

*Rec'd with letter dtd
11/17/94*

NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

**QUALITY ASSURANCE MANUAL:
POLICY, PROGRAM AND PROCEDURES**

DRAFT

*DAW-E
4/10/94*

Controlled Copy Number _____
Issued to _____

102.7

9411210097 941111
PDR WASTE
WM-11 PDR

NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

**QUALITY ASSURANCE MANUAL:
POLICY, PROGRAM AND PROCEDURES**

DRAFT

*Jan E
4/10/74*

Controlled Copy Number _____
Issued to _____

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

1.2 QUALITY ASSURANCE POLICY

1.3 QUALITY ASSURANCE PROGRAM

1.3.1 Purpose

1.3.2 Scope

1.4 QUALITY ASSURANCE MANUAL

1.4.1 Purpose

1.4.2 Organization of QA Manual

2.0 ORGANIZATION

2.1 PURPOSE

2.2 RESPONSIBILITIES

2.2.1 Project Quality Assurance Officer

2.2.2 Project Manager

2.2.3 Principal Investigator

2.2.4 Task Manager

2.2.5 Staff

2.3 REQUIREMENTS FLOW-DOWN

2.4 FLOW-DOWN PROCEDURES

2.4.1 Delegation of Responsibility

2.4.2 Performance Accountability

2.5 PERSONNEL QUALIFICATIONS AND TRAINING

TABLE OF CONTENTS (Continued)

3.0 WORK PACKAGES

3.1 DESCRIPTION OF THE WORK

3.2 WORK PLANS

3.3 TECHNICAL PROCEDURES

3.4 EQUIPMENT AND PERSONNEL REQUIREMENTS

3.5 SAMPLE MANAGEMENT REQUIREMENTS

 3.5.1 Purpose

 3.5.2 Responsibilities

 3.5.3 Functions

 3.5.4 Identification and Control of Samples

 3.5.5 Sample Storage and Chain-of-Custody

 3.5.6 Housing for Sample Storage

 3.5.7 Release of Samples for Analysis

 3.5.8 Records Management

3.6 FIELD DATA COLLECTION AND ANALYTICAL EQUIPMENT
REQUIREMENTS

 3.6.1 Applicability

 3.6.2 Responsibilities

 3.6.3 Requirements

3.7 WORK PACKAGE INDEPENDENT REVIEW

4.0 DOCUMENTATION OF WORK PERFORMANCE

4.1 SCIENTIFIC NOTEBOOK

4.2 TECHNICAL REPORTS

 4.2.1 Characteristics

 4.2.2 Drawings, Illustrations, Tables, and Calculations

TABLE OF CONTENTS (Continued)

4.2 TECHNICAL REPORTS (con't)

 4.2.3 Input Data

 4.2.4 Title Page

 4.2.5 Drafts for Review

4.3 PROGRESS REPORTS

 4.3.1 Responsibilities

 4.3.2 Format, Content, Preparation, and Approval

 4.3.3 Alternative Format

 4.3.4 Quality Assurance Records and Distribution

5.0 AUDITING AND VERIFICATION OF
CONFORMANCE TO REQUIREMENTS

5.1 PURPOSE

5.2 RESPONSIBILITIES

5.3 REQUIREMENTS

 5.3.1 Auditing Personnel

 5.3.2 Scheduling

 5.3.3 Preparation for Audit

 5.3.4 Auditing Scientific Notebooks

 5.3.5 Performance of Audit

 5.3.6 Reporting

 5.3.7 Response

 5.3.8 Follow-up Action

 5.3.9 Resolution of Disputes

 5.3.10 Records

TABLE OF CONTENTS (Continued)

6.0 INDEPENDENT REVIEW

6.1 RESPONSIBILITIES

6.1.1 Project Manager

6.1.2 Principal Investigator

6.1.3 Quality Assurance Officer

6.2 INTERNAL OR EXTERNAL TECHNICAL REVIEW

6.2.1 Criteria for Securing Reviewers

6.2.2 Scope of Review

6.2.3 Selection of Technical Reviewers

6.2.4 Resolution of Comments

6.2.5 Documentation

6.3 EXTERNAL PEER REVIEW

6.3.1 Criteria for Securing Reviewers

6.3.2 Scope of Review

6.3.3 Selection of Peer Reviewers

6.3.4 Peer Review Process

6.3.5 Resolution of Comments

6.3.6 Documentation

7.0 RECORDS MANAGEMENT

7.1 RESPONSIBILITY

7.2 REQUIREMENTS

7.2.1 Records System

7.2.2 Generation of Records

7.2.3 Records Classification

7.2.4 Record Validation

7.2.5 Master Record Index

7.2.6 Record Identification

7.2.7 Record Collection

7.2.8 Record Filing and Storage

TABLE OF CONTENTS (Continued)

7.2 REQUIREMENTS (con't)

 7.2.9 Record Retrieval

 7.2.10 Record Revision or Correction

 7.2.11 Completed Activity Records

8.0 DOCUMENT CONTROL

 8.1 DOCUMENTS TO BE CONTROLLED

 8.2 RESPONSIBILITIES

 8.2.1 Project Manager

 8.2.2 Quality Assurance Officer

 8.2.3 Principal Investigator

 8.3 REQUIREMENTS

 8.3.1 Document Preparation, Review, and Approval

 8.3.2 Issuance

 8.3.3 Document Changes

APPENDIX A: Sample Chain-of-Custody Form

APPENDIX B: Documenting Scientific Investigations

APPENDIX C: Document Control Forms

The Nuclear Waste Policy Act of 1982 (NWP) 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 NWP 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.

1.1 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.

1.2 QUALITY ASSURANCE POLICY

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.

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 is in compliance 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.

1.3 QUALITY ASSURANCE PROGRAM

1.3.1 Purpose 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. 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.

1.3.2 Scope NWRPO's Quality Assurance Program includes all aspects of NWRPO's work judged by the Project Manager 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.

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'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.

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.

1.4 QUALITY ASSURANCE MANUAL

1.4.1 Purpose This Quality Assurance Manual 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.

1.4.2 Organization of QA Manual This manual 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 packages, establish technical procedures for conducting the work, identify and qualify resources, specify procedures for sample management, as needed, and control analytical work.

Three mechanisms are identified for documenting work that include the scientific notebook, technical reports and progress reports.

The QA Manual also describes the procedures to be followed for auditing and verifying that work being performed conforms to requirements. Nonconformances that may be identified will be tracked and corrected. Disputes will be resolved by the Project Manager, as necessary.

The Manual also provides guidance for conducting and documenting independent reviews of work that has been completed for NWRPO at the direction of the Project Manager.

Finally, the Manual addresses records management and document control requirements.

2.1 PURPOSE

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 and Manual. This section describes NWRPO's organizational structure, functional responsibilities, levels of authority, and lines of communication.

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 2-1) illustrates the lines of authority, and QA responsibilities, communications and advisory links between the project personnel. Project 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.

2.2 RESPONSIBILITIES

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.

- 2.2.1 Project Quality Assurance Officer** The Assistant Project Administrator is the designated Project QA Officer reporting to the NWRPO Project Manager. He 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. Additionally, the QA Officer assesses the effectiveness of the QA Program, and initiates and/or reviews appropriate revisions of the QA Manual or related documents. The QA Officer also reviews contractor and subcontractor QA programs and recommends their acceptance to the Project Manager.
- 2.2.2 Project Manager** The Project Manager is responsible for the technical performance and staffing of the project. The Project Manager is also responsible for implementation of the QA Program, and the development, maintenance, and safekeeping of the project administrative and technical files. He verifies that all QA records have been properly validated, peer reviews are conducted as required, nonconformances are adequately addressed, job descriptions and qualifications of project personnel are on file, and controlled documents are appropriately distributed. He also assures that the QA Officer periodically audits project activities and verifies that they are being conducted in accordance with established project procedures. He 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 other participants.
- 2.2.3 Principal Investigator** Principal Investigators are under the direction of the Project Manager 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.
- 2.2.4 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.
- 2.2.5 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.

2.3 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:

- 2.3.1 **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.
- 2.3.2 **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.
- 2.3.3 **Verification of Conformance** The QA Officer will verify that the contractor principal investigators and subcontractor task managers conform to the QA Program requirements.

2.4 FLOW-DOWN PROCEDURES

- 2.4.1 **Delegation of Responsibility** The Nye County Commission 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 Project Manager 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 Project Manager 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 maintains a record of their qualifications in their files.

The Project Manager 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 Project Manager and a designated representative from the other organization(s).

2.4.2 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, at its most effective, the responsibility of the whole NWRPO operation, including County personnel, contractors and their subcontractors.

2.5 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 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.

Work that is to be performed under the NWRPO's QA Program shall be described in a work package. Work packages include a description of the work to be performed, a plan for completing the work, technical procedures required to control the work, and equipment and personnel required to complete the work. For work that includes the generation and analysis of samples, the work package will describe how sample management and sample analysis requirements will be met. Finally, as appropriate, the work package will address specific field data collection and analytical equipment requirements, such as calibration.

Work packages will be subjected to review through the use of internal or external technical reviewers, or by a peer review process, as the activity may warrant in accordance with criteria specified in Section 6. All documents that report on the results of the work performed will be technically or peer reviewed before final publication.

3.1 DESCRIPTION OF THE WORK

The Work Description generally describes the work to be performed by NWRPO personnel or by a contractor organization. The Work Description includes a general description of the work to be completed or the product to be generated, more detailed goals and objectives, and, where appropriate, the performance basis for completing the work (*i.e.*, task based or level-of-effort). Where appropriate the required qualifications of key personnel can be specified, as well as preferences for equipment, materials, apparatus, or instruments to be utilized.

3.2 WORK PLANS

Work plans shall (1) be developed and implemented for each major and discrete quality-related element of the work defined in the Work Description that involves the gathering or use of technical data, (2) identify the various tasks necessary to achieve the work's overall purposes, and (3) describe the sequence of activities to be accomplished in the field, laboratory, or project offices. Under the direction of the Project Manager, principal investigators shall be responsible for the development and review of applicable work plans. The following provides guidance regarding work plan contents:

- **Introduction** Describes the work plans framework, including (a) the plan's purpose, (b) what the plan encompasses, (c) the priorities, (d) how the plan is organized, and (e) how the plan relates to NWRPO's work description.
- **Purpose** Provides an explanation for why the plan is necessary and lists its objectives. Also, describes the purposes for individual investigations that are planned.

- **Background** Summarizes what is already known and how it has been established. This should explain why items identified in the scope of work were determined by NWRPO to be necessary.
- **Approach** Describes the overall logic for undertaking the scope of work described in the next session in order to meet project's purpose.
- **Scope of Work** Identifies what work is planned, or defines the types of tests to be conducted, and specifies who has responsibility for each activity. Specifically, identifies the following:
 - Types of investigations that are planned
 - Extent or scale of the investigations
 - Where the investigations are to be conducted
 - A schedule for conducting the investigations, including milestones pertinent to the plan
 - The investigators and their responsibilities
 - Equipment and related calibration requirements
 - Number and types of samples to be collected
- **Management** Describes the organization and management scheme that will ensure that the work will be quality controlled and accomplished in accordance with the project's objectives and scope.

3.3 TECHNICAL PROCEDURES

Technical activities performed by NWRPO, contractors, and subcontractors shall be controlled by technical procedures. The procedures that will be used to accomplish the scope of work will be described in detail in this section of the work package. Data collection for purposes of developing monitoring and assessment socioeconomic models should be described in technical procedures. Procedures for obtaining and preserving samples should be included. Technical procedures governing NWRPO technical activities shall be prepared by NWRPO, and technical procedures governing contractor and subcontractor activities shall be prepared by the appropriate contractors or subcontractors. It is acceptable to reference existing or pending technical procedures; however, a summary description should be provided so the work package can be a stand-alone document. At a minimum, the following items should be identified:

- The type of data to be acquired.
- Data collection methodology and uncertainties in the method
- Special requirements of personnel, if any, for performing the activity beyond those described in Section 2.5.

- The recording of data and analysis (*e.g.*, laboratory notebook), its presentation (*e.g.*, maps, tables, graphs, technical report), and how it will be reviewed and checked. The recording of the data and analysis must be such that they can be readily traceable to the corresponding generating activity.
- As applicable, the following:
 - Drawings, including geologic maps
 - Calculations
 - Technical reports
 - Peer reviews
 - Calibration
 - Sample identification, handling, shipment and storage
 - Special apparatus and equipment
 - Inspection and monitoring
- How data will be integrated into NWRPO's overall database, technical issues priorities, and overall analytical approach

3.4 EQUIPMENT AND PERSONNEL REQUIREMENTS

The work package will include a description of equipment, apparatus, or instruments required for data acquisition. Any equipment, apparatus, or instruments that will be used for quality-affecting data acquisition shall be secured through a documented, systematic and planned procurement process. Design specifications will be defined (*e.g.*, accuracy, precision, and calibration requirements). Equipment acceptance criteria will be defined (*e.g.*, by Certificate of Conformance, source verification, inspection, or post-installation testing) to verify that the item can perform as designed and intended.

Specialty personnel requirements will also be specified in the work package.

3.5 SAMPLE MANAGEMENT PROCEDURES

3.5.1 Purpose 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. Integrity will be achieved by storage in a controlled environment. Traceability will be achieved by maintaining sample histories from collection, transport, processing, shipping, testing, and storage activities.

3.5.2 Responsibilities The responsibilities related to sample management predominantly rest with the principal investigator (PI) and the QA Officer.

The principal investigator defines the sample collection methodology in the Work Package and implements them in the field. The QA Officer defines procedures for field logging and documentation and for sample transport for storage.

While sample collection can be delegated within defined procedures, the PI is ultimately responsible for the sample collection, identification and control. Once samples are collected, the PI verifies that samples have been permanently identified and chain-of-custody forms have been completed. The PI also releases samples for analysis and ensures that documentation of samples returned from analysis is correct.

The QA Officer conducts audits or surveillances of field sample collection to assure that samples are being collected and identified in conformance with defined procedures. The QA Officer also audits project records and procedures to assure that chain-of-custody forms are correctly completed, and traceable to samples.

The Project Manager is responsible for securing a facility for sample storage.

The Project Manager and the PI are only personnel who can release samples for analysis.

3.5.3 Functions The functional requirements for sample management broadly fall into three categories: (1) provide quality control of samples and records, including physical protection, traceability, and controlled access; (2) provide adequate space, facilities, and procedures for the handling of samples (including receiving, processing, handling, distribution, storage, curation, and examination); and (3) provide a records management system and facilities to store physical documents and records.

3.5.4 Identification and Control of Samples Technical procedures shall be established within the work package to control the acquisition and identification of samples. These procedures shall assure that identification is maintained either on the samples or their containers, or on records traceable thereto. Identification of samples shall be traced to the appropriate documentation such as drawings, field logs, test records, survey documents, and any nonconformance reports.

The PI is responsible for the collection of samples according to procedures defined in a Work Package. When a sample is obtained, the PI, or his formally appointed agent, labels it or immediately places the sample in a suitable container that is labelled with the following minimum information:

- Project/Task Numbers
- Collector
- Date
- Sample Location
- Other Pertinent Information

3.5.5 Sample Storage and Chain-of-Custody As soon as is practical, the PI, or his formally appointed agent, will transport the sample to the designated secured storage area and a chain-of-custody record will be completed by the PI or his formally appointed agent (see Appendix A for chain-of-custody record form). A copy of this form will be made and filed in the project files. Each time the sample is moved, the form will be updated by authorized personnel and a copy sent to the project files. It is critical to NWRPO's responsibilities to maintain a complete, unbroken record of sample location history, including who had access to the sample, duration of access, and what was done with the sample.

3.5.6 Housing for Sample Storage The minimum physical security functional requirements for controlled sample management include: (1) protection from environmental factors, such as extreme temperatures, high humidity, excessive dust, and air pollution; (2) protection from natural disasters such as high winds, water damage and fire; (3) protection from infestation by insects, rodents, and mold; (4) protection from man-made damage such as fire, mechanical failure (eg. waterpipe damage, collapse of storage racks), acts of vandalism and larceny; and (5) protection from administrative loss and mishandling of samples.

3.5.7 Release of Samples for Analysis Once in storage, only the NWRPO Project Manager and the PI may release samples for analysis. Personnel authorizing the release of samples have the responsibility for ensuring that the correct sample is made available for analysis and protects the integrity of the samples that are returned to storage.

3.5.8 Records Management Management of sample records involves control of documents generated by collection of geotechnical samples during site investigation. Sample records management will comply with Section 7 (Records Management).

3.6 FIELD DATA COLLECTION AND ANALYTICAL EQUIPMENT REQUIREMENTS

Measuring and test equipment (M&TE) which affect quality shall be controlled, and at specified periods calibrated and adjusted, as necessary, to assure that data derived from this equipment are accurate. This section describes the requirements and methods for the control, calibration, and adjustment of measuring and test equipment.

3.6.1 Applicability M&TE requirements are to be selectively applied to measuring and test equipment important to quality, when used to generate data and/or monitor testing operations that have potential application within a future site suitability or licensing context. For example, calibration and control measures shall be required for down-hole instrumentation packages used by NWRPO but commercial equipment such as rulers, tape measures, levels, and other such devices will not be so controlled.

3.6.2 Responsibilities The Project Manager shall determine the types of equipment to be controlled and he is also responsible for having adequate procedures developed by the staff to assure that control of M&TE meet the requirements of this section.

The PI shall be responsible for the development and implementation of procedures to select, control, handle and store measuring and test equipment used for activities affecting quality. These procedures will be described within the activity work plans or technical procedures.

Technical staff shall be responsible for fulfilling any M&TE control requirements specified in this section, appropriate work plans or technical procedures.

The Project QA Officer is responsible for reviewing QA requirements as they apply to the control of measuring and test equipment; for reviewing, monitoring and auditing the calibration and control process for M&TE as developed and implemented; for reviewing and verifying that calibration results of M&TE are documented and evaluated as acceptable; and for reviewing storage and handling and records management procedures with regard to M&TE.

3.6.3 Requirements Selection and procurement/leasing of measuring and test equipment shall be controlled to ensure that it will function as required for the project, and that the items are of proper type, range, accuracy and tolerance to determine conformance to specified requirements.

3.6.3.1 Controls and Calibration Technical procedures shall be established within the work package for the calibration, handling and storage, and records management of measuring and test equipment.

When purchasing M&TE, or subcontracting the use thereof, the PI shall secure copies of documentation of calibration and quality standards employed by the manufacturer or subcontractor. The calibration of gauges and/or other recording instruments will include a record of measurements in laboratory or factory conditions, as well as records of zero adjustment and/or calibration.

The Project Manager will determine whether the equipment used to perform field testing or data recording operations will be calibrated prior to use. Calibration on selected equipment shall be at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions that could affect measurements. Technical procedures for applicable activities will include criteria, a schedule and rationale for calibration, and requirements for documentation.

3.6.3.2 Documentation The PI shall be responsible for ensuring that documentation is maintained in the form of a notation in the scientific notebook or a separate calibration status log. Notations will include, at a minimum, the following entries:

- Positive identification of the specific device (i.e., serial number)
- Date of calibration
- Results of calibration
- Reference to national standards or recognized physical constraints on which the calibration was based, or a description of the procedure if another calibration process was used.
- Signature of the person performing the calibration

Laboratories providing subcontractor services shall provide documentation of calibration performed on the laboratory equipment used for testing. Documentation will include:

- Description of the calibration method
- Identification of the equipment calibrated and of the equipment used in the calibration
- Signature of the person performing the calibration
- Documented frequency of calibration and the dates that calibrations were performed

3.6.3.3 Tagging Where applicable, equipment shall be tagged to indicate when the forthcoming calibration is due.

3.6.3.4 Equipment Out of Calibration If after performing measurements or tests it is determined that the equipment used is out of calibration, an evaluation shall be made and documented on the validity of previous tests results and the acceptability of items previously tested.

Equipment that is out of calibration shall be tagged, segregated, and not used until recalibrated. If it is not possible to recalibrate an equipment item, it shall be permanently removed from usage and replaced if appropriate.

3.6.3.5 Storing M&TE Equipment Measuring and testing equipment not being utilized shall be properly handled and stored to maintain accuracy. This will require that equipment be packaged (*e.g.*, cushioned) properly so as not to damage or alter the equipment recording components and that it be stored in a suitable (*i.e.*, environmentally stable) area that will not be susceptible to frequent temperature, pressure, and moisture changes. Any unique procedure required for proper handling and/or storage of the M&TE shall be included in the document describing calibration of the equipment.

3.6.3.6 Records Records shall be maintained to indicate calibration status (*i.e.*, due date of the next calibration, traceability to calibration test date). The QA Officer, or a designated representative, shall periodically audit documentation related to M&TE to verify that control of equipment is in accordance to specified procedures. Records management procedures specified in Section 7 shall be followed.

3.7 WORK PACKAGE INDEPENDENT TECHNICAL REVIEW

The completed work package, as well as subsequent analysis and technical reports, will be independently reviewed prior to final NWRPO approval. The type of review to be undertaken will be determined by the Project Manager according to the criteria defined in Section 6 and will entail either a technical review or a peer review. Technical reviews will be conducted either internally or externally.

DOCUMENTATION OF WORK PERFORMANCE

NWRPO will ensure that work performance, data collection, and analysis are documented through the use of three techniques: 1) scientific notebooks, 2) technical reports, and 3) progress reports.

4.1 SCIENTIFIC NOTEBOOK

Notebooks are used to document scientific investigations. A notebook is normally used for a single purpose, (e.g., to document work done for an activity fully described in an NWRPO approved plan or to document sample storage). There are three types of notebooks: lab notebooks, field notebooks, and log notebooks (a.k.a. logbooks). Lab and field notebooks provide a detailed, chronological description of the various activities performed during research and development.

Lab and field notebooks may also be used to document miscellaneous activities (e.g., ideas, phone calls, and field trips). Log notebooks are generally used to record activities prescribed by procedures or to record tabulated data (e.g., lists of calibrations, sample tracking, numerical data, and other technical data).

Procedures for using the scientific notebook approach to documenting quality affecting scientific investigations are described in Appendix B.

4.2 TECHNICAL REPORTS

Technical Reports are used to a) document the results of scientific and socioeconomic investigations, b) report on subsequent analysis and conclusions, and c) submit the investigation procedures and results for peer review per Section 6.

4.2.1 Characteristics Technical Reports will normally represent the third phase of NWRPO's technical investigations, with the first phase being a defined work plan and the second phase being work-in-progress, as reported in the scientific notebook, interim reports, or monthly progress reports. As Technical Reports are to be subject to internal technical review or external peer review, they shall be written a clear and logical manner such that a person technically qualified in the subject matter can review and understand the report without recourse to the author.

Each report shall include a table of contents, a clear statement of purpose, a summary, conclusions, and recommendations, as well as a narrative description of the investigation and analysis. Each report shall provide a reference list identifying

sources of all data used, including unpublished information. As appropriate, reports shall include methodologies of data acquisition and analysis and of conclusions.

4.2.2 Drawings, Illustrations, Tables, and Calculations All drawings, illustrations, tables, and calculations issued as part of the report shall be suitably numbered, referenced, and sufficiently annotated to be able to be understood if they were to stand alone, removed from the context of the report itself.

4.2.3 Input Data Input data may be derived from sources such as, but not limited to, field or laboratory scientific notebooks, or other acceptable input/support documents, aerial photographs, boring logs, published or unpublished technical or scientific articles, or published drawings.

Insofar as possible, the Technical Report author shall use current and verified input data. The author shall identify any unverified data, assumptions, or technical scientific judgements indicating those items expected to be verified in the future by anticipated additional data or methods of analysis as they become available.

Each report shall address accuracy, precision, and potential sources of error in input data, results, and conclusions. Calculations not issued as part of the report, but used as input data, shall be suitably referenced.

All input data sources shall be readily available in the NWRPO Records Center, or be readily accessible elsewhere.

4.2.4 Title Page Upon completion, the Technical Report shall be signed and dated on the title page by the author. The title page shall also include a signature line for the peer reviewer or panel, as appropriate.

4.2.5 Drafts for Review All Technical Reports will first be completed in draft form and will be designated accordingly on the title page and each page of the Report. Draft Technical Reports will be subject to internal technical review or external peer review per Section 6.0

4.3 PROGRESS REPORTS

Progress Reports for all quality-related scientific and technical investigations shall be prepared on a regular basis (*e.g.*, monthly), as determined by the Project Manager. The purpose of progress reports is to facilitate project management by 1) tracking the current status of work being performed, 2) identifying problems being experienced or that are anticipated, and 3) highlighting activities to be performed during the next reporting period.

4.3.1 Responsibilities The Project Manager will determine the projects for which progress reports are completed and their frequency. The PI will direct the completion of each progress report and will sign and date it before submitting it to the Project Manager. The Project Manager and the Quality Assurance Officer shall each review the progress report and approve it for comprehensiveness and adherence to format by signing and dating each report.

4.3.2 Format, Content, Preparation, and Approval The format for each progress report will include the following as a minimum:

- The **heading** will clearly identify the project title, the report's author, the PI (if they are different), and the reporting period.
- Each page will include a completion date, a page number, and total number of pages for the complete report (*e.g.*, Page 1 of 5).
- A **progress summary statement** which provides the status of the overall project, notes any variances from approved plans, and anticipates changes in the project completion tasks and timelines.
- A description of **activities completed during reporting period**.
- An identification of **problems experienced or anticipated**, especially those that affect the quality of the work, its timeliness, or require management support.
- A listing of activities to be undertaken during the next reporting period.
- Signature and date lines for the report author, PI, quality assurance officer, and project manager, indicating their approval and/or acceptance of the progress report.

4.3.3 Alternative Format The Project Manager may approve an alternative format at the request of the PI.

4.3.4 Quality Assurance Records and Distribution Approved Progress reports shall be submitted to the NWRPO Records Center. Distribution of the report shall be the discretion of the Project Manager.

AUDITING AND VERIFICATION OF CONFORMANCE TO REQUIREMENTS

5.1 PURPOSE

This section addresses the planning, scheduling, and quality assurance (QA) requirements of NWRPO audits. It also presents qualification requirements for QA Program audit personnel. Audits generally include an objective evaluation of the quality-related practices, work packages, procedures, instructions, activities, use of the scientific notebook approach to documenting scientific investigations, and review of documents and records to verify compliance with all aspects of the QA program and to determine its effectiveness.

Audits are applicable to all quality-related activities and their related documentation.

Audits shall be performed to (1) determine that a QA program has been developed, documented, and implemented in accordance with the specified requirements, (2) verify, examine, and evaluate the objective evidence that elements of the QA program are in compliance with the requirements, (3) assess the effectiveness of controls and verification activities, (4) identify any nonconformances to the PI, and (5) verify that corrective action has been planned, initiated, and completed.

5.2 RESPONSIBILITIES

The NWRPO QA Officer is responsible for the development and implementation of the project audit program.

The Project Manager assures that the QA Officer establishes an auditing program for the project, and that auditing personnel have appropriate independent support and authority to meet audit objectives.

The PI shall acquire an audit schedule from the Project Manager that pertains to his activity, or contractors involved with their activities. The PI shall inform ontractors of any upcoming audits that may affect or involve them.

5.3 REQUIREMENTS

5.3.1 Auditing Personnel It is the responsibility of the QA Officer to establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of QA programs. Personnel selected for auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits.

The QA Officer shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. Records of personnel qualification requirements for auditors performing audits shall be established and maintained.

5.3.2 Scheduling QA audits shall be periodically scheduled for all quality affecting activity. The number of audits of an activity during a year shall be determined by the Project Manager after consideration of the QA Officer's recommendation. The audit schedule shall be reviewed periodically and revised as necessary to assure that audit coverage is maintained and current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects and activities when necessary to provide adequate coverage.

5.3.3 Preparation for Audit The QA Officer shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedules, and written procedures or checklists.

The QA Officer shall select and assign a qualified audit leader, and if appropriate, auditors who are independent from the activities which they will audit. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. In selecting personnel as audit leaders, qualified personnel shall have effective communication skills, technical training, and prior audit experience. An audit leader shall be identified prior to the beginning of each audit.

Involved PIs should be notified of an audit at a reasonable time before the audits are to be performed except for unannounced audits. This notification should be in writing and include such information as the scope and schedule of the audit and the name of the auditor. All PIs will be advised if unannounced audits are to be performed for that activity.

5.3.4 Auditing Scientific Notebooks NWRPO will use the scientific notebook for documenting scientific investigations. The procedures for implementing this approach are described in Appendix B. An independent technical review of the notebook will be conducted quarterly. After the completion of the technical review, the QA Officer will conduct a quality assurance review to ensure that the investigator and the technical reviewer adhered to the requirements specified in Appendix B.

5.3.5 Performance of Audit Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the first phase of the activity as is practical and possible, and shall be continued at intervals consistent with the established schedule for accomplishment of the activity or task. Elements that have been selected for audit shall be evaluated against specified requirements.

Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by the NWRPO Project Manager. Nonconforming conditions requiring prompt corrective action shall be reported immediately to the activity's PI and the Project Manager.

5.3.6 Reporting The audit report shall be signed by the audit leader and issued. It shall include the following information, as appropriate:

- Description of the audit scope
- Identification of the auditor(s)
- Identification of persons contacted during audit activities
- Summary of audit results, including a statement on the effectiveness of the quality assurance program elements that were audited
- Description of the root cause of each reported nonconformance finding in sufficient detail to enable corrective action to be taken by the PI.

The audit report should be issued within 15 days and include a requested date of 30 days for response by the audited activity. The audit report with adequate explanation (including those for corrective action) should be distributed to both the Project Manager and the PI.

5.3.7 Response The PI responsible for the audited task shall investigate all nonconformance findings, schedule corrective action, including measures to prevent recurrence, and notify the QA Officer in writing of action taken or planned by or before the requested date. The adequacy of the audit responses shall be evaluated by QA Officer.

5.3.8 Follow-up Action The QA Officer will follow-up at the appropriate time to verify that corrective action is accomplished as scheduled and to close-out the audit. Close-out of the audit should be timely and will address the following considerations:

- Timely written response to the audit report
- Adequacy of the response
- Corrective action accomplished as scheduled
- Proper implementation of corrective action.

The QA Officer shall track noncompliances, determine if a pattern exists, and investigate root causes that should be corrected. Root cause recommendations will be made to the PI. The PI will notify the QA Officer when and how corrective action was taken.

5.3.9 Resolution of Disputes The key purpose for audits is to objectively determine whether NWRPO program activities are in compliance with procedures designed to achieve quality. Audits will be undertaken with the presumption that all program participants are committed to quality and seek to implement the QA Program in good faith. However, while NWRPO's objective is to keep them to a minimum, nonconformances will occur that need to be corrected. Nonconformances will be addressed professionally and in the spirit of mutual cooperation; a "gotcha" approach to auditing will not be tolerated by NWRPO. Participant antagonism toward QA auditors and anything less than 100% participant cooperation will be equally intolerable.

Program participants and QA auditing personnel are expected to maintain a spirit of cooperation, *i.e.*, PIs will work diligently with QA auditors to resolve findings. Notwithstanding this expectation, NWRPO understands that reasonable people can reasonably disagree. If resolution on a finding is not possible, and to avoid protracted debate that in itself is adverse to quality, the parties will request that the nonconforming finding be reviewed by the Project Manager.

The Project Manager will ensure that he understands the basis for the disagreement and will make a written finding for the record. The Project Manager's finding will either confirm, in his judgement, that a nonconformance has been identified for which corrective action is required, or that the condition identified was in conformance with procedures.

5.3.10 Records Audit records shall include audit plans, reports, written replies, the record of corrective action completion. Records should also include details such as auditor's name, identification of the audit leader, dates of auditing and corrective action, modifications (if any) in the procedures and the reasons for modifications, and all other details of auditing activities.

SURVEILLANCES OF WORK IN PROGRESS

6.1 PURPOSE

This section addresses the planning, scheduling, and quality assurance (QA) requirements of NWRPO surveillances. It also presents qualification requirements for QA Program surveillance personnel. Surveillances generally include an objective evaluation of the adequacy of work in progress to verify compliance with the QA program, to determine its effectiveness, identify nonconformances to the PI, and verify that corrective action has been implemented in a timely fashion. Surveillances are applicable to all quality-related activities and their related documentation. The nature of surveillances is to provide a more frequent and less formalized opportunity than audits to monitor for practices that could be detrimental to quality if not corrected.

6.2 RESPONSIBILITIES

The NWRPO QA Officer is responsible for the planning and implementation of surveillances.

The Project Manager assures that the QA Officer conducts surveillances, as appropriate, and that surveillance personnel have appropriate independent support and authority to meet surveillance objectives.

The PI shall fully cooperate with surveillance personnel and ensure full cooperation from contractors.

6.3 REQUIREMENTS

6.3.1 Surveillance Personnel It is the responsibility of the QA Officer to assemble the surveillance team in conformance with established personnel qualifications. Personnel selected for surveillance assignments shall have experience or training commensurate with the scope, complexity, or special nature of the work in progress to be reviewed. Surveillance personnel shall have, or be given, appropriate training or orientation to develop their competence for performing surveillances.

The QA Officer shall select and assign personnel who are independent of any direct responsibility for performance of the work in progress to be reviewed. Records of personnel qualification requirements for surveillance personnel shall be established and maintained.

6.3.3 Preparation for, and Documentation of, a Surveillance The QA Officer shall determine and document in a memo to the Project Manager the general scope of the surveillance, related objectives, and the surveillance date. Based on the scope, the QA Officer shall indicate who will lead the surveillance. He may designate himself, another qualified individual as Surveillance Leader, and may assemble a qualified surveillance team whose members are knowledgeable about, and not directly responsible for, the work in progress to be reviewed.

6.3.4 Performance The surveillance is to be undertaken to verify conformance of work in progress to the specified requirements through one or more of the following methods:

- observation of work in progress
- review of documentation, such as the scientific notebook
- interview of personnel performing the work or responsible for the documentation

6.3.5 Reporting The surveillance report shall be signed by the surveillance leader and issued. It shall include the following information, as appropriate:

- Description of the surveillance scope
- Identification of the surveillance team
- Identification of persons contacted during the surveillance
- Summary of surveillance results, including a statement on the conformance of the work in progress to quality assurance requirements
- Description of the root cause of each reported nonconformance finding in sufficient detail to enable corrective action to be taken

Since the surveillance purpose is to verify that work in progress is in conformance with quality requirements, the QA Officer and PI should work together to expeditiously resolve identified nonconformances without waiting for the formal surveillance report to be issued. A formal report should be issued within 10 days and include a requested date of 5 days for response by the PI. The surveillance report with adequate explanation (including those for corrective action) should be distributed to both the Project Manager and the PI.

6.3.7 Response The PI responsible for the work in progress shall investigate all nonconformance findings, schedule corrective action, including measures to prevent recurrence, and notify the QA Officer in writing of action taken or planned by or before the requested date. The adequacy of the PI's responses shall be evaluated by QA Officer.

6.3.8 Follow-up Action The QA Officer will follow-up at the appropriate time to verify that corrective action is accomplished as scheduled and to close-out the surveillance. Close-out of the surveillance should be timely and will address the following considerations:

- Timely written response to the surveillance report
- Adequacy of the response
- Corrective action accomplished as scheduled
- Proper implementation of corrective action.

The QA Officer shall track noncompliances, determine if a pattern exists, and investigate root causes that should be corrected. Root cause recommendations will be made to the PI. The PI will notify the QA Officer when and how corrective action was taken.

6.3.9 Resolution of Disputes The key purpose for surveillances is to objectively determine whether NWRPO work in progress is being performed in compliance with procedures designed to achieve quality. Program participants and QA auditing personnel are expected to maintain a spirit of cooperation, *i.e.*, PIs will work diligently with QA auditors to resolve findings. Notwithstanding this expectation, NWRPO understands that reasonable people can reasonably disagree. If resolution on a finding is not possible, and to avoid protracted debate that in itself is adverse to quality, the parties will request that the nonconforming finding be reviewed by the Project Manager.

The Project Manager will ensure that he understands the basis for the disagreement and will make a written finding for the record. The Project Manager's finding will either confirm, in his judgement, that a nonconformance has been identified for which corrective action is required, or that the condition identified was in conformance with procedures.

6.3.10 Records Audit records shall include the surveillance memo to the Project Manager, reports, written replies, the record of corrective action completion. Records should also include details such as auditor's name, identification of the audit leader, dates of auditing and corrective action, modifications (if any) in the procedures and the reasons for modifications, and all other details of auditing activities.

Independent review has two purposes:

- To ensure that planned technical work is founded upon sound and defensible technical concepts, methods, assumptions, calculations, and projections.
- To verify the accuracy and completeness of data acquisition and analysis, and overall study methodologies. Specific activities to be evaluated may include mapping, surveys, instrumentation, analytical processes, modeling, among others.

Independent review will be accomplished by internal or external technical reviews or by external peer reviews.

7.1 RESPONSIBILITIES

7.1.1 Project Manager The Project Manager authorizes a PI to undertake the development of a work package to complete an activity. He reviews and approves the work packages and ensures that the activity is executed in accordance with QA requirements and has undergone independent review. The Project Manager is the final arbitrator of any unresolved conflicts between reviewers and principal investigators originating the work being reviewed.

7.1.2 Principal Investigator The principal investigator, in conjunction with the Project Manager, develops the activity objectives, identifies specific issues to be addressed, and defines the verification/review requirements of the activities. The PI assigns qualified personnel to develop the work package and to conduct independent review and verification of the package. He verifies that reviews are conducted properly and are adequate.

7.1.3 Quality Assurance Officer The QA Officer shall review completed work packages developed for the various project activities and approves those in which the QA requirements have been adequately addressed. He advises the Project Manager and PI on the extent of review and verification required for the work packages and subsequently generated documents and data collection and analysis that are conducted for the project. The QA Officer, or designee, conducts periodic audits and surveillances to assess if QA needs are being adequately addressed. He will report any findings and nonconformances to the appropriate PI and to the Project Manager.

7.2 INTERNAL OR EXTERNAL TECHNICAL REVIEW

External technical review shall be regularly undertaken as a check on the thoroughness and accuracy of the work packages and subsequent analysis after work is completed. Technical reviews, while formally documented, are convened to provide timely, informal, yet independent feedback for the primary benefit of the PI.

7.2.1 Criteria for Securing Reviewers Technical review of work packages, or subsequent data collection and analysis, calculations, maps, and graphs, as examples, must be performed by competent individual(s) or group(s) who meet the following criteria:

- reviewer is independent from the work being reviewed, *i.e.*, to the extent practical, not involved as a participant, supervisor, or technical advisor in developing the original work package or performing the work
- reviewer has technical/scientific qualifications at least equal to those needed for the work or analysis under review

Technical reviewers meeting these criteria may be internal NWRPO personnel or its contractors.

Use of external reviewers will be at the discretion of the PI, in consultation with the QA Officer, and with the concurrence of the Project Manager. External reviewers, however, will be required if, in the judgement of the Project Manager, doubt can reasonably be cast on the independence of prospective internal reviewers.

Reviewer qualifications to conduct the technical review shall be included in the documentation of the completed technical review.

7.2.2 Scope of Review The scope of a technical review shall include an evaluation of the approach or methodology proposed for an activity. The reviewer shall also evaluate the consistency, applicability, and defensibility of all references, calculations, significant conclusions, technical concepts, expert judgement, assumptions, evaluations, recommendations, and other items that make up the report on the completed activity.

The review does not necessarily have to include a complete check of detailed calculations (if present), but shall include verification that checking of calculations by the report's author(s) has been adequate.

7.2.3 Selection of Technical Reviewers The principal investigator, in consultation with the QA Officer, shall designate a technical reviewer from the NWRPO staff, including consultants, or, if necessary, solicit technical reviewers external to NWRPO.

7.2.4 **Resolution of Comments** The principal investigator will work diligently with the technical reviewer to resolve review comments. If resolution on a comment is not achieved, the Project Manager, in consultation with the QA Officer, as necessary, will review and resolve any outstanding comments.

7.2.5 **Documentation** Documentation of a completed review shall be maintained by NWRPO that will include the comments resulting from the technical review and evidence that they have been resolved between the reviewer and the author, or by the Project Manager, as the need may arise. The QA Officer will verify that the technical review package is complete as submitted. The document cover page shall include signatures and dates from the PI, technical reviewer, Project Manager and QA Officer.

Documentation and records providing evidence that a technical review was performed in accordance with this procedure shall be collected and conveyed to the NWRPO Records Center for safe storage.

7.3 EXTERNAL PEER REVIEW

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. Peer review is more formal in nature than a technical review and provides the Project Manager the added confidence that the work being performed will be defensible if challenged. While a technical review verifies that the NWRPO principal investigator's plans will likely produce desired results and that completed analysis is accurate based on the available data, peer reviews are necessary to confirm judgements when decisions must be made in the absence of precedents and in spite of ambiguities. Examples for when peer review may be necessary include the following:

- critical interpretations or decisions must be made in the face of uncertainty
- novel or beyond the state-of-the-art testing, plans, procedures, or analysis are contemplated
- detailed technical criteria or standard industry procedures do not exist or are being developed
- results of tests are not reproducible or repeatable
- data or interpretations are ambiguous

7.3.1 Criteria for Securing Reviewers Peer reviews must be performed by competent individual(s) or group(s) who meet the following criteria:

- reviewer is independent from the work being reviewed
- reviewer has generally recognized and verifiable technical/scientific credentials in all or part of the subject matter under review, and at least equal to those needed for the work or analysis under review
- reviewer has sufficient financial independence to ensure impartiality

Peer reviewers will not be internal NWRPO personnel or its contractors.

Use of peer reviewers will be at the discretion of the Project Manager, in consultation with the PI and the QA Officer.

Reviewer qualifications to conduct the peer review shall be included in the documentation of the completed review.

7.3.2 Scope of Review The scope of a peer review shall be defined by the Project Manager indicating the data, interpretations, test results, assumptions, technical procedures and methods, or other issues requiring peer review, and the objectives to be achieved by the review. In addition, the Project Manager will describe how the peer reviewer's evaluation is to be documented. Options will include completing a form (designed by the QA Officer), a letter report, or a formal report.

7.3.3 Selection of Peer Reviewers The Project Manager shall solicit recommendations for peer reviewers from a variety of sources. The selection of the peer reviewers shall be made by the Project Manager, in consultation with the QA Officer and cognizant PI.

7.3.4 Peer Review Process The peer reviewer will complete the review according to the scope described in Section 7.3.2. The peer reviewer will record his comments per the directions provided by the Project Manager when the scope was detailed.

7.3.4 Resolution of Comments The reviewer will complete the review according to the scope defined in Section 7.2.2. The principal investigator will work with the peer reviewers to resolve review comments. If resolution on a comment is not achieved, the Project Manager, in consultation with the QA Officer, as necessary, will review and resolve any outstanding comments.

7.3.5 Documentation Documentation of a completed review shall be maintained by NWRPO that will include the peer review report and evidence that comments have been resolved between the reviewer and the author, or by the Project Manager, as the need may arise. The QA Officer will verify that the technical review package is complete as submitted. The document cover page shall include signatures and dates from the principal investigator, peer reviewer, Project Manager and QA Officer.

Documentation and records providing evidence that a technical review was performed in accordance with this procedure shall be collected and conveyed to the NWRPO Records Center for safe storage.

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 referenced that will not be readily available

Hydrologic and geotechnical samples are not considered records for purposes of this section, but are addressed under Section 3.5 Sample Management Procedures.

8.1 RESPONSIBILITY

The Project Manager is responsible for the development and maintenance 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 Project Manager.

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.

8.2 REQUIREMENTS

8.2.1 Records System A project records system shall be established by the Project Manager in compliance with the requirements specified below in Subsections 8.2.1 through 8.2.13. The project records system shall be implemented and enforced in accordance with the procedures given in Section 8.3, and other instructions and documentation as may be required by the Project Manager.

8.2.2 Generation of Records The records to be generated by NWRPO will be specified in applicable Work Plans and Technical Procedures. Documents that are classified as Quality Assurance records shall be legible, accurate, and complete.

8.2.3 Record Classification Documents generated or received by NWRPO shall be classified as "nonpermanent records", or "lifetime records" in accordance with the following criteria:

8.2.3.1 Lifetime Records. Lifetime records are those that meet one or more of the following criteria:

- Records that would be of significant value in establishing and validating NWRPO's position on the suitability or licensability of Yucca Mountain to store spent nuclear fuel or high-level nuclear waste.
- Records that would be of significant value in identifying or tracing basic data used in an analysis leading to a conclusion on the suitability or licensability of Yucca Mountain to store spent nuclear fuel or high-level nuclear waste.
- Records, such as socioeconomic baseline data, models, and analysis, designated by the Project Manager as potentially having significant value to Nye County for an indeterminate time into the future.

8.2.3.2 Nonpermanent Records. Nonpermanent records are those generated by NWRPO or its contractors and subcontractors that do not meet the requirements for Lifetime record designation. For nonpermanent records, a retention period in years shall be designated.

8.2.4 Record Validation Documents shall be considered valid records only if stamped, initialed, or signed and dated by the originator or PI and the Project Manager; or is otherwise authenticated. Validation shall occur within one month of receipt by NWRPO, at which time the record is added to the record inventory and record inventory listing. The validation requirements for each specific record type will be more definitively described in the Work Plans or Technical Procedures for a particular activity or scientific investigation. For example, independent scientific investigation data collection and analysis may have a record validation procedures distinct from those applied to socioeconomic monitoring and assessment.

8.2.5 Master Record Index A Master Records Index shall be maintained by the NWRPO that controls NWRPO, contractor, subcontractor, and vendor/supplier documents. The index shall contain category titles and subcategory designations that will provide for ready organization of documents by subject and classification within the subject.

The Master Records Index shall be controlled by the Project Manager.

- 8.2.5.1 Master Record Index Control** At a minimum, each page of the Master Record Index shall contain the following information:
- The words "NWRPO Master Record Index"
 - Date of issuance
 - Revision identification (the original issue is Revision 0)
 - Page identification including the total number of pages (e.g., Page 3 of 5)
- 8.2.5.2 Record System Explanation** The NWRPO Master Record Index will include an explanation of the Record System.
- 8.2.5.3 Master Record Index Approval** The NWRPO Project Manager shall sign and date the Index and transmit to the QA Officer, all staff, and contractors/subcontractors for their use.
- 8.2.5.4 Master Record Index Update** The Master Record Index shall be updated periodically to, among other reasons, incorporate additions from newly defined Activity Record Indexes developed under Section 8.2.5.5 below. The Project Manager shall be responsible for issuing Master Record Index updates using the Master Index Control designation described in Section 8.2.5.1 above.
- 8.2.5.5 Work Plan and Technical Procedures Index** The PIs shall be responsible for developing an "Activity Record Index" as part of their preparation of a work plan or technical procedure for an activity. The Activity Record Index shall be considered approved for incorporation into the Master Record Index upon the Project Manager's approval of the work plan or technical procedure.
- 8.2.6 Record Identification** A record designation system shall be established that specifies how each record will be uniquely identified and located for ready retrieval. At a minimum the record identifier will include reference to an Index category (and subcategory, as appropriate), the generating organization, the document classification (lifetime vs. nonpermanent) and a sequential number.
- 8.2.7 Record Collection** The Project Manager and QA Officer shall ensure that records generated by NWRPO and contractor/subcontractor personnel are transmitted to the NWRPO Records Center on a continuous basis, as soon as is feasible after generation. The PI shall be responsible for ensuring that records generated in the field are transmitted in a timely manner and according to prescribed procedures.

- 8.2.7.1 Work Packages and Technical Procedures** PIs will specify within work packages and technical procedures the individual responsible for records management for the activity to be undertaken (hereinafter called the "activity records manager" and any unique circumstances that may affect records management and control.
- 8.2.7.2 Submittal** The designated activity records manager shall transmit records to the QA Officer for processing and storage in the NWRPO Records Center, along with an attached transmittal sheet.
- 8.2.7.3 Transmittal Sheet** Records submitted to the NWRPO Records Center shall be attached to a standardized transmittal sheet entitled "Nye County Nuclear Waste Repository Project Office Records Center Record Transmittal Information". The transmittal sheet shall include the following information:
- Activity records manager name, position title, and affiliation
 - Master Record Index designation as specified under Section 8.2.5
 - Brief description of the type of record (*e.g.*, memorandum, computer disk, etc.)
 - Record title, revision designation, and/or completion date
 - Date of record submittal, number of records being submitted, and number of pages for each record
 - Signature line with date for the activity records manager and for a records reviewer/approver.
- 8.2.7.4 Multiple records per Transmittal** A single transmittal sheet may be used to transmit more than one record at a time provided that all records transmitted are from the same organization and have the same master record index designation.
- 8.2.7.5 Record Quality for Transmittal** The activity records manager shall ensure that the records are acceptable using the following criteria:
- Records shall be legible and of reproducible quality.

DRAFT

- Records shall be attached to a fully completed Records Transmittal Sheet.
- Records shall be of durable material that can be expected to be preserved for very long periods of time.
- Records shall include signatures of the activity records manager and of a reviewer with authority to verify the completeness of the overall record.
- Where records are in an electronic or photographic medium, the transmittal shall clearly specify the need for special handling.

8.2.7.6 Review by the NWRPO Records Center The QA Officer or trained designee shall review the transmittal sheet and records to verify that they are acceptable according to these requirements.

8.2.7.7 Unacceptable or Incomplete Records If the records are unacceptable or the transmittal sheet is incomplete, the QA Officer or designee shall so inform the activity records manager who shall resubmit the record or transmittal communication.

8.2.7.8 QA Officer as Activity Record Manager In cases where the QA Officer is the activity record manager, the QA Officer shall provide for independent review of the records being submitted.

8.2.8 Record Filing and Storage Master record storage shall be maintained by the Project Manager in the NWRPO Record Center located in NWRPO's Tonopah office. All pertinent administrative, technical, and quality assurance documents for the project shall be maintained in the NWRPO Record Center.

All such records shall be stored in metal file cabinets and shall not be vulnerable to fire damage. Records shall be firmly attached in binders, folders, or envelopes and protected from moisture, excessive heat, or pressure. Sensitive records, such as film negatives or electronic storage medium, such as voice, video and computer tapes or computer disks, shall receive special protection from hazards such as excessive light, magnetic fields, or stacking.

- 8.2.8.1 Access to Records** The records stored in the NWRPO Records Center are historical records not to be used for day-to-day reference. The QA Officer shall control access to the stored records. Procedures for retrieval of records are described in Section 8.2.6.
- 8.2.8.2 Storage is Permanent** Records placed in storage shall be permanently retained. Records later superseded, made obsolete, or withdrawn shall be maintained unchanged in the NWRPO Records Center.
- 8.2.8.3 Field and Field Office Files** Task files may be maintained in one or more "field" locations; however, field files shall contain only data pertaining to the activities of that field location. During actual field operation (*e.g.*, at a drill site), the PI shall establish a portable filing system and container to be used to store files generated in the field.
- 8.2.9 Record Retrieval** Any NWRPO, contractor or subcontractor personnel may request copies of records in storage by submitting a written request to the QA Manager or his designee. The request shall indicate, as may be known, the title, responsible organization, category master record index designation, record type, revision, and date of each record.

The QA Manager/designee shall retrieve the requested record from storage, send a copy to the requestor, as feasible, and immediately return the record to storage.

Special arrangements shall be made for large documents, or special records such as photographs or electronic media. In no case, however, shall stored files be removed from the NWRPO Records Center without the Project Manager's approval. The Project Manager must also approve written procedures designating how the stored version will be handled to protect its integrity and chain-of-custody will be documented.

- 8.2.10 Records Revision or Correction** Revision or correction can be made to records before or after filing by persons authorized by the Project Manager if the following procedures are used:

- The initials of person making the revision and the date shall be included in the margin next to the revision and the persons full name and the date of the revision are identified on the original transmittal sheet.

- Changes shall be made by crossing out (single line) in black ink the section to be revised.
- No changes shall be made with correction fluid or tape.

When a revision or correction is made, the Project Manager shall assure that the revised record is distributed to all persons that may be using that record.

8.2.11 Completed Activity Records Activity records are completed when no further use is anticipated. The PI or activity records manager conducts a final inspection of the file to ascertain that the contents coincide with the Activity Record Index previously approved along with the Work Package. The PI or activity records manager also ensures that all records are properly validated and classified as lifetime or nonpermanent. The files are then transmitted to, and inspected by, the NWRPO Records Center according to the procedures specified in Section 8.2.7 Records Collection.

Documents that specify quality requirements or prescribe activities affecting quality shall be controlled. The preparation, issuance, review, approval, and major/minor changes of these documents shall be controlled to ensure that current applicable documents are available at all necessary locations. Document control shall provide for 1) identification of documents to be controlled, 2) assignment of responsibility, and 3) documentation of the control.

9.1 DOCUMENTS TO BE CONTROLLED

The documents to be controlled are the following:

- This NWRPO Quality Assurance Manual
- Work Plans
- Technical Procedures
- Any other document so designated by the Project Manager

9.2 RESPONSIBILITIES

9.2.1 Project Manager The Project Manager has overall responsibility for implementing the control of documents. He identifies, with the QA Officer, which documents are to be controlled, and is responsible for document control, distribution, and revision.

9.2.2 QA Officer The QA Officer verifies that the QA requirements pertinent to controlled documents are implemented properly by the Project Manager and staff. To verify compliance, he signs off on all documents, and any revisions thereof, that specify quality assurance requirements or prescribe activities affecting quality. The QA Officer further assesses project compliance with the document control program through periodic reviews and audits.

9.2.3 Principal Investigator The Principal Investigator is responsible for having current controlled documents at locations where work pertaining to his activity is to be conducted, prior to commencement of work. In addition, he has the responsibility for supervising his staff in the proper use of all controlled documents. He shall periodically review controlled documents that pertain to his activity, and shall notify the Project Manager if revisions are needed.

9.3 REQUIREMENTS

9.3.1 Document Preparation, Review, and Approval Documents shall be controlled to assure that the most current applicable documents are available at the location where they are to be used. The controls begin with a designation and listing of documents to be controlled. This listing shall be maintained in NWRPO files. The Project Manager shall formally assign responsibility for preparing, reviewing, approving and issuing of the controlled documents. The QA Officer shall ensure that controlled documents are reviewed for adequacy, accuracy, completeness, and correctness prior to recommending Project Manager approval and issuance.

9.3.2 Issuance NWRPO controlled documents shall be distributed to all Principal Investigators and other key project personnel, such as consultants, as identified by the Project Manager. Distribution shall be recorded on a Controlled Document Assignment List (Appendix C Form 1) that is maintained by the Project Manager. The Project Manager also maintains a master list of all controlled documents, their revision number, and the date of their issuance. One copy of the original and all revisions of controlled documents will be kept in the NWRPO Records Center.

The Project Manager shall issue Acknowledgement of Receipt Forms (Appendix C Form 2) to recipients of the issued documents, and file the returned Forms in the Controlled Document project files, along with the Controlled Document Assignment List.

9.3.3 Document Changes Document changes can be minor or major. Minor changes, such as inconsequential editorial corrections, do not require the same review and approval as mandated for the original documents. However, to avoid a possible omission of a required review, the originator of the document shall discuss any changes with the QA Officer.

Major changes shall be reviewed and approved by the same process as was used for the original document.

**APPENDIX A
SAMPLE CHAIN-OF-CUSTODY FORM**

NYE COUNTY TRANSFER OF CUSTODY FORM

For Yucca Mountain Samples

Recipient: _____

Organization: _____

Sample Type: _____

Packaging: _____

Sample List:

Total Samples: _____

Releasing Custody for Nye County:

Acknowledging receipt of Custody:

Date: _____

Date: _____

Recipient: Please acknowledge receipt of this shipment and return completed form with 10 working days to:

Nye County Nuclear Waste Project Office
P.O. Box 675
Mercury, NV 89023-0675

APPENDIX B
DOCUMENTING SCIENTIFIC INVESTIGATIONS

B.1 PURPOSE

This procedure specifies the methods by which scientific investigations will be documented for Nye County's Nuclear Waste Repository Project Office (NWRPO).

B.2 APPLICABILITY

This procedure applies to NWRPO and contractor/subcontractor personnel who work under the NWRPO quality assurance program and perform NWRPO scientific investigations or activities in the field or laboratory. Contractor/subcontractor personnel may work under their own internally approved quality assurance procedures for scientific investigations upon the written determination by the NWRPO Project Manager, and upon the recommendation of the QA Officer, that the contractor/subcontractor program meets NWRPO QA requirements.

B.3 RECORDS MANAGEMENT

Records generated documenting scientific investigations under this appendix shall be managed in accordance with the procedures described in Section 8.

B.4 DEFINITIONS

B.4.1 Notebook Notebooks are used to document scientific investigations. A notebook is normally used for a single purpose (e.g., to document work for an activity fully described in an NWRPO approved plan or to document sample storage). There are three types of notebooks: lab notebooks, field notebooks, and log notebooks (a.k.a. logbooks).

B.4.1.1 Lab and Field Notebooks Lab and field notebooks provide a detailed, chronological description of the various activities performed during research and development. Lab and field notebooks may also be used to document miscellaneous activities (e.g., ideas, phone calls, and field trips).

DRAFT

- B.4.1.2 Log Notebooks** Log notebooks are generally used to record activities prescribed by technical procedures or to record tabulated data (e.g., lists of calibrations, sample tracking, numerical data, and other technical data).
- B.4.2 Scientific Investigations** Scientific investigations are of two types: research and development and procedural.
- B.4.2.1 Research and Development** All scientific activities, not specifically defined in detailed technical procedures, that are performed in the field or the laboratory having the purpose of systematically collecting and analyzing information to better understand a defined problem.
- B.4.2.2 Procedural** All scientific work performed according to a detailed set of required tasks and in a prescribed sequence, as described in previously approved written technical procedures.
- B.4.3 Technical Reviewer** Technical reviewers conduct periodic reviews of notebooks. To conduct the review, the technical reviewer must have the expertise necessary to understand the work being reviewed; however, the technical reviewer must not have performed the work itself.
- B.4.4 Employee** Employees include NWRPO staff and contractor/subcontractor staff.

B.5 PROCEDURE

- B.5.1 Selection of Notebook Medium** Employees must select one of the following media, as appropriate, for their notebooks: bound book, loose-leaf book, or electronic medium (*i.e.*, computer file). Employees generally use bound books with blank pages for their notebooks. However, employees may use loose-leaf notebooks providing they consecutively number the pages and keep them in an appropriate binder or folder. Loose-leaf and bound pages may also be numbered consecutively in a subdivided section providing a logical system is used (e.g., pages A1, A2, A3 in Section A).

If employees use electronic medium they must keep a printed, signed and dated hard copy of the notebook in an appropriate binder or folder.

B.6.2 Initiation of Notebooks

B.6.2.1 Identification Number Employees must initiate a notebook by obtaining a unique identification number from the NWRPO Quality Assurance (QA) Officer.

B.6.2.2 Title Page Employees must enter the following items on the notebook's first numbered page:

- unique identification number
- employee's name and company (if not NWRPO staff)
- program title
- title of activity
- name of PI conducting activity, if appropriate

B.6.2.3 Table of Contents or Index Employees must create a table of contents for listing the major sections within the notebook and all relevant attachments.

B.6.3 Attachments to Notebooks Employees must cross-reference all attachments (e.g., maps, photographs, videotapes, charts, graphs, and computer printouts) to the applicable notebook. Employees must keep loose-leaf attachments in a uniquely identified binder or folder and consecutively number the pages. Employees must keep copies of computer file attachments in a uniquely identified binder or folder. During the technical review and quality assurance audits and surveillances, attachments are to be reviewed along with their respective notebook.

NOTE: Attachments are considered part of the notebooks and must satisfy dual storage and other record requirements, as appropriate. This applies to electronic medium as well. Only electronic medium that can be ultimately translated into IBM-PC compatible files may be accepted as a record by the NWRPO QA Records Manager.

B.6.4 Criteria for Notebook Entries Employees will record all entries in notebooks according to the following criteria:

B.6.4.1 Recording Entries Entries are to be recorded in longhand, using black ink, or by using electronic media. Entries recorded by longhand will be dated and signed after completing a task or workday.

DRAFT

Two or more individuals may record entries in the same notebook provided that they each date and sign their own entry.

Entries recorded by electronic media will be printed out when the task or workday is finished and the hard copy will be dated and signed.

Each page of the notebook will be filled in completely, unless space needs to be reserved for future entries. Spaces for future entries must be clearly labeled and these entries must be recorded before the notebook is completed. After completing all entries, all blank spaces must be voided with a diagonal line. The void line must be dated and signed.

Only information will be recorded that is relevant to the activity for which the notebook is intended.

Entries will be recorded in sufficient detail such that another similarly qualified individual could repeat the work described and achieve comparable results without recourse to the original investigator.

B.6.4.4 Correcting Longhand Entries Entries will be corrected without using correction fluid or tape, as follows:

- The section to be revised is to be crossed out in black ink and with a single line;
- The revision is to be inserted directly on the page being corrected using arrows pointing to the location for the insertion; or
- For changes that are more extensive than can be accommodated on the page to be corrected, a convention will be established that will be consistently applied throughout handwritten notebooks. A reference letter and page number directing the reviewer to the location of the revised language will be assigned. For example, a notation could be made next to the crossed-out section that states "Insert Change __ from Page __"; and
- All revisions will be initialed and dated in the margins in black ink.

B.6.4.5 Correcting Electronic Entries Electronic medium entries will be corrected by performing the same tasks on the Section B.6.4.1 hard copy in the same manner as described in Section B.6.4.4.

B.6.5 Contents of Notebook Entries The content of notebook entries is divided into five categories: (1) entries that document research and development activities; (2) entries that document miscellaneous activities, (3) entries that document tabulated data, (4) entries that document activities prescribed by NWRPO procedures, and (5) entries that document prototype or scoping activities.

B.6.5.1 Entries that Document Research and Development Activities

B.6.5.1.1 For research and development activities, employees will document the items listed below (see Appendix B Form 1 for item definitions). If an item does not apply during any part of the work, "NA" will be marked beside that item. If an item becomes applicable during the process of the work, that item will be documented when it becomes applicable. Employees will provide detailed daily entries of the work performed and results obtained for each item as appropriate. Daily entries are not required for days in which work was not performed.

- Employee's Name
- Date
- Description
- Methods and Objectives
- Equipment
- Software
- Calibrations
- Set Up Requirements
- Samples
- Acceptance Criteria
- Sources of Error
- Data
- Conclusion (when appropriate)

B.6.5.1.2 Employees will describe any changes made to the original method(s) stated in B.6.5.1.1, as appropriate.

B.6.5.2 Entries that Document Miscellaneous Activities or Tabulated Data
Employees will follow the criteria in B.6.5.1, as appropriate, to document miscellaneous activities or tabulated data.

B.6.5.3 Entries that Document Activities Prescribed by NWRPO QA Procedures

B.6.5.3.1 Employees will record the identification number (including the revision number) of the applicable NWRPO QA procedure and any information required by the procedure.

- B.6.5.3.2 Employees may deviate from the procedural guidance of a QA procedure by identifying the step at which the deviation occurred, recording the reason for the deviation, and describing the results of the deviation.
- B.6.5.3.3 Employees will evaluate all data, including any data produced by a deviation from procedural guidance, and enter a statement in the notebook explaining the acceptance or rejection of the data. The employee will sign, date, and draw a diagonal line through rejected data, then date and sign the line.
- B.6.5.4 **Entries the Document Prototype or Scoping Activities** Employees may document prototype or scoping investigations in a notebook by making an initial entry that clearly identifies the work as non-quality affecting.

B.6.6 Technical Review of Notebooks

- B.6.6.1 **Quarterly Review** Employees must submit their notebooks for review on a quarterly basis. Employees must also submit their notebooks for review when the activity for which the notebook was intended is complete.
- B.6.6.2 **Technical Reviewer** NWRPO Project Manager will designate the technical reviewer to review employee notebooks. Technical reviewers may be NWRPO employees or contractors. All technical reviewers will complete and sign the Notebook Reviewer Qualification form (Appendix B Form 2) to be maintained by the NWRPO QA Officer.
- B.6.6.3 **Review Criteria** The QA Officer is responsible for ensuring that the technical reviewers adhere to the following criteria during the review:
 - B.6.6.3.1 The technical reviewer will determine whether the notebook entries are written in sufficient detail such that another similarly qualified individual could repeat the work described and achieve comparable results without the original investigator.
 - B.6.6.3.2 If the technical reviewer determines that the entries meet the criteria in B.6.6.3.1, the following steps will be performed:
 - a. The technical reviewer will provide a review statement that characterized the review (e.g., "notebook read and understood"). The technical reviewer will record this statement after the last entry

DRAFT

reviewed, after the review comments, or in a section designated for reviews.

- b. The reviewer will identify the pages reviewed, signs and dates the notebook after the review statement, and returns the notebook to the QA Officer.
- c. The QA Officer will conduct a Section B.6.7 quality assurance review

OR

B.6.6.3.3 If the reviewer determines that the entries do not meet the criteria in B.6.6.3.1, the following steps are performed:

- a. The technical reviewer will provide review comments that describe the deficiencies. The technical reviewer will record the review comments after the last entry reviewed or in a section designated for reviews.
- b. The technical reviewer will identify the pages reviewed, sign, and date the notebook after the review statement, and returns the notebook to the QA Officer for review and comment.
- c. The QA Officer and technical reviewer will meet with the employee to examine the QA Officer's and the technical reviewer's comments and they will attempt to resolve the issues together. If not possible, then the employee resubmits the notebook to the reviewer after addressing the concerns. Steps B.6.6.3.1 through B.6.6.3.3 are repeated until the notebook meets the criteria in B.6.6.3.1.

B.6.7 Quality Assurance Review of Notebooks

B.6.7.1 Timing After the technical review is completed, the QA Officer will conduct a quality assurance review.

B.6.7.2 Review Criteria The QA Officer will adhere to the following criteria during the review.

DRAFT

- B.6.7.2.1 The QA Officer will read the notebook and determine whether the notebook entries are legible and will follow the requirements in Sections 6.1 through 6.6 of this procedure.
- B.6.7.2.2 If the QA Officer determines that the entries meet the criteria in 6.7.2.1, the following steps will be performed:
- a. The QA Officer will provide a review statement that characterizes the review (e.g., "quality assurance review conducted and notebook acceptable"). The QA Officer will record this statement after the last entry reviewed, after the review comments, or in a section designated for reviews.
 - b. The QA Officer will identify the pages reviewed, sign and date the notebook after the review statement, and return the notebook to the employee.
 - c. The QA Officer will copy the notebook and attachment pages reviewed and will ensure that a copy is filed in the resident file.

OR

- B.6.7.2.3 If the QA Officer determines that the entries do not meet the criteria in B.6.7.2.1, the following steps will be performed:
- a. The QA Officer will provide review comments that describe the deficiencies. The QA Officer will record the review comments after the last entry reviewed or in a section designated for reviews.
 - b. The QA Officer will identify the pages reviewed, sign and date the notebook after the review statement, and return the notebook to the employee.
 - c. The QA Officer and the employee will address the QA Officer's comments together, if possible. If not, the employee must resubmit the notebook to the reviewer. Steps B.6.6.3.1 through B.6.6.3.3 and Steps B.6.7.2.1 through B.6.7.2.3 will be repeated until the notebook meets the criteria in B.6.7.2.1.

NOTE: The notebook and its attachments are considered an in-process record until all reviews are complete and a record package is submitted. Attachments are usually submitted with a notebook but may be treated as one-of-a-kind records in accordance with the records management procedures.

B.7.0 Records As a result of this document, a record package will be generated that consists of the following:

- copy of completed and reviewed notebook
- attachments to notebook, as appropriate

B.8.0 Software and Disk Compatibility The employee must document in the notebook all software, hardware, codes and operating systems used in the conduct of the scientific investigations and analysis.

B.9.0 Attachments

Form 1: Definition of Research and Development Activities

Form 2: Notebook Reviewer Qualifications

Appendix B Form 1
DEFINITION OF RESEARCH AND DEVELOPMENT ACTIVITY ENTRIES

DATE AND EMPLOYEE NAME

Put current date and the name of the employee completing the outline.

DESCRIPTION

Describe the proposed work or approach; or reference the study plan or other planning document that describes the work to be done. The description may include reference to other notebooks, manuals, texts, etc.

OBJECTIVES

State the objectives to be achieved.

METHODS

State the methods to be employed.

EQUIPMENT

List any major equipment and any special materials to be used. For example, special materials include items such as standards or specific labware (e.g., pyrex instead of plastic). Identify measuring and test equipment by manufacturer and model number, property number, or serial number. Common laboratory equipment does not need to be identified.

SOFTWARE

Identify any software to be used. Cite revision number, if available. Note how software is to be used.

CALIBRATIONS

Identify any calibration requirements, as appropriate. Calibration records should be affixed to the equipment.

NOTE: If a piece of equipment is not operable or not calibrated properly, the QA Officer should be notified and the equipment not used until the equipment is repaired or the calibration completed.

SET UP AND CONTROL REQUIREMENTS

Identify setup and control procedures. This includes characterization of any starting materials; any provisions for ensuring that experimental prerequisites are met; any special measures to be taken in handling, shipping, and storing equipment; and any needed controlled environmental conditions.

SAMPLES

Identify the types of samples to be used (e.g., core, cuttings, water, air, vapor, gas) and how they are to be generated.

DRAFT

ACCEPTANCE CRITERIA

Identify required levels of precision and accuracy, as applicable. Acceptance criteria may be qualitative or quantitative.

SOURCES OF ERROR

Identify potential sources of error or uncertainty that will be measured or uncontrolled that could affect the results or conclusions. Identify any suspected conditions that may adversely affect the results.

DATA

Identify all input data as well as data generated. Include reference to data files as appropriate.

CONCLUSIONS

At the conclusion of work, state your conclusions or observations, addressing whether the original objectives as stated in the initial entry were achieved. Deviations from the original approach are incorporated into this discussion.

DRAFT

**Appendix B Form 2
NOTEBOOK REVIEWER QUALIFICATION**

REVIEWER:

ADDRESS:

PHONE:

SUMMARY OF REVIEWER'S QUALIFICATIONS:

INSTRUCTIONS TO REVIEWER:

Read notebook and determine whether entries are in sufficient detail such that another similarly qualified individual could repeat the work described and achieve comparable results without recourse to the original investigator. After the last entry reviewed or in a section designated for reviews, describe any deficiencies or provide a statement that the notebook was "read and understood." Identify the pages you reviewed, sign and date your review and return the notebook to the author. If deficiencies were found, review the corrected notebook in a similar manner until they are all resolved to your satisfaction.

I have read and understand the above instructions.

Reviewer's Signature

Date

DRAFT

**APPENDIX C
DOCUMENT CONTROL FORMS**

Appendix C Form 1: NWRPO CONTROLLED DOCUMENT ASSIGNMENT LIST

Appendix C Form 2: ACKNOWLEDGEMENT OF RECEIPT OF CONTROLLED DOCUMENT

DRAFT

**QUALITY ASSURANCE MANUAL APPENDIX C FORM 1
NWRPO CONTROLLED DOCUMENT ASSIGNMENT LIST**

_____, Revision _____, has been issued to the following
(Document Title)
project personnel at the direction of the Project Manager.

Name	Document No.	Date Issued

APPROVED BY: _____
Project Manager Date

Quality Assurance Officer Date

DRAFT

**QUALITY ASSURANCE MANUAL APPENDIX C FORM 2
NWRPO ACKNOWLEDGEMENT OF RECEIPT OF CONTROLLED DOCUMENTS**

TO: Project Manager

FROM: _____

SUBJECT: Acknowledgement of Receipt of NWRPO Controlled Document

I hereby acknowledge receipt of the following NWRPO controlled document.

Document Title	Document No.	Date Issued

OR

I hereby acknowledge that I have inserted the revised pages into the above referenced document, and that the superseded pages have been marked "SUPERSEDED" in diagonal across the full page or have been destroyed.

ACKNOWLEDGED BY:

Signature

Date

This completed acknowledgement shall be returned to:

Project Manager
Nye County Nuclear Waste Project Office
P.O. Box 1767
Tonopah, NV 89049

RECEIVED AND PROCESSED BY:

Authorized NWRPO Representative

Date