DOE/NV/10872--T4

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UNIVERSITY OF NEVADA SYSTEM

QUALITY ASSURANCE PROGRAM PLAN
FOR YUCCA MOUNTAIN
SITE CHARACTERIZATION PROJECT

ENVIRONMENTAL RESEARCH CENTER

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MEMORANDUM

TO: William E. Schulze, Director of Research Administration
FROM: A. J. Cross-Smiecinski *ajc*
DATE: July 30, 1991
SUBJECT: UNS YMSCP QA Support Task - Quarterly Technical Progress Report

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Attached find the subject report for the quarters from 01/01/91 through 06/30/91. I will be happy to answer any questions that you may have concerning the report.

Enclosure

cc: D. Barth
P. Baldwin
K. Stetzenbach
K. Lauckner

MASTER

1. Environmental Research Center
2. YMSCP UNS Quality Assurance Support
3. For the cooperative agreement quarters 01/01/91 through 06/30/91:
  - The Environmental Research Center (ERC) composed and revised the YMSCP UNS Quality Assurance Program Plan (QAPP). The QAPP was submitted to the YMSCP project office on April 8, 1991. The QAPP is presently out to UNS for approval signatures before being submitted in final form to the YMSCP project office. See the attachment.
  - ERC has provided technical support to Tracer Study personnel in composition and revision of that study's QA Project Plan (QAPjP). The QAPjP was submitted to the project office on December 14, 1990. The QAPjP is presently in revision at the Tracer Study office. See the attachment.
  - ERC QA staff received formal training from Science Applications International Corporation through attendance on February 28 of the YMSCP Overview and the QA Indoctrination training classes.
  - ERC QA staff attended the Second International Conference on High Level Radioactive Waste Management April 28 to May 3, 1991 in Las Vegas.
4. For these reporting periods the objectives established for the QA support task are being met as needed by UNS YMSCP investigators.
5. Identification and Characterization of Conservative Organic Tracers for Use as Hydrologic Tracers for the Yucca Mountain Site Characterization Study - Quality Assurance Project Plan, December 1990. See attachment.

University of Nevada System Quality Assurance Program Plan for Yucca Mountain Site Characterization Project, July 1991 version. See attachment.

DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

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DOCUMENT APPROVAL

Concurrence

Title: Associate Vice President for Research, UNLV

Signature: _____ Date: _____

DOCUMENT APPROVAL

Concurrence

Title: Associate Vice President for Research, UNR

Signature: _____ Date: _____

DOCUMENT APPROVAL

Concurrence

Title: Vice President for Research, DRI

Signature: _____ Date: _____

INTRODUCTION

This Quality Assurance Program Plan (QAPP) provides specific requirements to University of Nevada System (UNS) project managers for complying with the UNS-Yucca Mountain Site Characterization Project (YMSCP) quality assurance (QA) program. Please refer to Appendix A for definitions of terms used in this QAPP. This program plan was established to address the controls in performance of activities affecting quality for the U.S. DOE for work on the project.

This QAPP describes the UNS-YMSCP QA Program requirements for the YMSCP (Cooperative Agreement DE-FC08-90NV10872). At this time the work that applies to this requirements document are those activities affecting quality delegated to the University of Nevada, Reno; the University of Nevada, Las Vegas; and Desert Research Institute by DOE for the YMSCP. Other components of the UNS may be added to the cooperative agreement with time.

This document has been prepared using the Interim Guidelines and Specifications for preparing QAPPs, QAMS-004/80,^[2] the ANSI/ASME NQA-1-1989 edition and its supplements,^[1] and the Office of Civilian Radioactive Waste Management Quality Assurance Requirements Document (OCRWM QARD).^[3] The provisions of these documents shall apply to those UNS-YMSCP studies specified by the DOE Project Office as described in this QAPP.

COMMITMENT

The UNS is committed to the achievement of quality in research. It is the policy of the UNS that all products resulting from its activities meet the highest standards.

To fulfill this commitment, the UNS has established organizational responsibilities, including Project Managers, Investigators, and Quality Assurance personnel to ensure that quality is integrated into UNS projects.

The achievement of quality is the responsibility of all personnel assigned to a project. Because time and cost are realistic constraints at UNS, planning to achieve quality without waste is top priority. Activities that support the production of quality data, such as training, recognition of performance, identification of problems, and verification of solutions, are supported in the UNS QA Program for the YMSCP.

The UNS has therefore prepared this QA Program Plan. The guidelines and requirements presented constitute the basis for the UNS commitment to quality.

_____
UNS Chancellor

_____
Date

SECTION 1.0

ORGANIZATION

The provisions of NQA-1 Basic Requirement 1 and Supplement 1S-1 shall apply with the following clarifications.

The UNS-YMSCP management and technical staff share the responsibility for implementing the QA policies and are accountable for those aspects of QA/Quality Control (QC) associated specifically with their work areas. An organizational chart showing UNS-YMSCP QA organization is given in Figure 1.

1.1 INDIVIDUAL QA RESPONSIBILITIES

1.1.1 UNS-YMSCP COOPERATIVE AGREEMENT MANAGEMENT

- * Assignment of a person or persons, for verifying quality, at the same or higher organizational level as the highest project manager responsible for performing activities affecting quality.
- * Assuring that the UNS-YMSCP QA program is described in a QAPP and that the QAPP meets the applicable requirements of the OCRWM QARD through review and concurrence.
- * Approval and control of the UNS-YMSCP QAPP.

1.1.2 UNS-YMSCP QUALITY ASSURANCE STAFF

The QA staff serves in a consulting, verification, and auditing capacity and is available to all project personnel in QA matters.

- * Assuring the correct application of appropriate QA requirements by line management through review of the QAPP, QA Project Plans (QAPjPs), and the technical detailed procedures (TDPs).
- * Monitoring the QA program through overview activities that, as a minimum, include audits and reviews.
- * QA Staff members shall meet the requirements listed in the OCRWM QARD^[3] Section 1.1, a.-g.

Figure 1. UNS-YMSCP QA Management Organization.

1.1.3 PROJECT MANAGERS

The project managers are responsible for the management of the project tasks and the ultimate product. Therefore, these individuals are the UNS's main contact with appropriate DOE project personnel and have the primary responsibility for ensuring that data quality objectives are met.

- * Assure that QA requirements of the UNS-YMSCP QAPP are met at the study level through the composition of a study-specific QAPjP and coordinating the composition of associated TDPs.
- * Assuring that all QA requirements are met at the study level and stopping, reporting, and correcting nonconformances.
- * Control of study or study level documents, data, and reports (Section 6).

1.1.4 INVESTIGATORS

The individual investigator is responsible for the quality of the results generated from his or her task. For cases where an investigator or study manager act as one, the individual assumes the responsibilities described for these positions.

- * Follow all QA requirements specified for the investigator in the QAPjP, the TDPs, and the QAPP.

1.2 STOP WORK PROVISIONS

Project managers are responsible to stop work in their respective study areas where QA documents are not being followed or data quality is out of control. Project managers are responsible for documenting the nonconformances or out-of-control process, and initiating and documenting corrective action. The QA staff will verify that adequate corrective action has been taken.

In cases of repeated nonconformances or disputes, then allowances will be made to escalate the issue to the respective cooperative agreement management staff member.

SECTION 2.0

QUALITY ASSURANCE PROGRAM

2.1 POLICY

The following UNS QA policies will be implemented upon approval by the UNS Cooperative Agreement Management, and concurrence by the YMSCP Project Office:

- * The UNS shall comply fully with all elements required for holders of cooperative agreements unless specifically excepted and approved in this document.
- * All UNS-YMSCP studies shall require an approved QAPjP.⁽¹⁾
- * The UNS shall anticipate the compliance with QA Policy in preparing costs and cost estimates for funding.
- * Technical detailed procedures (TDPs) shall be prepared for the performance of critical routine procedures as determined in Section 20.0 and specified in the QAPjP.
- * The authority to conduct independent audits, reviews, and surveillances of the projects is delegated to the QA staff.
- * All data generated by activities affecting quality as defined in Appendix A will be supported by appropriate QA criteria and documentation to ensure that all data collected, stored, reported, or used by the UNS are scientifically sound, defensible, and of adequately known precision and accuracy.

2.2 QA DOCUMENTS

The UNS has developed this QA Program Plan as the quality requirements document for performance of activities affecting quality on the YMSCP (see Figure 2).

UNS implements these requirements by the establishment of QA Project Plans (QAPjPs) for each study as well as scientific notebooks, study plans, and detailed implementing procedures (DIPs) as appropriate. These implementing procedures may be technical in nature called technical detailed procedures (TDPs) or there may be other implementing procedures such as auditing document control used for verification purposes by the QA staff. The scope of the UNS QA program covers those activities as delegated by U.S. DOE and implemented by the aforementioned program documents.

Figure 2. Hierarchy of YMSCP quality assurance documents.

2.3 DELIVERABLES

The accomplishment of activities affecting quality shall be executed in suitably controlled conditions utilizing appropriate equipment. The technical work performed by UNS shall take into consideration any special required skills, test equipment, or other needed special controls to ensure an acceptable deliverable.

2.4 PERSONNEL

The UNS QA program also requires that UNS personnel performing quality affecting activities be appropriately indoctrinated and trained as necessary, as determined by appropriate management.

The extent of indoctrination and training shall be commensurate with (a) scope, complexity, and nature of activity; and (b) education, experience, and proficiency of the person.

- A. Indoctrination shall include: (a) general criteria, applicable standards, codes and UNS procedures; (b) this QAPP, appropriate QAPjPs, appropriate TDPs, and other procedures; and (c) job responsibilities and authorities.
- B. Training shall be provided as needed to: (a) achieve initial proficiency and maintain proficiency; and (b) adopt to changes in technology, methods, and job responsibilities.

SECTION 3.0

DESIGN CONTROL

Design Control activities do not apply to UNS. The precursor to design control activities includes scientific investigation. The UNS controls for scientific investigation are delineated in Section 20.

SECTION 4.0

PROCUREMENT DOCUMENT CONTROL

Measures shall be established to insure that applicable regulatory requirements are included or referenced in the documents for procurement of material, equipment, and services utilized in activities affecting quality. Specifically, procurements documents issued by UNS shall address provisions for: a) Scope of work, b) QA requirements, c) Technical requirements d) access rights, and e) documentation, such as certificates of compliance and mill test reports. Procurement document review and any subsequent changes will be reviewed in a manner consistent with provisions of NQA-1.

UNS-YMSCP project personnel will review procurement documents and modifications of these prior to transmission to suppliers to assure that items or services will meet specified quality requirements. These reviews shall be performed and documented prior to contract award.

Reviews of procurement documents modified as a result of bid evaluations or precontract negotiations shall include: (a) consideration of any additional or modified technical criteria; (b) consideration of the provisions for scope of work, QA program requirements, right of access, documentation requirements, and nonconformances.

SECTION 5.0

INSTRUCTIONS, PLANS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by and performed in accordance with documented plans, procedures, or drawings, of a type appropriate to the circumstances. These documents shall contain qualitative and quantitative criteria, as appropriate, to determine that activities have been satisfactorily accomplished. The specific documents utilized to implement quality and technical requirements by UNS are described in Section 2.

The responsibility for preparing, reviewing, approving, and issuing documents is described in the following matrix.

<u>Document</u>	<u>Prepare</u>	<u>Review</u>	<u>Approve</u>	<u>Issue</u>
QARD	DOE	DOE	DOE	DOE
QAPP	UNS	UNS/DOE	UNS/DOE**	UNS
QAPjP	UNS	UNS/*DOE	UNS	UNS
TDP	UNS	UNS	UNS	UNS
DIPs	UNS	UNS	UNS	UNS
Scientific Notebooks	UNS	UNS	UNS	

* DOE technical monitors working cooperatively on studies with UNS.

** DOE approval is not formally made in this document, but via formal correspondence to UNS.

SECTION 6.0

DOCUMENT CONTROL

The provisions of NQA-1 Basic Requirement 6 and Supplement 6S-1 shall apply to the following documents:

- * UNS QA Program Plan
- * QA Project Plans
- * Technical detailed procedures
- * Scientific Notebooks
- * Instructions, procedures, and drawings

The preparation, review, issue, and change of the documents listed shall be controlled to assure that correct documents are being employed. These documents shall be reviewed for adequacy, completeness, and correctness before being approved for release by those indicated in Section 5.0. Reviews following major document modifications shall be performed by the organizations performing the original review. Document control responsibilities are given in Section 1.0. Those individuals are responsible for controlling and distributing the appropriate documents and maintaining associated records to assure that personnel are using the most current versions.

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.

SECTION 7.0

CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 GENERAL PURCHASING REQUIREMENTS

The provisions of NQA-1 Basic Requirement 7 and Supplement 7S-1 shall apply to purchased items and services used in activities affecting quality with the following amplifications.

Measures have been established to insure that purchased material, equipment, and services conform to state and Federal laws as well as UNS Board of Regents Policy (Title 4, Chapter 3).

Measures shall be established as needed for individual projects to ensure that applicable quality and technical requirements are included or referenced in the documents for procurement of material, equipment, and services used for activities affecting quality. If necessary, individual procurement documents will address the requirements that subcontractors provide a QA program which demonstrates adequate controls over the product(s) being procured.

7.2 SPECIFIC PROVISIONS

It is anticipated that most UNS-YMSCP purchases will be of commercial grade materials and subject to provisions listed except as noted in (B) and the requirements of Section 4.

- (A) The item is specified in a study document;
- (B)
  - 1. Evaluation of the supplier's history of supplying the material and current capabilities;
  - 2. The supplier's current records containing qualitative and quantitative parameters which can be evaluated objectively; and
  - 3. Supplier's technical and quality capability determined by evaluation of his facilities, personnel, and QA program;
- (C) Commercial grade materials shall be identified in the purchase order by the manufacturer's published product description (catalog number, etc.);
- (D) After receipt of the material, the purchaser shall determine:
  - 1) the material was not damaged in shipment,
  - 2) the item received is the item ordered;
  - 3) inspection or testing is accomplished as required by the purchaser to confirm conformance with the manufacturer's published requirements; and
  - 4) documentation as applicable to the item was received and is acceptable.

Those purchased items and services that are not commercial grade are subject to procurement planning, source evaluation and selection (as described previously in (B), bid evaluation, supplier performance evaluation, control of supplier generated documents, and control of supplier nonconformances.

SECTION 8.0

IDENTIFICATION AND CONTROL OF ITEMS

The requirements of this section apply to engineered items and do not apply to scientific investigations. Identification and control of samples and data is addressed in Section 20 Scientific Investigations.

SECTION 9.0

CONTROL OF PROCESSES

The activities associated with the UNS-YMSCP studies do not include processes that need to be controlled in the sense of this criterion.

SECTION 10.0

INSPECTION

The activities associated with the UNS-YMSCP studies do not require verification of conformance against standards or specified requirements, in the sense of this criterion.

SECTION 11.0

TEST CONTROL

The requirements of this provision pertaining to software validation are described in Section 19 and the requirements of this section pertaining to instrument and equipment calibration and testing are addressed in Sections 12 and 20.

SECTION 12.0

CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

12.1 CALIBRATION AND MAINTENANCE

Measures shall be established to insure that measuring and test equipment used in activities that affect quality are controlled, calibrated, and adjusted properly at specified periods to maintain accuracy within necessary limits. TDPs shall be composed where necessary as specified in individual QA Project Plans for the proper use of these devices. In cases where the manufacturer's recommendations are followed, a UNS cover sheet may be added onto these recommendations with appropriate approval signatures and entered into the UNS document control system.

Equipment shall be calibrated against certified standards having known valid relations to the National Institute of Standards and Technology, or to other nationally recognized standards. Equipment shall be calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration shall be documented.

The method and interval of calibration for each M&TE shall be defined, based on the type of equipment, stability characteristics, required accuracy precision, intended use, degree of usage, and other conditions that affect measurement control. Measuring and test equipment must be labeled, tagged, or otherwise documented, in a fashion that indicates the due date of the next calibration.

If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous results obtained, and of the acceptability of items previously inspected and tested, or data gathered since the last calibration. Devices that are out of calibration shall be tagged or segregated, and they shall not be used until they have been recalibrated. If any measuring or test equipment consistently is found to be out of calibration, it shall be repaired or replaced.

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

Records shall be maintained and equipment suitably marked to indicate calibration status. Records shall be maintained for daily/weekly routine calibration checks as well as for annual or semi-annual calibrations. Calibration records shall identify the calibration procedure utilized to perform the calibration.

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy.

There may be cases where the M&TE equipment will have to be calibrated by an outside source. In those cases, the service company may utilize the controls established by UNS or they have their own QA program. The service company's QA program shall be accepted for scope of services by UNS prior to performance of work.

SECTION 13.0

HANDLING, STORAGE, AND SHIPPING

Measures shall be established to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss or deterioration. Handling, storage, and shipping of items shall be conducted in accordance with established good work practices, TDPs specifications, shipment instructions, or other pertinent documents or procedures.

SECTION 14.0

INSPECTION, TEST, AND OPERATING STATUS

The requirements of this section apply to engineered items and do not apply to scientific investigations. The requirements of this criterion do not apply to this QA Program Plan.

SECTION 15.0

CONTROL OF NONCONFORMING CONDITIONS

The provisions of NQA-1 Basic Requirement 15 and Supplement 15S-1 shall apply for items or activities under the control of UNS including measurement and test equipment (M&TE) and instrumentation.

When a nonconforming item or condition is identified, it shall be documented, tracked, segregated, evaluated, and dispositioned as appropriate. Responsibility lies as follows for UNS-YMSCP personnel: (a) identify the nonconforming item or condition on a Nonconformance Report (NCR) form; (b) send the report to the UNS QA staff; (c) QA staff assigns and logs a number, reviews the report, and determines who will evaluate the item or condition; (d) the assigned personnel evaluate the condition and propose corrective action in report returned to QA staff; (e) the QA staff transmits the report to appropriate person for corrective action, (f) corrective action is completed; (g) the QA staff verifies the corrective action; (h) if the problem is resolved successfully, the QA staff closes out the report, updates the log, and sends the report to the YMSCP PO records department. The QA staff basically coordinates the nonconformance reporting and correction process.

Examples of nonconforming items are parts materials, components, and hardware that does not comply with documented requirements of QAPjPs, TDPs, etc. The disposition of a nonconforming item which may be use-as-is, repair, rework, or reject will be documented. Examples of nonconforming conditions (programmatic deficiencies) are those such as failures to comply with procedures, plans drawings, instructions, regulations, or other established requirements.

UNIVERSITY OF NEVADA SYSTEM
DOE-Yucca Mountain Site Characterization Project

NONCONFORMANCE REPORT

INITIATOR		
Initiator:	NCR Date:	NCR No.
Responsible Organization:	Location:	Hardware ☐ Programmatic ☐
Specification Requirements:		

Deficiency:

Initiator:

Date:

PROPOSED DISPOSITION

Disposition:

Technical Justification:

Approximate Cost to Implement Disposition:	Authorized Dispositioner:

DISPOSITION CONCURRENCE/APPROVAL

User:

UNS

Name/Title

Date

Project Manager

Date

DISPOSITION COMPLETION/NCR CLOSEOUT

Dispositioning Actions Completed:

NCR Closed:

Verified by Name/Title

Date

Date

DISTRIBUTION - UPON CLOSURE

DOE YMSCP
UNS Coop Mgr./V.P.
UNS Proj. Mgr.

User Organization
Responsible Organization QA Staff
Other

* Use additional pages as necessary, number each page, and cross reference NCR number.

SECTION 16.0

CORRECTIVE ACTION

The provisions of NQA-1 Basic Requirement 16 shall apply with the following amplifications and modifications. Note that most of the corrective action requirements refer to or are associated with QC indicators built into scientific studies. It is not anticipated that UNS-YMSCP participation will include processes, construction, or engineered items.

This section defines requirements for defining significant conditions adverse to quality and establishes the process to bring them to resolution. A significant condition adverse to quality (SCAQ) is a condition which represents a major breakdown in the QA program or which is repetitive in nature or would directly affect safety or waste isolation of the proposed repository. When an SCAQ is identified, it is documented and upper management is immediately notified. The SCAQ, which is documented on a Corrective Action Report (CAR), is evaluated for cause and stop-work considerations. The responsibilities and flow of the documentation shall be the same as that of a nonconforming condition.

UNIVERSITY OF NEVADA SYSTEM
DOE Yucca Mountain Site Characterization Project

CORRECTIVE ACTION REPORT

INITIATOR		
Initiator:	CAR Date:	CAR No.
Responsible Organization:	Location:	Stop Work Yes ☐ No ☐
Specification Requirements:		

Deficiency:

Initiator:

Date:

PROPOSED DISPOSITION

Disposition [Including Stopwork, if Determined]:

Technical Justification:

Approximate Cost to Implement Disposition:

Authorized Dispositioner:

DISPOSITION CONCURRENCE/APPROVAL

User:

UNS

_____
Name/Title

_____
Date

_____
Project Manager

_____
Date

DISPOSITION COMPLETION/CAR CLOSEOUT

Dispositioning Actions Completed: _____

CAR Closed:

_____
Verified by Name/Title

_____
Date

_____
Date

DISTRIBUTION - UPON CLOSURE

DOE YMSCP

UNS Coop Mgr./V.P.

UNS Proj. Mgr.

User Organization

Responsible Organization QA Staff

Other _____

Use additional pages as necessary, number each page, and cross reference CAR No.

SECTION 17.0

QUALITY ASSURANCE RECORDS

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. All documents shall be legible, identifiable, and retrievable. A document or other item is not considered a QA Record until it satisfies the definition given hereafter. QA Records include:

- * Individual documents that have been executed, completed, and approved, and that furnish evidence of the quality and completeness of data, and activities affecting quality.
- * Documents prepared and maintained to demonstrate implementation of QA programs, for example, reviews, audits, and surveillance.
- * Procurement documents.
- * Other documents, such as plans, QAPjPs, TDPs, NCRs, CARs, Study Plans, technical data, books, maps, papers, photographs, and data sheets that supply quality-affecting information.
- * Magnetic media.

A completed record is a document that will either receive no more entries, or whose revision normally would consist of the reissue of the document and is signed and dated by the originator, and as applicable by other personnel authorized to authenticate the document. Records shall be stored in duplicate where practical, distributed, handled, and controlled by UNS-YMSCP study personnel until transfer to YMSCP Project Office as a deliverable occurs.

Corrections to quality records shall be performed by drawing one line through the material that is to be corrected and providing an initial and date adjacent to the cross-out and/or the new entry, as appropriate. Correction fluid use is not permitted in quality documents.

QA records shall be completed using black ink with an indelible medium for reproducibility purposes.

SECTION 18.0

AUDITS

All UNS-YMSCP activities shall be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA Program and to determine their effectiveness. Audits shall be performed by personnel who are free of funding and organizationally independent (meet requirements of OCRWM QARD⁽³⁾ Section 1.1, a.-g.) of the study or activity being audited and shall be headed by an audit team leader. Audits will provide an objective evaluation of quality-related practices, procedures, instructions, and activities, including the review of documents and records, to insure that the QA Program is effective and implemented properly. The use of independent technical specialists to assist in audit performance may be undertaken based on the subject matter or activity being audited.

The audits shall be performed in accordance with written procedures, using checklists, by qualified personnel and other appropriately trained personnel as necessary. Results of audits are to be reported to the project manager with copies to the cooperative agreement project officer. Corrective action as a result of the audit findings shall be accomplished as addressed in Section 15 or 16.

All deficiencies, nonconformances, and potential quality problems identified during an audit are to be documented and monitored until verification of effective corrective action is made. That is, follow-up action, including verification of corrective action or reaudit of specific areas, shall be performed.

Management of the audited work group shall investigate adverse audit findings, and "give credit where credit is due" for good audit findings. In the case of adverse audit findings, the management shall schedule corrective action, including measures to prevent recurrence, and within 30 calendar days of receipt of the audit report, notify the auditing organization in writing of action taken or planned.

18.1 AUDIT REPORTING

The audit report shall be signed by the audit-team leader and issued in a timely manner as dictated by management. The report shall include the following information, as a minimum:

- * Scope of the audit.
- * Identification of the auditors.
- * Identification of persons contacted during audit activities.
- * Summary of audit results, including a statement of the effectiveness of the QA Program elements that were audited.

- * Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

Description of the audit finding may be in the form of nonconformance reports or corrective action reports, depending on the significance.

18.2 AUDIT RECORDS

As a minimum, audit records shall include the following:

- * Identification of the entity or activities, or items audited.
- * Description of any deficiencies, nonconformances, and potential quality problems identified.
- * Audit plans, audit reports, written replies, the record of completion of corrective action, and the close-out of the audit.
- * Records of personnel qualifications for auditors shall be established, updated annually, and maintained.

SECTION 19

COMPUTER SOFTWARE

19.0 APPLICATION OF REQUIREMENTS

The application of developed, commercially acquired, and existing computer software, in support of the YMSCP High-Level Waste Management Program, will be documented in a Software Quality Assurance Plan (SQAP) written for each UNS/YMSCP Project Plan that uses software that may affect data quality.

The direction expressed within the SQAP shall be consistent with and responsive to the software quality assurance requirements of this Quality Assurance Program Plan for YMSCP. The intent of this SQAP is to assure that work performed using computer software is traceable, reproducible and of value in supporting the YMSCP.

Each affected organization of the University of Nevada System ,i.e., UNLV, UNR, ERC, DRI, will implement the requirements of this Plan by issuing procedures that ensure software life cycles are identified and that methods for applying the program to software configuration management are established. Each procedure shall identify software classification, authorization, acquisition, verification/validation, operation and maintenance, application, and approval. All applied methods shall ensure software integrity and QA records to be generated and maintained in accordance with UNS/YMSCP records management procedures.

19.1 OBJECTIVES OF A SOFTWARE QUALITY ASSURANCE PLAN

This plan establishes requirements for software activities. These activities include the acquisition, management, control, documentation, and use of software in order to achieve a high-level of confidence in the data generated. Requirements that specify needed activities, documentation and reviews are the means by which this plan assures that software usage is traceable, reproducible, and of value. These requirements affect management of hardware, software, input, output and reporting in order to achieve quality data.

19.2 APPLICABILITY

The detailed requirements documented within a SQAP apply to computer software used to produce or manipulate data which is used directly in the design, analysis, performance assessment, and operation of YMSCP. The extent to which these requirements apply is related to the nature, complexity, and importance of the software application.

The UNS method of classification will be based on the following categories:

- * Calculational Software - This category of software includes spreadsheet programs when used for computing results, statistical packages, graphics packages when used with corresponding spreadsheets or statistical packages, data processors, and mathematical libraries.

- * Noncalculational Software - This category includes, but is not limited to, spreadsheets when not used for computing results, compilers, word processors, operating systems, interfaces, driver routines, and other peripheral product software.

19.3 RESPONSIBILITIES

The UNS Project Managers supporting the YMSCP are responsible for: (1) the overall implementation of the SQAP and its associated implementing procedure(s), (2) overview and monitoring of all disciplines to ensure compliance with this plan, and (3) assigning the organizational and functional responsibilities necessary to implement this plan.

Those personnel assigned to software QA shall assure that;

1. configuration management activities related to computer hardware, software, data output and access control are performed and recorded in accordance with the SQAP and its implementing procedures;
2. the proper personnel are identified, as necessary, for providing objective evidence that computer software has the traceable record established, been validated, verified, and documented before it is used in its intended application;
3. all maintenance records related to hardware and software validation are maintained;
4. objective evidence is presented verifying that all activities and documents required by the SQAP are being accomplished by the appropriate individuals; and
5. all required reports and records are distributed to the project manager.

Research personnel or other designated persons who are assigned the task of running software on a certified system for creating a deliverable item are responsible for assuring their activities are in accordance with this plan and its implementing procedures.

An independent reviewer, individual or organization, who performs an evaluation of the validity, accuracy, and adequacy of a particular activity must be as technically qualified as that person(s) needed for the original work under scrutiny. The individual or organization must not be the originator or one who developed the original software.

A Systems Manager is responsible for:

1. coordinating and approving any activity affecting data quality due to a system update,
2. coordinating and approving any configuration management activities,
3. coordinating and approving any system engineering or procedural changes.

SECTION 20.0

SCIENTIFIC INVESTIGATIONS

Research data is collected and developed for a variety of purposes requiring a broad range of approaches and may require differing degrees of data quality. The data quality must, however, be consistent with the intended use of the data. To ensure that the data meets the needs of the project, realistic data quality objectives (DQOs)^(3,4) must be established during the planning phase of the study program.

In general the process will proceed as follows. First, clearly stated objectives will be established for each experiment or investigation. Second, DQOs, based on allowable errors (see Figure 3), will be established for the resulting data. These DQOs must be balanced, but not compromised, with needs and available resources. Important factors which should be considered in specifying DQOs include Type I errors (false positives) and Type II errors (false negatives)⁽⁷⁾. It may be necessary for the project manager to specify probabilities of Type I and Type II errors that will be allowed in making decisions based on the study data. Third, the experiment or investigation will be designed to achieve the specified DQOs. If there is inadequate experience for a specific experimental design or investigation, then a pilot study will be conducted. Fourth, a QA project plan will be designed and implemented to verify the achievements of the DQOs.

20.1 QUALITY ASSURANCE PROJECT PLANS

QA Project Plans (QAPjPs) are to be written by the UNS-YMSCP project managers for any YMSCP study under the UNS coop specified by the DOE Project Office (see Figure 3). Project plans must be written to describe how the applicable requirements listed in this QAPP will be met on a project or study level. If any topic is not applicable to the task, this must be noted; and if guidelines and requirements are insufficient, supplementary sections are to be added to meet the individual study QA needs. QAPjPs should be well thought out and written to avoid redundancy of requirements that may already be addressed in the TDPs.

Basic requirements and associated supplements 8, 9, 10, most of 11, and 14 of NQA-1 apply to engineered items and are not pertinent to scientific investigations. The provisions of this section shall apply to those UNS-YMSCP experiments, investigations, or studies specified by the YMSCP Project Office.

Copies of the QAPjP shall reside in the study files, with the QA Staff, and with all study personnel. Each QAPjP shall address the following provisions as appropriate:

- * Project Description-task, subtask descriptions with timelines, resource requirements, divisions of responsibility, etc. (may serve as the work plan with sufficient detail)
- * Project Organization and Responsibilities (different from Basic Requirement 1)
- * QA Objectives for Measurement Data (DQOs), in terms of precision, accuracy, completeness, comparability, and representativeness, limits of detection, and Type I and II errors
- * Sampling procedures or references thereto

Figure 3. Flow diagram describing quality assurance process.

- * Sample Custody or procedure reference thereto
- * Calibration Procedures and reference standards
- * Analytical Procedures or references thereto
- * Data analysis, Validation, and Reporting
- * Internal QC Checks
- * Performance and Systems Audits-performance evaluation materials, lab audits, notebook checks, etc.
- * Preventive Maintenance Procedures and Schedules
- * Specific Procedures to be used to routinely assess data precision, accuracy, comparability, and representativeness of specific measurement parameters involved
- * Corrective action-based on QC indicators, how initiated, documented, etc.
- * QA Reports to Management

It should be noted that QA documents and procedures are to be useful to the study personnel in attaining the desired data quality. Therefore, prepare QA documents in a thorough but brief and concise manner.

20.2 SCIENTIFIC NOTEBOOKS

The scientific notebook will be used by investigators who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the QAPjP shall be the controlling document used to perform the activity. The contents of the notebook shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results if feasible, or repeat the investigation and achieve the same results without consulting the investigator. Documentation of experiments and research shall be accomplished in logbooks or notebooks to provide written record of the experiment or research.

The following entries shall be made in the notebook prior to initiation of the experiment or research:

- * Title of the experiment or research
- * Name(s) of the personnel performing the experiments or research
- * Description of or reference to the document (usually the QAPjP) which contains the study objectives, DQOs, and the approach.
- * Equipment and materials used
- * Calibration requirements
- * Special training or qualification requirements
- * Environmental conditions, if applicable
- * Data that is suspect or beyond the control of the performing organization
- * Dated signature of the individual(s) making these initial entries

The initial entries described are a general procedure. Modifications may be made to these initial entries by the scientists performing the study. If the change is not within the scope of the study documents, and the investigation is not repeatable, or the change could impact the waste isolation capacity of the YMSCP, or interfere with other site characterization activities, approval shall be obtained from the DOE YMSCP project office.

Subsequent entries made in a scientific notebook during the experiment or research shall be sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and shall include:

- * Date and name of individual making the entry
- * Provisions for assuring prerequisites have been met
- * Description of the experiment or research attempted, including detailed steps followed either by reference to the TDP or entry in the notebook.
- * Description of any conditions or observations which may adversely affect the results of the experiment or research
- * Identification of samples and equipment/instrumentation and materials not included as part of the initial entries
- * Data taken or reference to its identification and location (e.g., magnetic media) and a brief description of the results, including notation of any unaccepted results
- * Any deviations from the planned experiment or research
- * Any interim conclusions reached
- * Final disposition of project
- * Any notations necessary to provide traceability to raw data, samples, standardization procedures, data source, and other associated scientific notebooks.

Final entries in the record have as a minimum the signature of the experimenter and the signature of a competent technical reviewer.

20.3 TECHNICAL DETAILED PROCEDURES (TDPs)

TDPs are required when it is not possible to deviate from a prescribed sequence of actions without endangering the validity of the results. The importance, nature, and repetitiveness of an activity are factors to consider in requiring and developing TDPs. Again, the QAPjP is the overall controlling document for any given study. Management and technical staff must identify tasks and activities for which TDPs are needed. Examples of tasks that may need TDPs are sample management, management of study logs, site monitoring checklists, and use and calibration of portable pH meters.

Project managers assign responsibility for preparing TDPs to individuals who are intimately familiar with the details of the activities and procedures involved and who are able to consult with others who are knowledgeable and actively involved with the activities. TDPs must be approved by project management and the QA staff before they are used.

Copies of TDPs should reside with the QA staff, in the study files, and with study personnel, and shall be available at the work station.

20.3.1 TDP Objectives

All critical (see 20.3) routine studies shall have written TDPs. They should be detailed documents describing who does what, when, where, how, and why. They shall be sufficiently complete and detailed to ensure that:

- * Data of known quality and integrity are generated.
- * The loss of data due to out-of-control conditions is minimized.

TDPs shall be:

- * Adequate to establish the traceability of standard materials, instrumentation, samples, data, and processing personnel.
- * Consistent with sound scientific principles.
- * Consistent with the QAPjP objectives and cooperative agreement requirements.

TDPs shall also require for documentation to be sufficiently complete to:

- * Record the performance of procedures and results.
- * Explain the cause of missing data.

20.3.2 TDP Format - The TDP format shall consider the topics listed below in the development process. As a minimum, the format shall consist of items 1-5, 8, and 11.

1. Purpose
2. Scope of Compliance
3. Personnel Responsibilities
4. Applicability
5. Detailed Procedure
  - * Objective
  - * Methods Used
  - * Alternative Method(s)
  - * Materials/equipment Required
  - * Assumptions Affecting the Procedure
  - * Data Information
6. Calibration Requirements
7. Identification and Control of Samples
8. Quality Assurance Records
9. Modifications
10. References Cited
11. Attachments
12. Approvals

20.4 PERSONNEL QUALIFICATIONS

Qualifications of personnel involved in a study shall be described. Resumes of key study personnel shall be included in the QAPjP as an appendix. Specific required training shall be conducted as well as the provision for training documentation. UNS-YMSCP personnel shall be hired under UNS and Equal Employment Opportunity requirements.

20.5 FACILITIES, EQUIPMENT, AND SERVICES

Study needs that may affect costs and output quality such as specific facility, equipment, instrumentation, and services such as subcontracts shall be carefully planned for each study and specified in the appropriate section of the QAPjP.

Facilities requirements that may be critical to a project^(a) include:

- * Space; equipment capabilities
- * Temperature and air flow limitations.
- * Dust, outside access, and foot traffic limitations.
- * The need for fume hood, air conditioning, and heat installations.
- * Power and backup-power requirements.
- * Hazardous and/or radioactive waste storage space.

Equipment and instrumentation requirements for a study are predictable and are dictated by the task. In planning a project, listing what is available versus what needs to be purchased is helpful. This involves checking what is available in the facility with respect to what has been reserved for other projects. One should also consider the age and operating condition of candidate quality-affecting equipment/instrumentation when planning.

20.6 DATA PROCESSING

20.6.1 COLLECTION

The QAPjP shall address manual and computerized (Section 19) data acquisition and control systems. Internal checks that are used to prevent errors in data collection shall be identified. Data control is described in Section 20.8.2.2. For certain repetitive routine procedures for which the same measurements and/or notations are always made, log sheets rather than notebooks may suffice provided that the use and control are described in the appropriate QAPjP. The decision as to which to use is left up to management and shall be specified in the QAPjP.

20.6.2 VALIDATION

The QAPjP shall describe specific criteria for the acceptance or rejection of data as well as procedures for the determination of outliers and for flagging data. Critical control points should also be described. All data/reports shall be reviewed by the study personnel specified in the QAPjP.

20.6.3 STORAGE

QAPjPs shall indicate how data will be stored with respect to media, conditions, location, retention time, and access if other than described here.

20.6.4 TRANSFER

QAPjPs shall describe procedures which are used to assure the data transfer is error-free (or have an acceptable error rate), that information loss is minimal, and that the output is completely traceable to the input.

Data transfer shall be minimized. The possibility of human error shall be eliminated whenever possible. For example, if a pertinent note has been made on a notepad, rather than copying the information from the notepad to the laboratory notebook, error due to miscopying shall be avoided by permanently attaching the note to the laboratory notebook page.

20.6.5 REDUCTION

Data reduction includes validation, verification, and statistical and mathematical analysis-processes which change the expression or amount of data.

The QAPjP must address validation of any of the processes that are used to reduce data. Validation of the data reduction process itself must be addressed appropriately for the level of effort. Each type of data reduction can be validated against some prescribed methodology.

20.7 DATA QUALITY ASSESSMENT

Data quality assessment tells a scientific investigator if the study data satisfies the DQOs. Assessment involves calculations plus other pre-planned statistical treatments, equations, units, and assessment frequency. The assessment procedures must agree with the DQOs before data comparisons and quality statements can be made. All data must be assessed for accuracy and precision, and should be assessed for representativeness, completeness, and comparability. Data quality assessment procedures and frequency shall be specified in each QAPjP.

20.8 IDENTIFICATION AND CONTROL OF SAMPLES AND DATA

20.8.1 IDENTIFICATION AND CONTROL OF SAMPLES

Procedures shall be developed and implemented as specified in each QAPjP to insure that samples are identified and controlled in a manner consistent with their intended use. Procedures shall define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation, and the generation of records.

20.8.1.1 Identification

Physical identification shall be described. All identification (labelling) methods shall be traceable to the appropriate documentation, such as laboratory notebooks and raw data. Measures shall be taken to maintain sample identification in storage that is consistent with the planned duration and conditions of storage, and they shall describe actions to be taken where samples may have a maximum life expectancy.

20.8.1.2 Storage

Storage methods shall be developed and implemented to insure that samples are maintained in conditions that assure they do not degrade. Physical segregation of samples to preclude cross-contamination shall be used. Sample treatment and storage requirements shall be defined in the appropriate TDPs and/or QA Project Plan and shall include storage during transport when necessary.

20.8.1.3 Control

Controls shall be developed and implemented to assure that sample identification is verified and maintained when handled, transported, or transferred from one work station to another, such as from the field to analysis or from wet chemistry to analysis, etc.

20.8.1.4 Curation

In a case where sample volume remains after processing, provision must be made for curation or disposal of these residuals.

20.8.2 IDENTIFICATION AND CONTROL OF DATA

20.8.2.1 Identification of Data

Data shall be identified to assist in the determination of their correct use. Identification of such data shall be provided in all documents, information systems, or both in which such data appear. Identification shall be sufficient to provide traceability to other components of the project, such as log books, instrumentation, investigators, etc.

The identification of raw data shall include a reference to the origin of the data (study name), name or initials of the data generator, the date, and the instrument or other means of generation. Control measures shall be established and implemented to assure that data are identified properly. These measures shall include verification of the identification of such data prior to release for use.

All data prepared from raw data shall be referenced to the raw data by the same information plus the name or initials of the subsequent data preparer, and the source of the data (for example, log book number).

20.8.2.2 Control of Data

Other requirements for data control may apply as well. For example all study data must be traceable and retrievable. This means that in addition to being able to locate and retrieve all raw data, log books, and copies of reports, an investigator shall be able to trace calibrations and other quality affecting activities back to the sources of reagents and other materials or systems. All analytical standards shall be traceable to a national standard whenever possible.

20.8.2.3 Curation

All reproducible data produced and/or processed for UNS-YMSCP tasks will be maintained in duplicate storage until transmitted to the YMSCP Project Office as a deliverable. One-of-a-kind records will be sent to the YMSCP office as soon as each becomes a QA record.

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APPENDIX A

GLOSSARY OF QA TERMS⁽⁵⁾

Accuracy - the difference between the population mean and the true or reference value.

Activities affecting quality⁽³⁾ - Deeds, actions, processes, tasks, or work which influence the achievement or verification of program quality requirements and objectives. For the Mined Geologic Disposal System, this includes activities affecting the quality of all systems, structures, and components important to safety and the design and characterization of engineered or natural barriers important to waste isolation. Examples of such activities include site characterization, design, procurement fabrication, construction, erection, installation, inspection, testing, auditing, surveillance, assessment, handling, packaging, transportation, storage, cleaning, operations, maintenance, repairing, modifying, performance confirmation, permanent closure, decontamination, and dismantling.

Audit⁽¹⁾ - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Completeness - Refers to the amount of data that is successfully collected with respect to that amount intended in the design. A certain percentage of the intended amount of data must be successfully collected for conclusions based on the data to be valid. Completeness is an issue because missing data may reduce the precision of estimates, introduce bias, and thus lower the level of confidence in the conclusions. (EPA/600/X-87/241).

Computer program⁽¹⁾ - A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.

Corrective action⁽¹⁾ - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Design process⁽¹⁾ - Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Document⁽¹⁾ - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Supplement.

External audit⁽¹⁾ - An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Guideline⁽¹⁾ - A suggested practice that is not mandatory in programs intended to comply with a standard. The word *should* denotes a guideline; the word *shall* denotes a requirement.

Internal audit⁽¹⁾ - An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Measuring and testing equipment (M&TE)⁽¹⁾ - Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Method detection limit (MDL) - The lowest concentration of an analyte that a measurement system can consistently detect and/or measure in replicate field samples. (EPA/600/X-87/241).

Nonconformance⁽¹⁾ - a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Precision - Degree of mutual agreement among individual measurements made under prescribed conditions. (EPA/600/X-87/241).

Procedure⁽¹⁾ - A document that specifies or describes how an activity is to be performed.

Procurement document⁽¹⁾ - Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Qualification (personnel)⁽¹⁾ - The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

Quality - The totality of features and characteristics of a product or service that bear on its ability to satisfy a given need.
(EPA/600/X-87/241).

Quality assessment (quality evaluation)⁽⁸⁾ - The overall system of activities whose purpose is to provide assurance that the overall quality control job is being done effectively. It involves a continuing evaluation of the products produced and of the performance of the production system.

Quality assurance⁽¹⁾ - All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality assurance record⁽¹⁾ - A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

Quality control⁽⁸⁾ - The overall system of activities whose purpose is to control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economic.

Quality control sample - A sample used to determine whether the measurement process or some part of that process is in statistical control at a particular instant in the process.

Representativeness - Refers to the degree to which the data collected accurately reflect the population, group, or medium being sampled. (EPA/600/X-87/241).

Scientific Investigation⁽³⁾ - Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural system or man-made aspects of the Mined Geologic Disposal System, including the overall design of the facilities and waste package. This includes the various studies that are performed for, or in support of, the investigation, exploration, site characterization (including radiological and meteorological), design bases development, licensing, construction, operation, monitoring, performance evaluation, or closure of the Mined Geologic Disposal System or activities related thereto.

Scientific Notebook⁽³⁾ - A document which may be used to provide a written record of the methodology and results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods or both. These notebooks may be used in lieu of technical detailed procedures.

Traceability⁽¹⁾ - The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Technical detailed procedures - An approved and controlled procedure that governs the conduct of a quality affecting activity including technical, quality, scientific, or research activities.

1. Environmental Research Center
2. YMSCP UNS Quality Assurance Support
3. For the cooperative agreement quarters 01/01/91 through 06/30/91:
  - The Environmental Research Center (ERC) composed and revised the YMSCP UNS Quality Assurance Program Plan (QAPP). The QAPP was submitted to the YMSCP project office on April 8, 1991. The QAPP is presently out to UNS for approval signatures before being submitted in final form to the YMSCP project office. See the attachment.
  - ERC has provided technical support to Tracer Study personnel in composition and revision of that study's QA Project Plan (QAPJP). The QAPJP was submitted to the project office on December 14, 1990. The QAPJP is presently in revision at the Tracer Study office. See the attachment.
  - ERC QA staff received formal training from Science Applications International Corporation through attendance on February 28 of the YMSCP Overview and the QA Indoctrination training classes.
  - ERC QA staff attended the Second International Conference on High Level Radioactive Waste Management April 28 to May 3, 1991 in Las Vegas.
4. For these reporting periods the objectives established for the QA support task are being met as needed by UNS YMSCP investigators
5. Identification and Characterization of Conservative Organic Tracers for Use as Hydrologic Tracers for the Yucca Mountain Site Characterization Study - Quality Assurance Project Plan, December 1990. See attachment.

University of Nevada System Quality Assurance Program Plan for Yucca Mountain Site Characterization Project, July 1991 version. See attachment.

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