigned work and applying the NWRPO QA Program to their assigned activities.

**1.3.6 Staff** members are responsible to their respective Task Manager or Principal Investigator for completing the assigned work in accordance with applicable aspects of the NWRPO QA Program.

#### **1.4 REQUIREMENTS FLOW-DOWN**

In order to satisfactorily achieve NWRPO's QA Program purposes the following requirements shall be met when work is delegated to the principal investigators and the task managers of contractor organizations:

**1.4.1 Management Control and Lines of Communication** Clear management controls and effective lines of communication for quality-related activities shall be demonstrated between NWRPO and the principal investigator of any contractor organization. In turn, similar controls and lines of communication shall be demonstrated between the contractor and subcontractor task managers.

**1.4.2 Organization Chart** An organizational chart shall be formally accepted by the Project Manager which identifies how the contractor organization will function under the cognizance of the Project Manager and QA Officer. The chart shall include the line organizational elements and lines of responsibility.

**1.4.3 Verification of Conformance** The QA Officer will verify that the contractor principal investigators and subcontractor task managers conform to the QA Program requirements.

#### **1.5 FLOW-DOWN PROCEDURES**

**1.5.1 Delegation of Responsibility** The Nye County Board of Commissioners has authorized the County Manager to implement the Nye County Nuclear Waste Repository Project by staffing the Project Manager position to manage the Nuclear Waste Repository Project Office, the County Manager authorizes the Project Manager to implement the QA Program herein defined and managed by the QA Officer.

The On-Site Geotechnical Representative has developed an organization chart that defines the lines of responsibility in the QA and line organizations. The QA Officer shall establish,

and propose amendments to, the NWRPO procedures that may be required to guide QA Program implementation.

The On-Site Geotechnical Representative formally designates the principal investigators, produces job descriptions for them, fills these positions with qualified personnel, and documents their qualifications. The principal investigators, in turn, produce job descriptions for personnel performing work under their authority, fill positions with qualified individuals, and maintain a record of their qualifications in their files.

The On-Site Geotechnical Representative shall identify and establish any needed interface with other organizations, or designate a qualified representative to define and document any such interaction. The respective responsibilities of each organization shall be clearly defined by the On-Site Geotechnical Representative and a designated representative from the other organization(s).

**1.5.2 Performance Accountability** The NWRPO Project Manager is responsible for ensuring through formal written communication and contracts that NWRPO personnel and contractors/subcontractors know they, individually and as an organization, must comply with the NWRPO QA Program. Since compliance with the QA Program is critical to the success of NWRPO's mission to protect Nye County citizen's health and safety, their environment, and their overall well-being, the Project Manager will include QA effectiveness in personnel and contractor performance evaluations.

The QA Officer is responsible to the NWRPO Project Manager for assuring that an appropriate QA program is established and verifying that activities affecting quality have been correctly performed. While the QA Officer describes, integrates, and monitors the agreed-upon QA activities of the whole program. QA is the responsibility of the whole NWRPO operation, including County personnel, contractors and their subcontractors.

## **1.6 PERSONNEL QUALIFICATIONS AND TRAINING**

All personnel performing work that affects quality shall have experience or training commensurate with the scope, complexity, or special nature of the activities they perform for NWRPO. Personnel will be provided a written general description of their role and responsibilities. Personnel experience and or training to perform their assigned responsibilities must be independently verifiable. Personnel must be knowledgeable of their QA responsibilities.

The effectiveness of the QA program implementation of the personnel qualifications and training requirements is monitored and verified by the QA Officer.

## 2.0 QUALITY ASSURANCE PROGRAM

### 2.1 PURPOSE

This section describes how the overall NWRPO Quality Assurance Program is designed to incorporate and conform to applicable sections-portions of ANSI/ASME NQA-1, as well as the criteria delineated in 10CFR50, Appendix B. All quality-related activities performed by the NWRPO are covered by this QA Program.

NWRPO's Quality Assurance Program is designed to assure that all data, analysis, and conclusions developed by its monitoring, oversight, and independent scientific investigations are credible, defensible, retrievable, and traceable within any future licensing or impact mitigation proceedings.

Software Quality Assurance (SQA) is applied as part of the Quality Assurance Program and is applicable exclusively to software<sup>3</sup> that generates quality affecting data -e.g., those with potential importance in Yucca Mountain-related suitability and licensing proceedings. Quality affecting software shall be developed, controlled, and used in accordance with the SQA implementation procedures

SOA implementation procedures conform to the guidance of NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Isolation" . NUREG/CR - 4640, Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry may be consulted for guidance as appropriate.

The program ensures that the activities are conducted under suitably controlled conditions, and that involved personnel are appropriately informed and trained. To achieve this overall purpose, control and verification measures shall be planned, documented, and implemented. Documents and electronic medium that are used to record NWRPO data, analysis, and conclusions important to quality shall be protected for future reference.

### 2.2 SCOPE

NWRPO's Quality Assurance Program includes all aspects of NWRPO's work judged by the On-Site Geotechnical Representative to potentially affect the credibility, defensibility, and traceability of future claims concerning the suitability of Yucca Mountain for a nuclear waste repository and the potential impacts of DOE's Yucca Mountain-related activities on Nye County residents.

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<sup>3</sup>This is exclusively Modeling software - computer codes that simulate environmental processes. .

The Quality Assurance Program applies, in particular, to all levels of data collection and analysis activities. However, application of the QA Program control and verification procedures to specific activities will be commensurate to their potential importance in Yucca Mountain-related suitability and licensing proceedings.

NWRPO considers the controls of NUREG-1298, "Generic Technical Position of Qualification of Existing Data for High-Level Nuclear Waste Repositories" as not applicable. All data directly collected by NWRPO is gathered under our QA Program (NWRPO's) and is considered qualified. NWRPO does not intend to qualify data obtained from outside the controls of the NWRPO QA Program -however these "outside" data will be identified as not qualified under the NWRPO QA Program

The NWRPO Quality Assurance Program is fashioned to address activities performed while executing its program of independent scientific investigation, monitoring, and oversight. This Quality Assurance Program does not conform to regulatory requirements that are intended to control the license applicant (DOE) as it designs, constructs, and operates the geologic repository. Therefore specific portions of 10CFR50 Appendix B, and ANSI/ASME NOA-1 are considered Not Applicable to the NWRPO QA Program. .

Additionally various US NRC guidance documents are also categorized as Not Applicable. For example NUREG-1318, " Technical Position of Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, "April, 1988 deals with determination of activities subject to QA based upon their "importance to safety" or "importance to waste isolation." Both of these elements are directly connected to "structures, systems, components, and barriers" which constitute the actual constructed repository and therefore not applicable to the work of the NWRPO.

### **2.3 RESPONSIBILITIES**

NWRPO's work and performance requirements related to quality will be delegated to qualified implementing personnel, contractors, and subcontractors by providing a description of the work to be completed and requiring compliance with the Quality Assurance Program. Implementing personnel, contractors and subcontractors will be responsible for (1) devising a work plan and appropriate technical procedures for completing the work and protecting datasets, (2) securing resources needed to perform the work, and (3) documenting work that is being performed.

Task Managers and PIs with the aid of the QA staff shall regularly assess the adequacy of that part of the Program for which they are responsible and ensure its effective implementation.

NWRPO will verify that (1) the work has been performed as planned or that variances from plans have been documented, (2) quality assurance requirements are being met, and (3) documented nonconformances have been corrected.

#### **2.4 IMPLEMENTATION**

This Quality Assurance Program Plan is written to communicate Nye County's quality assurance policy for NWRPO's operation, delineate responsibilities for implementing program elements, to describe the manner in which work will be defined, implemented, documented, and reviewed to assure quality, and to verify that quality assurance requirements have been met.

This plan describes the manner in which Nye County's Nuclear Waste Repository Project Office is organized to perform work and how requirements flow down through lines of authority to personnel, contractors and subcontractors. In addition, prerequisites to performing quality-related work are described which include requirements to define the work, develop work plans, establish technical procedures for conducting the work, and identify and qualify resources.

The QA Program Plan shall be prepared under the direction of the Project QA Officer and reviewed annually by the On-Site Geotechnical Representative. Revisions to the QA Program Plan are prepared, approved, and distributed in accordance with Quality Administrative Procedure QAP-6.1. "Procedures for Issuance and Control of Quality Assurance Documents."

## 3.0 DESIGN CONTROL

### 3.1 PURPOSE

This section describes how design control (as defined by the NWRPO) ~~(using independent review)~~ applies to the work performed by the NWRPO.

The standard regulatory definition of design control is modified for the NWRPO QA Program. The difference lies in the scope of activities performed by NWRPO versus the designing of the repository system included in DOE's scope. NWRPO work consists of data acquisition and analysis of existing data, monitoring DOE activities, and executing a program of independent scientific investigation. Therefore, the application of "design control" to NWRPO is limited to independent review and analysis of the products of its monitoring/scientific investigations and of its QA Program. These products include Quality Administrative Procedures (QAPs) Work Plans (WPs), Technical Procedures (TPs), Scientific Notebooks, Technical Reports, Test Plans and Progress Reports.

NWRPO's application of design control also ensures that changes to any of these documents are subject to the same controls as originally applied in the original independent review and approval process.

~~Work is documented through the use of the scientific notebook, technical reports, and progress reports.—This section also describes how the NWRPO reviews plans for acquisition of information and data. Independent reviews are utilized to ensure that planned technical work (including computer software) is founded upon sound and defensible technical concepts, methods, assumptions, calculations, and projections and to verify the accuracy and completeness of data acquisition and analysis, and overall study methodologies. This section satisfies the requirements for ANSI/ASME NQA-1 (subject to the NWRPO's limited definition of design control), as well as criterion III of 10CFR50, Appendix B.~~

### 3.2 SCOPE

This section applies to the independent review of all NWRPO-products of its monitoring/scientific investigations work-plans developed by the NWRPO. Because of the potential uncertainty in most geotechnical data, and their analyses, expert judgment is needed in assessing the adequacy of some work. External peer review ~~shall~~ may be utilized as one of the mechanisms by which these judgments shall be made.

### 3.3 RESPONSIBILITIES

Design Control through independent review will be accomplished by internal or external technical reviews or, if appropriate, by external peer reviews.

The Project Manager authorizes a PI to undertake the development of a work plan to complete an activity. The principal investigator, in conjunction with the On-Site Geotechnical Representative, develops the activity objectives, identifies specific issues to be addressed, and defines the verification/review requirements of the activities. The QA Officer shall review completed work plans, scientific notebooks, technical reports, and progress reports, developed for the various project activities and approves those in which the QA requirements have been adequately addressed. The QA Officer's review and approval includes the verification that appropriate quality standards have been incorporated and specified. Additionally the QA Officer's review will ensure that plans for data collection and analysis are completed prior to the actual collection and analysis activities.

### 3.4 IMPLEMENTATION

Independent review shall be undertaken as a check on the thoroughness and accuracy of the work plans and subsequent analysis after work is completed. Independent reviews facilitate the documentation and correction of errors and deficiencies – review comments are formally documented as is the resolution of those comments. Additionally, the independent review process assures the following: the criteria for determination of the method of verification; the persons performing the review are qualified, their qualifications documented, and they have not been responsible for the work being reviewed.

The issuance of scientific notebooks will be controlled by the QA staff. Scientific notebooks will be reviewed to verify the accuracy of the notebook as a record.

Technical reviews, while formally documented, are convened to provide timely, informal, yet independent feedback for the primary benefit of the PI.

Peer reviews shall be conducted in situations where uncertainties inherent in geotechnical/geological data, methodologies, interpretations, or conclusions can be resolved in no other way. NWRPO peer review procedures are generally based upon the guidance of NUREG-1297-" Peer Review for High-Level Nuclear Waste Repositories" February 1988, with the

understanding that the NWRPO's scope of activities are more limited than DOE's which includes repository system design and construction.

Quality Administrative Procedure QAP-3.1, "Procedures for Independent Review" establishes a system for internal and external technical review. Documentation and review of scientific investigations through the use of scientific notebooks, technical reports, and progress reports isare -controlled through QAP-3.2, "Procedures for Documentation of Scientific Investigations."

## 4.0 PROCUREMENT DOCUMENT CONTROL

### 4.1 PURPOSE

This section describes how applicable design bases, regulatory requirements, or other requirements necessary to assure adequate quality are suitable included or referenced in procurement documents. This section is designed to incorporate and conform to applicable portions ~~satisfies~~ of ANSI/ASME NQA-1, as well as criterion IV of 10CFR50, Appendix B.

### 4.2 SCOPE

This section applies to all NWRPO procurement documents regarding subcontracts for analytical tests or for items and services.

### 4.3 RESPONSIBILITIES

The QA staff is responsible for the review of all quality-related procurement documents. Documents containing subcontracts for analytical tests, items, or services shall be reviewed by the QA Officer for conformance to procurement document requirements.

### 4.4 IMPLEMENTATION

All quality-related procurement documents and changes thereto shall be reviewed by a member of the QA staff. Before a request for quotation or proposal is issued, the QA staff shall review the contract to assure that the applicable QA Program requirements are included. All quality-related procurement documents shall contain the right of NWRPO for access to subcontractor's and/or vendors' facilities and records for source inspections and audits including field locations when and where applicable. Adequate acceptance or rejection criteria will be included in all quality-related procurement documents.

Procurement activities are controlled by Quality Administrative Procedure QAP-7.1, "Procedures for Control of Purchased Items and Services."

## **5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

### **5.1 PURPOSE**

This section describes how quality-related activities are prescribed by and accomplished in accordance with documented procedures which include appropriate qualitative or quantitative acceptance criteria. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion V of 10CFR50, Appendix B.

### **5.2 SCOPE**

This section applies to the development of instructions and procedures for the performance of quality-related work – including the documentation of that work. NWRPO prescribes work through Quality Administrative Procedures, Technical Procedures and, Work Plans.

### **5.3 RESPONSIBILITIES**

All NWRPO staff are responsible for performing quality-related activities in accordance with the requirements of the applicable Quality Administrative Procedures (QAPs), Technical Procedures (TPs), and Work Plans - including documentation of work via the scientific notebook, technical report, progress report, and procedural forms.

### **5.4 IMPLEMENTATION**

Procedures controlling quality-related activities (including scientific investigations) are developed and approved on a timely basis, with an adequate level of detail to enable the activities to be carried out in a timely manner. The procedures will also be developed to provide a consistent basis for making decisions, accomplishing verification measures, and evaluating changes.

Review, approval, issuance, change, revision and cancellation of procedures shall be controlled. The controls on the review and issuance of procedures will ensure that technical and quality requirements are included prior to issuance.

The preparation of Quality Administrative Procedures, Work Plans and Technical Procedures is delineated in the Quality Administrative Procedures, QAP-5.1, "Preparation of Quality Administrative Procedures." and QAP-5.2, "Preparation of Work Plans and Technical Procedures."

## **6.0 DOCUMENT CONTROL**

### **6.1 PURPOSE**

This section describes how the use of quality-related documents is controlled. This section ~~section~~ is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion VI of 10CFR50, Appendix B.

### **6.2 SCOPE**

This section applies to the issuance, distribution control, and revision of ~~all~~ NWRPO QA and technical program documents ~~such as~~ including Quality Assurance Program Plans, Quality Administrative Procedures, Work Plans, and Technical Procedures, Test Plans, and Nonconformance Reports and Suggested Corrective Action Reports and any other documents seen as necessary to control by the Quality Assurance Officer.

### **6.3 RESPONSIBILITIES**

The QA Officer is responsible for issuance and distribution of controlled documents that regulate the manner in which quality-related activities are to be performed. The QA Officer's staff is assigned the responsibility for the issuance, distribution, and revision of controlled documents.

### **6.4 IMPLEMENTATION**

Current and applicable documents will be available at the location where the activity will be performed prior to commencing the work. Superseded or cancelled documents will be removed and replaced by applicable revisions at work areas in a timely manner.

Changes to controlled documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless the On-Site Geotechnical Representative designates another responsible organization.

No controlled documents will be released for official usage prior to review, and signature approval.

Quality Administrative Procedure QAP-6.1, "Procedure for Issuance and Control of Quality Assurance Documents" stipulates the manner in which controlled documents are issued, revised, and archived to ensure retrievability and traceability. The QA Officer's staff shall maintain a master list of all controlled documents issued by the NWRPO, as well as a controlled document distribution list that includes the number of the document and to whom it was issued.

## 7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

### 7.1 PURPOSE

This section describes the manner in which conformance to a specified requirement for purchased items and services is to be controlled. This section is designed to incorporate and ~~conform~~conform to applicable portions of ANSI/ASME NQA-1, as well as criterion VII of 10CFR50, Appendix B.

### 7.2 SCOPE

This section applies to all purchased items and services (including software) that are used in the conduct of NWRPO's program of oversight and investigation.

### 7.3 RESPONSIBILITIES

It shall be the responsibility of the On-Site Geotechnical Representative to maintain a current file of all purchase orders. The QA Officer's staff shall be responsible for source evaluation of objective evidence of quality furnished by the supplier, source inspection, audit and examination of items or services upon delivery or completion. Technical specialists may assist the QA staff with these activities as necessary.

The supplier shall furnish the following to NWRPO: documentation that identifies the procurement and the specific procurement requirements met (e.g. codes, standards, and specifications); documentation identifying any procurement requirements that have not been met; and a description of any nonconformance resulting from not meeting the procurement requirements.

### 7.4 IMPLEMENTATION

The control of purchased items and services is delineated in the Quality Administrative Procedure QAP-7.1, "Procedures for Control of Purchased Items and Services." As described in the QAP the QA Officer will review all purchases and designate them as (1) normal commercial equipment or service, (2) a standard commercial service or equipment with quality impact, or (3) a nonstandard commercial service or equipment with quality impact. Items having quality impacts (categories 2 and 3) require QA staff inspection upon receipt by the NWRPO. Nonstandard items or services with quality impact may require a source evaluation/audit to be performed before the issuance of a purchase order. Suppliers' certificates of conformance for items, services, and software are periodically evaluated by surveillance or inspections to assure that they are valid and the results are documented.

## **8.0 IDENTIFICATION AND CONTROL OF ITEMS**

### **8.1 PURPOSE**

This section describes how the NWRPO assures that geologic and hydrologic samples are adequately identified and controlled and how their use at any stage is traceable through appropriate documentation. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion VIII of 10CFR50, Appendix B.

Nye County's independent oversight drilling program is designed to produce short and long term geohydrologic data that will be used to track progress of the DOE during development activities at Yucca Mountain. All data produced from samples taken during drilling exercises may be used at the NRC proceedings to evaluate DOE's license application. Identification and control of samples is essential for assuring that (1) the integrity of samples is protected over a long time horizon and (2) the data secured from the samples is directly traceable to the source material.

### **8.2 SCOPE**

This section applies specifically to geologic and hydrologic samples collected and handled by NWRPO (including gas samples).

### **8.3 RESPONSIBILITIES**

The responsibilities related to sample management predominantly rest with the On-Site Geotechnical Representative and the QA Officer. The On-Site Geotechnical Representative defines the sample collection methodology in the Work Plan supplemented by Technical Procedures and implements them in the field. The QA Officer defines procedures for field logging and documentation and for sample transport and storage.

The QA Officer shall verify use of appropriate identification and control procedures through audits and surveillance of all NWRPO personnel involved in the control or handling of samples.

### **8.4 IMPLEMENTATION**

Physical identification shall be used to ensure the relating of a sample at any time to its applicable documentation. Correct identification of samples shall be verified and documented before release for use or analysis. The Quality Administrative Procedure "QAP-8.1, Procedures for Sample Management" provide direction for sample handling and control for the NWRPO.

## **9.0 CONTROL OF PROCESSES**

This Basic Requirement of ANSI/ASME NQA-1, section II, subsection 9 states:

Processes affecting the quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

**NOT APPLICABLE TO CURRENT NWRPO WORK**

## **10.0 INSPECTION**

### **10.1 PURPOSE**

This section describes how inspections are incorporated into NWRPO activities that have a bearing on quality. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion X of 10CFR50, Appendix B.

### **10.2 SCOPE**

This section applies to all NWRPO activities where inspection is applicable.

### **10.3 RESPONSIBILITIES**

Inspection is fundamental to all activities where the verification that required characteristics have been included in an item or activity. The QA Officer is responsible for ensuring that inspection activities are included in QA Program documents where appropriate.

### **10.4 IMPLEMENTATION**

Inspection activities are included in many of the NWRPO Quality Assurance Program documents. All areas where it is necessary to verify that conformance of an item or activity to specified requirements include inspection in some form. Characteristics to be inspected and the inspection methods to be employed shall be specified. The results of the inspection shall be documented. Only persons other than those who performed or directly supervised the work shall perform inspections for acceptance purposes.

Quality Administrative Procedure QAP-18.1, "Procedures for Quality Assurance Audits And Surveillances" implements the majority of NWRPO inspection activities.

## **11.0 TEST CONTROL**

### **11.1 PURPOSE**

This section describes how test control is incorporated into NWRPO activities that affect quality. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion X of 10CFR50, Appendix B.

### **11.2 SCOPE**

This section applies to all NWRPO activities where test control is applicable.

### **11.3 RESPONSIBILITIES**

Tests are used to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service. Principal Investigators are responsible for ensuring test control activities are included in Work Plans and other QA documents as appropriate, including trained and appropriately qualified personnel. The QA Officer is responsible for verification that appropriate test control activities are planned, executed, documented, and evaluated.

### **11.4 IMPLEMENTATION**

Test control activities are generally included in Work Plans, however appropriate sections of related documents such as ASTM methods, suppliers manuals, equipment maintenance instructions, or approved drawings with acceptance criteria may be used when appropriate.

Test procedures will include or reference test objectives and provisions for assuring that prerequisites for the test have been achieved. Test procedures or instructions provide for the following: the requirements and acceptance limits, including required levels of precision and accuracy, as appropriate, are contained in applicable documents; instructions for performing the test; test prerequisites such as: calibrated instrumentation; adequate test equipment and instrumentation; completeness of item to be tested; suitable and controlled environmental conditions; and provision for data collection and storage.; mandatory inspection hold points (as required); acceptance and rejection criteria, including required levels of precision and accuracy; methods of documenting or recording test data and results; provisions for assuring test prerequisites have been met.

Test items tested shall be identified, controlled, and ultimately dispositioned, and samples should be archived, as required by the test procedures.

The potential sources of uncertainty and error in test plans, procedures, and parameters, which must be controlled and measured to assure that tests are well-controlled, shall be identified.

Adequate instrumentation will be available and utilized. Necessary monitoring will be performed under appropriate environmental conditions. Test results will be documented and evaluated by the Principal Investigator to assure that test requirements have been met.

Quality Administrative Procedure QAP-5.2, "Preparation of Work Plans and Technical Procedures" implements applicable portions of test control.

## **12.0 CONTROL OF MEASURING AND TEST EQUIPMENT**

### **12.1 PURPOSE**

This section describes how the NWRPO assures that measuring and test equipment are properly controlled, calibrated at specified intervals, and adjusted when necessary. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion XII of 10CFR50, Appendix B.

### **12.2 SCOPE**

This section applies to NWRPO staff responsible for field and laboratory testing and measurement. Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy.

### **12.3 RESPONSIBILITIES**

The QA staff shall maintain a list of all measuring and test equipment and monitor the effectiveness of the control system.

It shall be the responsibility of the staff utilizing the measuring and/or testing equipment to assure that it is properly controlled, calibrated, and adjusted. If any equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of the previous data and the acceptability of items previously tested or inspected. Out-of-calibration equipment shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect.

### **12.4 IMPLEMENTATION**

All measuring and test equipment shall be assigned a unique NWRPO identification number. All applicable equipment shall have one of three different types of labels or tags (if physically possible to attach):

1. A label stating that no calibration is required
2. A label stating that the equipment requires calibration prior to, and after every use
3. A label stating the last and next date of required calibration

All labels shall display the instrument identification, and the name of the person who performs calibration. Measuring and test equipment shall be calibrated, adjusted, and maintained at

prescribed intervals, or prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration shall be documented.

-Calibration standards shall have greater accuracy than the measuring and test equipment being calibrated. Calibration standards with the same accuracy may be used if they are shown adequate for the requirements and the basis for acceptance is documented by the PI and authorized by the QA Officer.

Quality Administrative Procedure QAP-12.1, "Procedures for Control of Measuring and Test Equipment." provides detailed information about the implementation of the measuring and test equipment system.

## **13.0 HANDLING, STORAGE, AND SHIPPING**

### **13.1 PURPOSE**

This section describes how the NWRPO assures that the handling, storage, and shipping of geoscience samples is accomplished by procedures that prevent damage, deterioration, or loss. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion XIII of 10CFR50, Appendix B.

### **13.2 SCOPE**

This section applies to geoscience cores, cuttings, fluids, and other physical samples collected for testing and evaluation, including their packaging and preservation.

### **13.3 RESPONSIBILITIES**

The Principal Investigator in cooperation with QA Officer shall be responsible for specifying special handling, shipping, and storage requirements, including packaging and preservation of all borehole cores, borehole cuttings, fluids, and other geoscience samples. The QA Officer shall verify, through audits and surveillance, compliance with the requirements of this section.

### **13.4 IMPLEMENTATION**

Borehole samples associated with the NWRPO's independent drilling program shall be maintained and preserved in a manner which will insure the integrity for the life of the NWRPO project, unless limited by expiration of shelf life limitations for specific analytes.

Detailed procedures for handling, storage, packaging, preservation and shipment of geoscience samples can be found in the Quality Administrative Procedure "QAP-8.1, Procedures for Sample Management".

## **14.0 INSPECTION, TEST, AND OPERATING STATUS**

### **14.1 PURPOSE**

This section describes how inspection, test and operating statuses are incorporated into NWRPO work. This section ~~section~~ is designed to incorporate and conform to applicable portions ANSI/ASME NQA-1, as well as criterion X of 10CFR50, Appendix B.

### **14.2 SCOPE**

This section applies to all NWRPO activities where the status of inspections, tests, and operational status is applicable.

### **14.3 RESPONSIBILITIES**

The Principal Investigator is responsible for the inclusion of appropriate status indicators (e.g., tags, labels, segregation) where applicable within inspections, tests, and to indicate operational status (including computer software). The Quality Assurance Officer is responsible for verification that the uses of status indicators are properly documented in procedures and that only authorized personnel apply or remove indicators.

### **14.4 IMPLEMENTATION**

The status of inspection and test activities will be indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location, tags, labels, markings, stamps, or inspection records.

The modification of the sequence of required tests, inspections, and other will be documented. Such modifications are subject to the same controls as the original review and approval.

Quality Administrative Procedure QAP-12.1, "Procedures For Control Of Measuring And Test Equipment" implements the majority of NWRPO inspection, test, and operating status activities

## **15.0 CONTROL OF NONCONFORMING ITEMS**

### **15.1 PURPOSE**

This section describes how the NWRPO assures that items, activities, and services that are found not to conform to program specifications and/or procedures are prevented from being used inadvertently. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion XV of 10CFR50, Appendix B.

### **15.2 SCOPE**

This section applies to samples, data, software, and other items and activities that would have adverse technological or programmatic impacts if they were found to have a deficiency in characteristic, documentation or procedure that renders the quality of an item or activity unacceptable or indeterminate.

### **15.3 RESPONSIBILITIES**

It shall be the responsibility of the researcher performing the nonconforming activity or discovering the nonconformance to bring the nonconformance to the QA Officer's attention. The QA Officer shall verify that the documentation of nonconformances is carried out according to the requirements of this section.

### **15.4 IMPLEMENTATION**

Nonconforming items must be reported to the QA Officer within 2 days. A nonconformance report shall be initiated by the discoverer. The sequentially numbered nonconformance report shall include the name of the person responsible for correcting the nonconformance, description of the problem, action taken or proposed, originator's acknowledgment, and the discoverer's signature. The discoverer shall submit the original nonconformance report to the supervisory person in the area having the nonconforming activity and a copy shall be sent to the QA Officer for review and disposition.

Nonconforming items shall be tagged or segregated immediately upon discovery to prevent inadvertent use. All nonconformance reports must be acted upon within two weeks of the time of discovery.

Quality Administrative Procedure, QAP-16.1, "Procedures for Control of Nonconforming Items", details the methods for reporting, labeling, dispositioning, and correcting nonconformances. QAP-17.1, "Procedures for Corrective Action," details the steps required to correct a nonconformance.

## **16.0 CORRECTIVE ACTION**

### **16.1 PURPOSE**

This section describes how the NWRPO assures that conditions adverse to quality are promptly identified and corrected. This section is designed to incorporate and conform to applicable portions of ANSI/ASME NQA-1, as well as criterion XVI of 10CFR50, Appendix B.

### **16.2 SCOPE**

This section applies to samples, data, and other items and activities that would have adverse technological or programmatic impacts if they were found in error and permitted to be used as a basis for further studies.

### **16.3 RESPONSIBILITIES**

It shall be the responsibility of the NWRPO staff or QA Auditors to notify the QA Officer of the nonconforming activity or item.

### **16.4 IMPLEMENTATION**

Nonconformance reports shall be reviewed by the QA Officer within two days of the discovery of the nonconformance.

Nonconformance reports shall be reviewed by the QA Officer for evaluation of problem trends resulting from failures or deviations from requirements. The QA Officer, through consultation with NWRPO staff, shall be responsible for determining if corrective action is necessary.

If corrective action is deemed necessary, QA shall issue a corrective action request to the area in which the nonconformance occurred. The corrective action shall involve determining the underlying cause of the adverse condition in order to rectify the current condition, as well as to prevent reoccurrence. The corrective action shall also provide for evaluation of effects on past work/data/analyses/experiments resulting from the reported deficiencies. A follow-up audit or surveillance shall be conducted by the QA Officer or staff to ensure the adequacy of the corrective action and a copy of the corrective action request will be placed in the QA Records Center files.

Quality Administrative Procedure, QAP-17.1, "Procedures for Corrective Action." details the system for application of corrective action.

## 17.0 QUALITY ASSURANCE RECORDS

### 17.1 PURPOSE

This section describes how records are to be prepared to furnish documentary evidence of the quality of activities and items affecting quality as work is performed. ~~This section~~ This section is designed to incorporate and conform to applicable portions ANSI/ASME NQA-1, as well as criterion XVII of 10CFR50, Appendix B. Records important to quality and Nye County's effective participation in Yucca Mountain-related suitability and licensing proceedings must be collected, stored and protected in a manner that will ensure their retrievability for as long as they have potential use. Records can be maintained in paper, microfilm, photographic, or electronic medium, such as computer disks and tapes, and can include, but are not necessarily limited to the following:

datasets  
scientific notebooks  
maps  
letters  
memoranda

technical reports  
technical and peer reviews  
source documents/books/articles  
references that will not be readily available

Hydrologic and geotechnical samples are not considered records for purposes of this section, but are addressed under Section 8.0.

### 17.2 SCOPE

This section applies to the responsibilities and requirements for record transmittal, retention, and maintenance. This section also applies to the individuals responsible for the collection, storage, and disposition of quality records and the types of records to be maintained.

### 17.3 RESPONSIBILITIES

The On-Site Geotechnical Representative is responsible for the development of a document system that controls identification, generation, validation, classification, filing, and storage of quality assurance records. The Project QA Officer is responsible for reviewing, monitoring, and auditing project QA records to assure that they meet the requirements specified herein and other procedures designated by the On-Site Geotechnical Representative. The PI is responsible for control of his data and for the proper definition, retention, authentication, and securing of QA records in their activity's files. The QA staff is also responsible for implementing a system to assure only authorized access to QA files.

### 17.3 IMPLEMENTATION

Criteria are established and described the implementing procedure for determining when a document becomes a QA record, subject to the controls of this section and the retention periods for such records

Quality Assurance Records shall be maintained in accordance with the requirements of Quality Administrative Procedure, QAP 17.1, "Quality Assurance Records Management Procedures." The records to be generated by NWRPO will be specified in applicable Quality Administrative Procedures, Work Plans, and Technical Procedures. Documents that are designated to become Quality Assurance records shall be legible, accurate, and completed appropriate to the work accomplished.

## 18.0 AUDITS

### 18.1 PURPOSE

This section describes how the NWRPO audits and surveillances, both planned and periodic, are carried out to verify compliance with all aspects of the NWRPO Quality Assurance Program and to determine its effectiveness. These verification actions include those carried out on subcontractors.

This section is designed to incorporate and conform to applicable portions ANSI/ASME NQA-1, as well as criterion XVIII of 10CFR50, Appendix B.

### 18.2 SCOPE

This section applies to the audits and surveillances that are conducted by NWRPO QA and include audits of external and audits and surveillances of internal activities.

### 18.3 RESPONSIBILITIES

The QA Officer shall be responsible for scheduling the audits. The Auditors shall be responsible for planning, accomplishment and follow-up of audit activities. Auditors may be assisted by technical personnel. Audits are performed in accordance with pre-established written approved procedures and conducted by trained, qualified, competent QA and technical personnel having expertise which encompasses the area being audited and having no direct responsibilities in the areas being audited.

The supervisor of the audited area shall be responsible for assuring that necessary actions are taken to correct deficiencies found during the audit.

Audit results are documented and analyzed by the QA and technical staff organization, and the results are reported to responsible management for review, assessment, and appropriate action.

### 18.4 IMPLEMENTATION

Audits and surveillances shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities, including the use of computer software classified as quality affecting. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that current coverage is maintained. A tracking system for audit findings is established to help assure that all findings are appropriately addressed, prioritized and

trended. The cause of each finding is also identified, the corrective action for it described, and follow-up action is accomplished to assure proper closeout of deficiencies.

"Procedures for Quality Assurance Audits and Surveillances"; QAP-18.1 provides detailed instructions for the performance and reporting of audits and surveillances.