



Department of Energy  
Washington, DC 20585

MAR 09 1989

Mr. John J. Linehan, Director  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management  
Nuclear Materials Safety and  
Safeguards Division  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Dear Mr. Linehan:

On February 14 and March 3, 1989, the Department of Energy (DOE) transmitted four Quality Assurance Program Plans (QAPPs) for information purposes to the Nuclear Regulatory Commission (NRC). The four documents were from the following project participants:

- 1) Fenix and Scisson, Inc. (F&S)
- 2) Reynolds Electrical and Engineering Co., Inc. (REECO)
- 3) Holmes and Narver (H&N)
- 4) Lawrence Livermore National Laboratory (LLNL)

Included with the QAPPs, DOE also sent matrix checklists for each QAPP which showed a consistency with review requirements governed by NNWSI/88-9, Revision 2.

With this letter, we have enclosed copies of four checklists against the NRC Standard Review Plan (June 1984, Revision 0) which was used during the compliance review of each of the four QAPPs. We hope that you find this information useful in your assessment of the QAPPs.

Sincerely,

Gordon J. Appel, Chief  
Licensing Branch  
Systems Integration and  
Regulations Division  
Office of Civilian Radioactive  
Waste Management

Enclosure

cc:  
S. Zimmerman, State of Nevada  
J. Blaylock, YMPO  
M. Baughman, Lincoln County, NV  
S. Bradhurst, Nye County, NV  
D. Bechtel, Clark County, NV

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WBS #1.2.9.3  
"QA"

FEB 09 1989

Lake H. Barrett, Quality Assurance, HQ (RW-3) FORS

PROJECT OFFICE REVIEW OF FENIX & SCISSON, INC. (F&S), REYNOLDS ELECTRICAL AND ENGINEERING CO., INC. (REECO), HOLMES & NARVER, INC. (H&N), AND LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) QUALITY ASSURANCE PROGRAM PLANS (QAPPS) - NUCLEAR REGULATORY COMMISSION (NRC) STANDARD REVIEW PLAN (SRP)

Enclosed are copies of the SRP checklists that were used during the compliance review of F&S, REECO, H&N, and LLNL QAPPS.

Should you have any questions, please contact Albert C. Williams of my staff at (702) 794-7591 or FTS 544-7591 or Kent B. Johnson of Science Applications International Corporation at (702) 794-7751 or FTS 544-7751.

James Blaylock  
Project Quality Manager  
Yucca Mountain Project Office

YMP:JB-2050

Enclosures:  
F&S, REECO, H&N, and LLNL  
SRP Checklists

- cc w/o encls:
- S. H. Klein, SAIC, Las Vegas, NV
  - Stephen Metta, SAIC, Las Vegas, NV
  - J. W. Estella, SAIC, Las Vegas, NV
  - K. B. Johnson, SAIC, Las Vegas, NV
  - B. W. Hurley, SAIC, Las Vegas, NV
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  - E. L. Wilmot, YMP, Las Vegas, NV
  - N. A. Voltura, YMP, Las Vegas, NV
  - A. C. Williams, YMP, Las Vegas, NV
  - A. L. Baca, YMP, Las Vegas, NV
  - C. P. Gertz, YMP, Las Vegas, NV

Received w/Ltr Dated 3/9/89

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

Revision 6/84 <sup>N-0A-059</sup>  
10/88

PREPARED BY STEVEN P. NOLAN

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <u>φ</u>	COMMENTS
<b>I. ORGANIZATION</b>		
<p>The organization elements responsible for the QA program are acceptable to the NRC staff if:</p>		
<p>1. The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.</p>		<u>DOE RESPONSIBILITY</u>
<p>2. DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</p>	<p><u>033-YMP-R 1 REV0</u> • PARA 1.0</p>	
<p>3. DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.</p>	<p>• PARA 1.0</p>	
<p>4. DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of the representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.</p>	<p>• PARA 2.1 <u>033-YMP-R 1B REV0</u> • PARA 1.22 <u>033-YMP-R 7 REV0</u> • PARA 1.4.2.1</p>	
<p>5. Qualified individuals or organization elements are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.</p>	<p>• <u>033-YMP-R 1 REV0</u> • PARA 2.1</p>	
<p>6. Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</p>	<p>• PARA 1.0</p>	
<p>7. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.</p>	<p>• PARA 2.3 • FIGURE 1.0.1</p>	<b>"BEST AVAILABLE COPY"</b>

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8. The QA organization is involved in the aspects of the high level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.

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- PARA 1.0  
- PARA 2.0

9. DRI and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.

- PARA 2.3

10. DRI and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:

- PARA 1.0  
- PARA 2.1

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

- PARA 2.3  
- PARA 2.1

b. Has effective communication channels with other senior management positions.

- PARA 2.1

c. Has responsibility for approval of QA manuals, changes thereto, and interpretations thereof.

- PARA 2.1

d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

- PARA 2.1

11. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for design (item 3.7), inspections (item 10.2) and test data evaluation (item 11.3) are outlined in these sections.

- PARA 2.0

12. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

- PARA 2.0

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REQUIREMENT	WHERE LOCATED IN REV. <u>0</u> OF PARTICIPANT QAPP	COMMENTS
<p>a. Identify quality problems. b. Initiate, recommend, or provide solutions through designated channels. c. Verify implementation of solutions. d. Stop unsatisfactory work.</p>	<p><u>033-1ND-K 1 100 0</u>  • PARA 2.0</p>	
<p>The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.</p>	<p>• PARA 2.3</p>	
<p>13. Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.</p>	<p>• PARA 2.2</p>	
<p>14. Policies regarding the implementation of the QA program are documented and made mandatory.</p>	<p>• PREFACE • PARA 1.0</p>	
<p>15. The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.</p>	<p>• PARA 2.1</p>	

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II. QUALITY ASSURANCE PROGRAM

Activities related to the QA program are acceptable to the NRC staff if:

1. The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.
2. The QA program includes a commitment that all development, control and/or use of computer programs will be conducted in accordance with the QA program. Requirements or the content of documentation of computer codes is provided by NUREG-0826, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."
3. Provisions are established to assure that technical and QA procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document consistent with QA program requirements and are properly documented and signed by a responsible official.
4. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.
5. The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities.

033-YMP-R 2 UO 0

- PARA 16
- PARA 2.0
- " 2.1.1
- " 2.1.2
- " 2.1.3
- " 2.2 ALL

033-YMP-R 3 UO 0

- PARA 15

• PARA 12  
033-YMP-R 2 UO 0

- PARA 1.0

- PARA 1.2

- PARA 1.0

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This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and other described in 10 CFR 50, Appendix B.

033-YAP-R 2 REV 0  
• PARA 2.6  
• PARA 1.7

6. Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR 50, Appendix B, appropriate to specific items and activities, will be met.

• PARA 1.0

7. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR 50, Appendix B. These measures should include:

• PARA 1.0

A. Frequent contact with program status through reports, meetings, and/or audits.

• PARA 1.0 & PARA 3.1  
033-YAP-R - 18 REV 0

B. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.

• PARA 12.1  
033-YAP-R 2 REV 0  
• PARA 4.1

8. Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-related activities are instructed to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

• PARA 5.1  
• PARA 5.1.3

b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

• PARA 5.1  
• PARA 5.1.4

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

• PARA 5.1.6.3

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d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retaining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.

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• PARA 5.1.5*

e. Qualified personnel are certified in accordance with applicable codes and standards.

*• PARA 5.1*

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<p style="text-align: center;"><b>III. DESIGN CONTROL</b></p> <p>Activities related to design control are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and components performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR 60 and the Atomic Energy Act of 1954.</li> <li>The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.</li> <li>Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.</li> <li>Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.</li> </ol>	<p style="text-align: center;"><u>025-YMP-R 3 Revision 6</u></p> <p><u>Appendix A</u></p> <p><u>Para 1.1.2</u>  " 2.2.1  " 2.3.1  " 2.3.2  " 2.4 ALL  " 2.5 ALL  " 2.6 ALL  " 2.7 ALL</p> <p><u>Para 1.2.1</u>  " 1.2.2  <u>035-YMP-R 2 Revision 6</u></p> <p><u>Para 2.2</u>  " 2.2.1  " 2.2.2  " 2.2.2.1  " 2.2.2.2  <u>035-YMP-R 3 Rev 4</u></p> <p><u>Para 1.1.1</u>  " 1.1.1  " 1.1.2  " 2.4.6.1</p> <p><u>Para 1.6.2.2</u>  " 1.6.2.2</p>	<p style="text-align: right;"><b>"BEST AVAILABLE COPY"</b></p>

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP	COMMENTS
<p>5. Interface controls among organizations or groups involved in design development and other design activities are described.</p> <p>6. Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.</p> <p>7. Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification provided:</p> <p>a. The supervisor is the only technically qualified individual.</p> <p>b. The need is individually documented and approved in advance with concurrence of the quality assurance manager.</p>	<p><u>033-YAW-R 3 REV. 5/88 0</u></p> <p>• PARA 1.8.1 • PARA 2.4.1, 2.4.2 • PARA 1.0.1</p> <p>• PARA 1.3.1 " 1.9.2 " 1.9.3 " 1.9.1</p>	
<p>It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.</p> <p>8. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.</p>	<p>• PARA 1.9.2 • " 1.9.3 • " 1.12 • PARA 1.3.3 Appendix - J • PARA 2.4.6.4 • PARA 4.0</p>	<p>"BEST AVAILABLE COPY"</p>

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<p>9. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.</p> <p>10. Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.</p>	<p><u>OB-IMP-R. 3. LWISON 6</u></p> <ul style="list-style-type: none"> <li>- PARA 1.9.2</li> <li>- 1.9.3</li> <li>- 2.4; 2.4.1; 2.4.2; 2.4.3</li> <li>- 2.4.5; 2.4.6</li> </ul> <p>- PARA 1.7</p> <p>- PARA 2.2.2</p> <ul style="list-style-type: none"> <li>" 2.4.4</li> <li>" 2.5.1</li> </ul>	

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IV. PROCUREMENT DOCUMENT CONTROL

Activities related to procurement document control are acceptable to the NRC staff if:

035-TMP-R 4 REVISED-0

1. Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants to provide an acceptable quality assurance program.
2. Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations, and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

*PARA 2.2*

*PARA 2.1.1*

*PARA 2.1.1*

*PARA 2.1.2*

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*PARA 1.1*

*PARA 1.0*

*PARA 1.2.1 ; 1.2.2 ; 1.2.3 ; 1.3*

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V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities related to instructions, procedures, and drawings are acceptable to the NRC staff if:

1. Organizational responsibilities are described for assuring that quality related activities are (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described under verification in Section III of this document.
2. Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality related activities have been satisfactorily accomplished.

033-IMP-R 5 REVISED

*Para 1.0*

*Para 2.0*

*Para 1.0*

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<p>VI. DOCUMENT CONTROL</p>		
<p>Activities related to document control are acceptable to the NRC staff if:</p>	<p><u>033-IMP-R 6 DIVISION 0</u></p>	
<p>1. The scope of the document control program is described, and the types of controlled documents are identified.</p>	<p>-PARA 1.1</p>	
<p>2. Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality related aspects.</p>	<p>-PARA 1.1 -PARA 1.2</p>	
<p>3. Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.</p>	<p>-PARA 1.2</p>	<p><i>DRES NOT SPEC. ADDRESS "M.I.M." COMMENCING THE WORK"</i></p>
<p>4. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.</p>	<p>-PARA 1.2</p>	
<p>5. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.</p>	<p>-PARA 1.2</p>	
<p>6. When documents which require verification are released prior to verification, they are so identified and controlled.</p>	<p>-PARA 2.1</p>	
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<b>VII. CONTROL OF PURCHASED ITEMS AND SERVICES</b>		
<p>Activities related to control of purchased materials, equipment, and services are acceptable to the NRC staff if:</p>	<p><u>033-1AD-R 7 revision 0</u></p>	
<p>1. Organizational responsibilities are described for the control of purchased material, equipment, and services.</p>		
<p>2. Procedures governing procurement of items and services, including appropriate QA organization participation, provide for (a) evaluation and selection of supplier's; (b) verification of supplier's activities; and (c) receiving inspections.</p>	<p>• PARA 1.2.1 • " 1.2.2 • " 1.4 • 1613 • " 1.4.2</p>	
<p>3. The organization providing materials, equipment, or services furnishes the following records to the purchaser:</p>		
<p>a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.</p>	<p>• PARA 16.1.1</p>	
<p>b. Documentation identifying any procurement requirements that have not been met.</p>	<p>• PARA 16.1.1</p>	
<p>c. A description of these nonconformances from the procurement requirements dispositioned "accept as is" or repair."</p>	<p>• PARA 1.8.1.2</p>	
<p>The procedure for review and acceptance of these documents should be described in the purchaser's QA program.</p>	<p>• PARA 1.2 ALL</p>	
<p>4. Supplier certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.</p>	<p>• PARA 1.6.1.1</p>	
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5. In developing quality assurance requirements for data collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment.

033-YAW-R 4 LAW 6

• PARA 2.1.3.2

033-YAW-R 7 revision 6

• PARA 2.1.4

• 033-YAW-R 3 revision 6

• PARA 1.4.2.3

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VIII. IDENTIFICATION AND CONTROL OF ITEMS

Activities related to sample identification and control are acceptable to the NRC staff if:

1. Controls are established and described to identify and control samples. The description should include organizational responsibilities.
2. Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.
3. Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.
4. Correct identification of samples is verified and documented prior to release for use or analysis.

033-TMP-R 8 LIVING D

• PART B

• PART 11

• PART 10

• PART 10

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REQUIREMENT	WHERE LOCATED IN REV. <i>6</i> OF PARTICIPANT QAPP	COMMENTS
<p style="text-align: center;"><b>IX. CONTROL OF PROCESSES</b></p> <p>Activities related to control of special processes are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.</li> <li>2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.</li> <li>3. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.</li> <li>4. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.</li> <li>5. Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.</li> </ol>	<p style="text-align: center;"><u>035-100-9 9</u> <i>Revision 6</i></p> <ul style="list-style-type: none"> <li>• <i>PARA 2.0</i></li> <li>• <i>PARA 2.3.1</i></li> <li>• <i>PARA 2.4.1</i></li> <li>• <i>PARA 2.5</i></li> <li>• <i>PARA 2.3.1</i></li> <li>• <i>PARA 2.4.1</i></li> <li>• <i>PARA 2.6</i></li> <li>• <i>PARA 2.6</i></li> </ul>	

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REQUIREMENT	WHERE LOCATED IN REV. <i>β</i> OF PARTICIPANT QAPP	COMMENTS
<p>X. INSPECTION</p> <p>Activities</p>	<p><i>OSS-YNP-R 10 LISTEN β</i></p>	
<p>1. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.</p>	<p><i>• PARA 1.0</i></p> <p><i>• PARA 2.1</i></p>	
<p>2. Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.</p>	<p><i>• PARA 2.1</i></p> <p><i>• PARA 2.2</i></p>	
<p>3. A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.</p>	<p><i>• PARA 2.2</i></p> <p><i>• PARA 2.0</i></p>	
<p>4. Inspection procedures, instructions, or checklists provide for the following:</p> <p>a. Identification of characteristics and activities to be inspected.</p> <p>b. A description of the method of inspection.</p> <p>c. Identification of the individuals or groups responsible for performing the inspection operation.</p> <p>d. Acceptance and rejection criteria.</p> <p>e. Identification of required procedures, drawings, and specifications and revisions.</p> <p>f. Recording inspector or data recorder and the results of the inspection operation.</p>	<p><i>• PARA 2.0</i></p> <p><i>" 4.0</i></p> <p><i>" 4.0</i></p> <p><i>" 4.0</i></p> <p><i>" 4.0</i></p> <p><i>" 4.0</i></p> <p><i>" 4.0</i></p>	<p>"BEST AVAILABLE COPY"</p>

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REQUIREMENT	WHERE LOCATED IN REV. <u>4</u> OF PARTICIPANT QAPP	COMMENTS
4. Specifying necessary measuring and test equipment including accuracy requirements.	<u>033-IMP-R 10 revision 4</u> • PARA 4.0	
5. Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.	• Para 3.0	
6. Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.	• Para 1.0 • " 6.0 • " 6.2	

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <i>f</i>	COMMENTS
<p style="text-align: center;"><b>XI. TEST CONTROL</b></p> <p>Activities related to test control are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>1. The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, admits these functions.</li> <li>2. Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.</li> <li>3. The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.</li> <li>4. Test procedures or instructions provide the following:             <ol style="list-style-type: none"> <li>a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.</li> <li>b. Instruction for performing the test.</li> <li>c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.</li> <li>d. Mandatory inspection hold points (as required).</li> <li>e. Acceptance and rejection criteria, including required levels of precision and accuracy.</li> </ol> </li> </ol>	<p><u>033-TMP-R 11</u> <i>revision 6</i></p> <ul style="list-style-type: none"> <li>- Para 1.0</li> <li>- " 2.0</li> </ul> <p><u>033-TMP-R 18</u> <i>revision 6</i></p> <ul style="list-style-type: none"> <li>- Para 12.1</li> </ul> <p><u>033-TMP-R 11</u> <i>revision 6</i></p> <ul style="list-style-type: none"> <li>- Para 3.8</li> <li>- Para 3.4</li> <li>- Para 2.0</li> <li>- Para 5.1</li> <li>- Para 5.2</li> <li>- Para 3.5</li> <li>- Para 2.0</li> </ul>	<p style="text-align: right;">"BEST AVAILABLE COPY"</p>

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REQUIREMENT	WHERE LOCATED IN REV. <u>4</u> OF PARTICIPANT QAPP	COMMENTS
f. Methods of data analysis.	<p><u>033 YWP-R 11 Revision 4</u></p> <ul style="list-style-type: none"> <li>• <u>PARA 3.5</u></li> </ul>	
g. Methods of documenting or recording test data and results, only required for	<ul style="list-style-type: none"> <li>• <u>PARA 4.0</u></li> </ul>	
h. Provisions for assuring test prerequisites have been met.	<ul style="list-style-type: none"> <li>• <u>PARA 3.2</u></li> </ul>	
5. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.	<ul style="list-style-type: none"> <li>• <u>PARA 4.0</u></li> </ul>	

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP	COMMENTS
<p>XII. CONTROL OF MEASURING AND TEST EQUIPMENT</p>	<p><u>033-1741-R 12 REVISION 8</u></p>	
<p>Activities related to control of measuring and test equipment are acceptable to the NRC staff if:</p>		
<p>1. The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.</p>	<p>- Para 1.2</p>	
<p>2. QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.</p>	<p>- Para 1.3</p>	
<p>3. Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instrument, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.</p>	<p>- Para 2.2</p>	
<p>4. Measuring and test equipment is labeled, tagged, or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.</p>	<p>- Para 2.3</p>	
<p>5. Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics and other conditions which could affect measurement.</p>	<p>- Para 2.2 " 2.1</p>	
<p>6. Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.</p>	<p>- Para 2.2</p>	
<p>7. When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.</p>	<p>- Para 2.3</p>	

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REQUIREMENT	WHERE LOCATED IN REV. <i>8</i> OF PARTICIPANT QAPP	COMMENTS
<p style="text-align: center;">XIII. HANDLING, STORAGE, AND SHIPPING</p> <p>Activities related to sample handling, storage, and shipping are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>1. Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.</li> <li>2. Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.</li> </ol>	<p><u>033-IMP-R 15</u> <i>written</i></p> <p><i>PARA 10</i></p> <p><u>033-IMP-R 8</u> <i>written</i></p> <p><i>PARA -B</i></p> <p><i>PARA 11</i></p> <p><i>PARA 12</i></p>	

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XIV. INSPECTION, TEST, AND OPERATING STATUS

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Activities related to inspection, test, and operating status are acceptable to the NRC staff if:

1. Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.

*-Para 1.0*  
*-Para 2.0*

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP	COMMENTS
<p style="text-align: center;"><b>XV. CONTROL OF NONCONFORMING ITEMS</b></p> <p>Activities related to non-conformances are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>1. Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. Procedures identify individuals authorized to dispose of and close out nonconformances</li> <li>2. QA responsibilities related to nonconformance control are described.</li> <li>3. Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.</li> <li>4. Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.</li> </ol>	<p><u>033-144-R 15 Revision 4</u></p> <p><i>PARA 1.0</i></p> <p><i>PARA 1.4.2</i></p> <p><i>PARA 1.4.2</i></p> <p><i>PARA 1.4.4</i></p> <p><i>PARA 3.0</i></p>	

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP	COMMENTS
<p style="text-align: center;"><b>XVI. CORRECTION ACTION</b></p> <p>Activities related to corrective action are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.</li> <li>Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.</li> <li>Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.</li> <li>Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.</li> </ol>	<p style="text-align: center;"><u>033-YMP-R 16</u> <i>Revision 8</i></p> <p>• <i>PARA 1.1</i> <i>033-YMP-R 5</i>          " <i>1.2</i> <i>PARA 2.6</i></p> <p>• <i>PARA 1.2</i></p> <p>• <i>PARA 1.2</i></p> <p>• <i>PARA 1.3</i></p>	

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REQUIREMENT	WHERE LOCATED IN REV. <i>of</i> OF PARTICIPANT QAPP	COMMENTS
<p style="text-align: center;"><b>XVII. QUALITY ASSURANCE RECORDS</b></p> <p>Activities related to QA records are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>1. The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspection; tests; audits and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports; peer review reports; nonconformance reports; and corrective action reports.</li> <li>2. QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.</li> <li>3. Inspection and test records contain the following where applicable:               <ol style="list-style-type: none"> <li>a. A descriptor of the type of observation. ✓</li> <li>b. The date and results of the inspection or test. ✓</li> <li>c. Information related to conditions adverse to quality. ✓</li> <li>d. Inspector or data recorder identification. ✓</li> <li>e. Evidence as to the acceptability of the results. ✓</li> <li>f. Action taken to resolve any discrepancies noted. ✓</li> </ol> </li> <li>4. Suitable facilities for the storage of records are described and utilized.</li> </ol>	<p><u>033-YMP-R 17 revision 4</u></p> <p>• <i>PARA 1.1</i></p> <p>• <i>PARA 1.2.1</i></p> <p><u>033-YMP-R 10 revision 0</u></p> <p>• <i>PARA 9.1</i></p> <p style="text-align: center;">↓</p> <p><u>033-YMP-R 17 revision 0</u></p> <p>• <i>Section 10.0 ALL</i></p>	

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<p>XVIII. AUDITS</p>	<p><u>DS3-YMP-R 14 (Revision 6)</u></p>	
<p>Activities related to audits are acceptable to the NRC staff if:</p>		
<p>1. Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program.</p>	<p>- Para 1.0 - Para 1.2.1 &amp; 1.2.2 - Para 1.1</p>	
<p>2. An audit plan is prepared identifying audits, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.</p>	<p>- Para 1.1.2 - Para 1.2</p>	
<p>3. Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.</p>	<p>- Para 1.0 - Para 1.2</p>	
<p>4. Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.</p>	<p>- Para 1.4 - Para 1.6 - Para 1.7</p>	
<p>5. Audits are performed in accordance with preestablished written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.</p>	<p>- Para 1.4</p>	
<p>6. A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.</p>	<p>- Para 1.0</p>	
<p>7. The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.</p>	<p>- Para 1.0 - Para 1.4</p>	
<p>8. In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.</p>	<p>- Para 1.6</p>	<p>"BEST AVAILABLE COPY"</p>

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PREPARED BY

*Ken M. Wouerton*

PARTICIPANT CONTRACTOR *Leitz and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

I. ORGANIZATION

The organization elements responsible for the QA program are acceptable to the NRC staff if:

- |  |   |                      |
|--|---|----------------------|
| <p>1. The responsibility for the overall program is retained and exercised by the DOL at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.</p> | <p><i>N/A</i><br/><i>SECTION 1.1</i></p>        | <p><i>ACCEPT</i></p> |
| <p>2. DOL describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</p>  | <p><i>1.1, 1.4</i></p>                          | <p><i>Accept</i></p> |
| <p>3. DOL describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOL headquarters and from the field office should be addressed.</p>   | <p><i>1.4.1, 1.2.1</i></p>                      | <p><i>Accept</i></p> |
| <p>4. DOL evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of the representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.</p>  | <p><i>1.1.11, 1.2,<br/>18.1, 18.2</i></p>       | <p><i>Accept</i></p> |
| <p>5. Qualified individual(s) or organization elements are identified within DOL's organization as responsible for the quality of the delegated work prior to initiation of activities.</p>  | <p><i>Section 1.1</i></p>                       | <p><i>Accept</i></p> |
| <p>6. Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</p>   | <p><i>1.1, 1.2</i></p>                          | <p><i>Accept</i></p> |
| <p>7. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.</p>   | <p><i>Section II, Figure II<br/>42P-1.1</i></p> | <p><i>Accept</i></p> |

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PREPARED BY *[Signature]*

PARTICIPANT CONTRACTOR Leix and Scisson, Inc.

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
<p>8. The QA organization is involved in the aspects of the high level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.</p>	<p>1.2.1, 2.1, 2.2.1, 2.2.2, 2.2.2.1</p>	<p>- <i>Accept</i></p>
<p>9. DRI and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.</p>	<p>1.3, QAP-1.1, QAP 2.1</p>	<p>- <i>Accept</i></p>
<p>10. DRI and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:</p> <ul style="list-style-type: none"> <li>a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.</li> <li>b. Has effective communication channels with other senior management positions.</li> <li>c. Has responsibility for approval of QA manuals, changes thereto, and interpretations thereof.</li> <li>d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters</li> </ul>	<p>1.2.1, 1.2.2</p> <p style="text-align: center;">↓</p>	<p>- <i>Accept</i></p> <p style="text-align: center;">↓</p>
<p>11. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for design (item 3.7) inspections (item 10.2) and test data evaluation (item 11.3) are outlined in these sections</p>	<p>1.3.2, 3.2.4.5, 10.2.1, 10.3.2</p>	<p>- <i>Accept</i></p>
<p>12. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:</p>	<p>1.2</p>	<p>- <i>Accept</i></p>

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PREPARED BY *W. J. ...*

PARTICIPANT CONTRACTOR Leix and Scisson, Inc.

REQUIREMENT	WHERE LOCATED IN REV. 6 OF PARTICIPANT QAPP	COMMENTS
<p>a Identify quality problems.                      b Initiate, recommend, or provide solutions through designated channels.                      c Verify implementation of solutions.                      d Stop unsatisfactory work.</p> <p>The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.</p>	<p>1.2, QAP-1.1                      PMA. 6.2</p>	<p>Accept</p>
<p>13. Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.</p>	<p>1.2.2, QAP-1.1                      Introduction, Statement of Policy + Authority</p>	<p>Accept                      ↓</p>
<p>14. Policies regarding the implementation of the QA program are documented and made mandatory</p> <p>15. The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.</p>	<p>1.2.1</p>	<p>Accept</p>

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PREPARED BY

*McCluskey*

PARTICIPANT CONTRACTOR *Leinix and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. *6*  
OF PARTICIPANT QAPP

COMMENTS

II. QUALITY ASSURANCE PROGRAM

Activities related to the QA program are acceptable to the NRC staff if:

1. The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.

*1.1.6, 2.1.7, 2.2*

*Accept*

2. The QA program includes a commitment that all development, control and/or use of computer programs will be conducted in accordance with the QA program. Requirements for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

*3.2.3.3, 3.3.1, 3.3.7*

*- Accept*

3. Provisions are established to assure that technical and QA procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document consistent with QA program requirements and are properly documented and signed by a responsible official.

*1.1, 2.1.1, 2.1.7*

*- Accept*

4. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.

*2.1.2*

*- Accept*

5. The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities.

*1.1.6, 2.1.7,*

*2.2*

*- Accept*

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

N-0A-059  
10/88

PREPARED BY *W. D. ...*

PARTICIPANT CONTRACTOR *Lenix and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
<p>This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and other described in 10 CFR 50, Appendix B.</p>	<p><i>1.2</i></p>	<p><i>- Accept</i></p>
<p>6. Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR 50, Appendix B, appropriate to specific items and activities, will be met.</p>	<p><i>Procedure Table of Contents</i></p>	<p><i>- Accept</i></p>
<p>7. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR 50, Appendix B. These measures should include:</p> <ul style="list-style-type: none"> <li>A. Frequent contact with program status through reports, meetings, and/ or audits</li> <li>B. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.</li> </ul>	<p><i>2.3.1, 2.3.2</i></p> <p>↓</p>	<p><i>- Accept</i></p> <p>↓</p>
<p>8. Indoctrination, training, and qualification programs are established such that:</p> <ul style="list-style-type: none"> <li>a. Personnel responsible for performing quality-related activities are instructed to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.</li> <li>b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.</li> <li>c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance</li> </ul>	<p><i>2.5</i></p> <p>↓</p>	<p><i>- Accept</i></p> <p>↓</p>

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10/88

PREPARED BY

*W. J. ...*

PARTICIPANT CONTRACTOR

*Leix and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

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

2.5  
↓

- kept  
↓

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PREPARED BY *W. White*

PARTICIPANT CONTRACTOR *Leitz and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

III. DESIGN CONTROL

Activities related to design control are acceptable to the NRC staff if:

1. The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and components performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR 60 and the Atomic Energy Act of 1954.
2. The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.
3. Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.
4. Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

- 3.2.1.1

- *Accept*

- 3.2

- *Accept*

- 3.2.2.1, 3.2.2.2,  
3.2.3.1, 3.2.3.2, 3.2.4.6  
+ 3.2.4.6.1

*Accept*

- 3.2.5.1

- *Accept*

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NQA-059  
11/88

PREPARED BY *W. Roberts*

PARTICIPANT CONTRACTOR Lenix and Scisson, Inc.

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
5. Interface controls among organizations or groups involved in design development and other design activities are described.	3.2.6.1, 3.2.6.2	<i>Accept</i>
6. Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.	3.2.7.1.3, 3.2.3.1 + 3.2.2.1	<i>- Accept</i>
7. Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification provided: <ul style="list-style-type: none"> <li>a. The supervisor is the only technically qualified individual.</li> <li>b. The need is individually documented and approved in advance with concurrence of the quality assurance manager.</li> </ul> It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.	3.2.4.5, <i>01-04 para. 6.1.1</i>	<i>- Accept</i>
8. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.	<i>- 3.4, Appendix T</i>	<i>- Accept</i>

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*[Signature]*

PARTICIPANT CONTRACTOR *Leix and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
9 The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.	- 3.2.4.1, 3.2.4.2, 3.2.4.3, 3.2.4.5, 3.2.4.6	- <i>Accepted</i>
10 Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.	- 3.2.5.1	- <i>Accepted</i>

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*[Signature]*

PARTICIPANT CONTRACTOR Leitz and Seisson, Inc.

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

IV. PROCUREMENT DOCUMENT CONTROL

Activities related to procurement document control are acceptable to the NRC staff at:

1. Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors, and consultants to provide an acceptable quality assurance program.

- 4.2.2, 4.2.3, 4.4,  
4.2.1

- *Accept*

2. Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations, and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

- 4.2.1.3.1, 4.2.2  
+ 7.2 (ALSO CONSISTENT  
WITH 88-9)

- *Accept*

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N QA-059  
10/88

PREPARED BY

*W. Roberts*

PARTICIPANT CONTRACTOR *Genix and Seisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. *6*  
OF PARTICIPANT QAPP

COMMENTS

V INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities related to instructions, procedures, and drawings are acceptable to the NRC staff if:

- 1 Organizational responsibilities are described for assuring that quality related activities are (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described under verification in Section III of this document.
- 2 Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality related activities have been satisfactorily accomplished.

*2.0, 5.2  
(consistent with 2.8-9)*

*Accept*

*5.1*

*Accept*

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

NQA-059  
10/88

PREPARED BY *Medwick*

PARTICIPANT CONTRACTOR *Leix and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
VI. DOCUMENT CONTROL		
Activities related to document control are acceptable to the NRC staff if:		
1 The scope of the document control program is described, and the types of controlled documents are identified.	6.1.1, 6.1.1.1	- <i>Accept</i>
2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality related aspects.	QAP-6.1, 5.1.3.2, 3.3 <i>section 6.1.3, DC-16</i>	- <i>Accept</i>
3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.	6.1.3	- <i>Accept</i>
4 Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.	6.1.3.1, DC-16	- <i>Accept</i>
5 A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.	6.1.3.1, QAP 6.1	- <i>Accept</i>
6 When documents which require verification are released prior to verification, they are so identified and controlled.	6.3.1	- <i>Accept</i>

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

N-QA-059  
11/88

PREPARED BY

*W. Luera*

PARTICIPANT CONTRACTOR *Lenix and Seisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

VII. CONTROL OF PURCHASED ITEMS AND SERVICES

Activities related to control of purchased materials, equipment, and services are acceptable to the NRC staff if:

1. Organizational responsibilities are described for the control of purchased material, equipment, and services.
2. Procedures governing procurement of items and services, including appropriate QA organization participation, provide for (a) evaluation and selection of supplier's; (b) verification of supplier's activities; and (c) receiving inspections.

- 7.1, 7.2.1 (Consolidated with 68-9) AP 60-02,  
- QAP-4.1, 7.1 & 10.1

- Accept (NRC) Receiving Inspection RECO RECO (S.I.) ACCEPT

3. The organization providing materials, equipment, or services furnishes the following records to the purchaser:
  - a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.
  - b. Documentation identifying any procurement requirements that have not been met.
  - c. A description of these nonconformances from the procurement requirements dispositioned "accept as is" or repair.

7.7.2  
↓

- Accept  
↓

1.9.2 7.7.3

- Accept

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

4. Supplier certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

1.7.2

- Accept

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10/88

PREPARED BY

*Handwritten signature*

PARTICIPANT CONTRACTOR Lenix and Scisson, Inc.

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

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

4.2.1.3.2

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N JA 059  
11/88

PREPARED BY

*Wolverton*

PARTICIPANT CONTRACTOR *Leitz and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

VIII IDENTIFICATION AND CONTROL OF ITEMS

Activities related to sample identification and control are acceptable to the NRC staff if:

1. Controls are established and described to identify and control <sup>\*</sup>samples. The description should include organizational responsibilities.
2. Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.
3. Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.
4. Correct identification of samples is verified and documented prior to release for use or analysis.

N/A

\* FJS TAKES EXCEPTION  
TO CONTROL OF SAMPLES  
AS THIS IS NOT UNDER  
THEIR SCOPE OF WORK; THEY  
SO INCORPORATE "CONTROL OF  
ITEMS" IN SECTION 8.0 OF  
THEIR QAPP.

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

N-0A-059  
10/08

PREPARED BY

*Richard*

PARTICIPANT CONTRACTOR *Lenix and Scisson, Inc*

REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP	COMMENTS
IX CONTROL OF PROCESSES		
Activities related to control of special processes are acceptable to the NRC staff if:		
1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.	- 9.2.1	- <i>Accept</i>
2 Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.	- 9.2.1.1, 9.2.2 + 9.2.3	- <i>Accept</i>
3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.	- 9.2.2, <sup>rev 1-18-89</sup> 9.2.3 + 9.2.4	- <i>Accept</i>
4 Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.	- 9.2.5	- <i>Accept</i>
5 Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.	- 9.2.5	- <i>Accept</i>

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N-QA-059

10/1988

PREPARED BY *[Signature]*

PARTICIPANT CONTRACTOR Penix and Scisson, Inc.

REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <u>6</u>	COMMENTS
<b>X. INSPECTION</b>		
<b>Activities</b>		
1. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.	<i>rev 1-19-89</i> <i>H-1, H-2</i> 10.1	<i>- Accept</i>
2. Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.	10.2.1	<i>Accept</i>
3. A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.	10.2.2, Appendix C, QAP-5.2	<i>- Accept</i>
4. Inspection procedures, instructions, or checklists provide for the following:	10.4, 10.10	<i>- Accept (to be developed as needed)</i>
a. Identification of characteristics and activities to be inspected.	↓	↓
b. A description of the method of inspection		
c. Identification of the individuals or groups responsible for performing the inspection operation.		
d. Acceptance and rejection criteria.		
e. Identification of required procedures, drawings, and specifications and revisions		
f. Recording inspector or data recorder and the results of the inspection operation.		
	10.4, 10.10	<i>Accept</i>

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10/81

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*[Signature]*

PARTICIPANT CONTRACTOR *Leitz and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
4 Specifying necessary measuring and test equipment including accuracy requirements.	10.10	<i>Accept</i>
5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.	10.3	<i>Accept</i>
6 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.	10.6.2	<i>Accept</i>

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11/88

PREPARED BY *W. W. [Signature]*

PARTICIPANT CONTRACTOR Lenix and Scisson, Inc.

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
XI. TEST CONTROL		
Activities related to test control are acceptable to the NRC staff if:		
1. The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.	11.1, 11.2	- Accept
2. Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.	11.3.3	- Accept
3. The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.	11.2.4	- Accept
4. Test procedures or instructions provide the following:		
a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy. ✓	11.3.3, 11.3.1, 11.3.2, 11.2	- Accept - Accept
b. Instruction for performing the test. ✓		
c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.		
d. Mandatory inspection hold points (as required). ✓		
e. Acceptance and rejection criteria, including required levels of precision and accuracy. ✓		

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N-QA-059  
10/88

PREPARED BY

*W. L. Lantz*

PARTICIPANT CONTRACTOR *Conix and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT OAPP	COMMENTS
f. Methods of data analysis.	- 11.3.3	- <i>Accept</i>
g. Methods of documenting or recording test data and results. only required for	- 11.3.3	- <i>Accept</i>
h. Provisions for assuring test prerequisites have been met.	- 11.3.2	- <i>Accept</i>
5. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.	- 11.4, 11.5	- <i>Accept</i>

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PREPARED BY *[Signature]*

PARTICIPANT CONTRACTOR *Terix and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <i>6</i>	COMMENTS
XII CONTROL OF MEASURING AND TEST EQUIPMENT		
Activities related to control of measuring and test equipment are acceptable to the NRC staff if:		
1. The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.	12.1.2	- <i>Accept</i>
2. QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.	12.1.3	- <i>Accept</i>
3. Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.	QAP-12.1	- <i>Accept</i>
4. Measuring and test equipment is labeled, tagged, or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.	12.2.1, 12.2.3	- <i>Accept</i>
5. Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions which could affect measurement.	12.2.2, 12.2.3	- <i>Accept</i>
6. Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.	12.2.2	- <i>Accept</i>
7. When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.	12.2.3	- <i>Accept</i>

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N-DA-059  
10/88

PREPARED BY

*Michael*

PARTICIPANT CONTRACTOR

*Leuk and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

XIII. HANDLING, STORAGE, AND SHIPPING

Activities related to sample handling, storage, and shipping are acceptable to the NRC staff if:

1. Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.
2. Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

*13.0 IN ITS ENTIRETY; SECTION 2.0 ON INDOCTRINATION + TRAINING (CONSISTENT WITH 88-9)*

*Accept*

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10/88

PREPARED BY

*Wooler*

PARTICIPANT CONTRACTOR

*Lenix and Scisson, Inc.*

REQUIREMENT

WHERE LOCATED IN REV. 6  
OF PARTICIPANT QAPP

COMMENTS

XIV. INSPECTION, TEST, AND OPERATING STATUS

PAGE 23 OF 26

Activities related to inspection, test, and operating status are acceptable to the NRC staff at:

1. Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.

*14.1, 14.2, 14.3*

*(Consistent with 88-9)*

*- accept*

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10/88

PREPARED BY

*W. G. ...*

PARTICIPANT CONTRACTOR

*Leix and Scisson, Inc.*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
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XV. CONTROL OF NONCONFORMING ITEMS

Activities related to nonconformances are acceptable to the NRC staff if:

1. Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. Procedures identify individuals authorized to dispose of and close out nonconformances
2. QA responsibilities related to nonconformance control are described.
3. Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.
4. Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.

15.1, 15.1.4.3, 15.3, 15.3

*Accept*

15.1.6.2

*Accept*

15.1.6

*Accept*

15.3

*Accept*

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

N-QA-059  
10/88

PREPARED BY

*W. D. ...*

PARTICIPANT CONTRACTOR *Genix and Scissun, Inc*

REQUIREMENT	WHERE LOCATED IN REV. <u>6</u> OF PARTICIPANT QAPP	COMMENTS
XVI. CORRECTION ACTION		
Activities related to corrective action are acceptable to the NRC staff if:		
1. Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.	16.1.1, 16.1.3, 15.2, QAP- 16.2, QAP-16.3	- <i>Accept</i>
2. Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.	15.2, 16.1.2, QAP- 16.2, PARA. 6.4	- <i>Accept</i>
3. Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.	16.1.2	- <i>Accept</i>
4. Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.	16.1.1	- <i>Accept</i>

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N-QA-059  
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PREPARED BY *W. J. ...*

PARTICIPANT CONTRACTOR *Leix and Scisson, Inc.*

REQUIREMENT

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COMMENTS

XVII QUALITY ASSURANCE RECORDS

Activities related to QA records are acceptable to the NRC staff if:

1. The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspection; tests; audits and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports; peer review reports; nonconformance reports; and corrective action reports.
2. QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.
3. Inspection and test records contain the following where applicable:
  - a. A description of the type of observation
  - b. The date and results of the inspection or test.
  - c. Information related to conditions adverse to quality.
  - d. Inspector or data recorder identification
  - e. Evidence as to the acceptability of the results.
  - f. Action taken to resolve any discrepancies noted.
4. Suitable facilities for the storage of records are described and utilized.

*17.1, 17.1.1, 17.1.2.2,  
Appendix E (Consistent  
with 88-9)*

*- Accept*

*17.3.1, 17.3.2, 17.1.2.1,  
17.4.1, AP-50-01*

*- Accept*

*10.10*

*- Accept*

*17.10, 17.10.2,  
17.10.1, 17.7, 17.6*

*Accept*

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N-OA-059  
10/88

PREPARED BY

*W. Roberts*

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REQUIREMENT

WHERE LOCATED IN REV. 6  
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COMMENTS

XVIII. AUDITS

Activities related to audits are acceptable to the NRC staff if:

- 1 Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program.
- 2 An audit plan is prepared identifying audits, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.
- 3 Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.
- 4 Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.
- 5 Audits are performed in accordance with preestablished written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.
- 6 A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.
- 7 The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.
- 8 In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.

18.1

*Accept*

18.1, 18.7, 18.8,  
18.3, QAP-18.1

*Accept*

18.4, 18.1 (inserted  
with 88-9

*Accept*

18.6, 18.7

*Accept*

18.4, 18.1

*Accept*

18.1, 18.6, 18.7, 18.8,  
QAP 18.1, 16.2 + 16.3

*Accept*

18.6

*Accept*

QAP-16.2, PARA. 1.4  
16.2.2.1

*Accept*

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PARTICIPANT CONTRACTOR Reynolds Electric and Engineering Company

REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <u>7</u>	COMMENTS
<p><i>Replace "DOE" with "participant" where appropriate</i></p> <p>I. ORGANIZATION</p> <p>The organization elements responsible for the QA program are acceptable to the NRC staff if:</p> <ol style="list-style-type: none"> <li>1. The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.</li> <li>2. DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</li> <li>3. DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.</li> <li>4. DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of the representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.</li> <li>5. Qualified individual(s) or organization elements are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.</li> <li>6. Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</li> <li>7. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.</li> </ol>		<p><i>Policy Statement Chapter 1</i></p> <p><i>NA</i></p> <p><i>NA</i></p> <p><i>Section IV and VII</i></p> <p><i>Section I, IV and VII</i></p> <p><i>Section I</i></p> <p><i>Fig 1, 2, 3</i></p>

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8. The QA organization is involved in the aspects of the high level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.

*I, 2.1*

9. DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.

*I*

10. DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:

*1.1*

*1.3*

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

*2.0*

*2.1*

b. Has effective communication channels with other senior management positions.

*2.1*

c. Has responsibility for approval of QA manuals, changes thereto, and interpretations thereof.

d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

*I, 2.0*

11. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for design (item 3.7) inspections (item 10.2) and test data evaluation (item 11.3) are outlined in these sections.

12. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

*I, 2.0*

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- a. Identify quality problems.
- b. Initiate, recommend, or provide solutions through designated channels.
- c. Verify implementation of solutions.
- d. Stop unsatisfactory work.

I.2.0



13. The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

F.2.2

14. Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

I.2.2

15. Policies regarding the implementation of the QA program are documented and made mandatory.

I.3.0  
*Policy Statement*

16. The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.

2.1

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II. QUALITY ASSURANCE PROGRAM

Activities related to the QA program are acceptable to the NRC staff if:

1. The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.
2. The QA program includes a commitment that all development, control and/or use of computer programs will be conducted in accordance with the QA program. Requirements for the content of documentation of computer codes is provided by NUREG-0456, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."
3. Provisions are established to assure that technical and QA procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document consistent with QA program requirements and are properly documented and signed by a responsible official.
4. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.
5. The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities.

*II. 2.2*

*NA*

*II. 1*

*II 1.2*

*II 1.5.  
2.1.1, 2.1.2, 2.1.3, 2.1.4*

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This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and other described in 10 CFR 50, Appendix B.

6. Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR 50, Appendix B, appropriate to specific items and activities, will be met.

*II.1.0*

*Addresses project QA requirements in general*

7. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR 50, Appendix B. These measures should include:

*II 4.0, 4.1, 4.2*

A. Frequent contact with program status through reports, meetings, and/ or audits.

b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.

8. Indoctrination, training, and qualification programs are established such that:

*5.0, 5.1, 5.1.1 - 5.1.6.4*

a. Personnel responsible for performing quality-related activities are instructed to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.



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WHERE LOCATED IN REV. 7  
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COMMENTS

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



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WHERE LOCATED IN REV.  
OF PARTICIPANT QAPP7

COMMENTS

## III. DESIGN CONTROL

Activities related to design control are acceptable to the NRC staff if:

NA

1. The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and components performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR 60 and the Atomic Energy Act of 1954.
2. The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.
3. Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.
4. Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

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COMMENTS

5. Interface controls among organizations or groups involved in design development and other design activities are described.
6. Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.
7. Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification provided:
  - a. The supervisor is the only technically qualified individual.
  - b. The need is individually documented and approved in advance with concurrence of the quality assurance manager.

It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.
8. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.

NA

*[Handwritten vertical line]*

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- 9. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.
- 10. Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.

NA



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IV. PROCUREMENT DOCUMENT CONTROL

Activities related to procurement document control are acceptable to the NRC staff if:

1. Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants to provide an acceptable quality assurance program.
2. Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations, and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

*IV . 1.2.1.3*

*1.2.2*

*IV 1.2.1.3*

*1.2.2*

*1.2.4*

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V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities related to instructions, procedures, and drawings are acceptable to the NRC staff if:

V

1. Organizational responsibilities are described for assuring that quality related activities are (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described under verification in Section III of this document.

1.0

2.0

2. Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality related activities have been satisfactorily accomplished.

1.0

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VI. DOCUMENT CONTROL

Activities related to document control are acceptable to the NRC staff if:

- |  |                    |
|--|--------------------|
| 1. The scope of the document control program is described, and the types of controlled documents are identified.   | <i>VI 1.1, 1.2</i> |
| 2. Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality related aspects. | <i>1.1<br/>1.2</i> |
| ✓ 3. Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.   | <i>1.2</i>         |
| 4. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.   | <i>1.2</i>         |
| 5. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.   | <i>1.2</i>         |
| 6. When documents which require verification are released prior to verification, they are so identified and controlled.  | <i>3.1</i>         |

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VII. CONTROL OF PURCHASED ITEMS AND SERVICES

Activities related to control of purchased materials, equipment, and services are acceptable to the NRC staff if:

1. Organizational responsibilities are described for the control of purchased material, equipment, and services. *VII 1.1.1*
2. Procedures governing procurement of items and services, including appropriate QA organization participation, provide for (a) evaluation and selection of supplier's; (b) verification of supplier's activities; and (c) receiving inspections. *1.1.1*
3. The organization providing materials, equipment, or services furnishes the following records to the purchaser:
  - a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met. *1.6.1.1*
  - b. Documentation identifying any procurement requirements that have not been met. *1.6.1.1*
  - c. A description of these nonconformances from the procurement requirements dispositioned "accept as is" or repair. *1.8*

The procedure for review and acceptance of these documents should be described in the purchaser's QA program.
4. Supplier certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented. *↓*

*implied*

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

*NA*

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VIII. IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

Activities related to sample identification and control are acceptable to the NRC staff if:

1. Controls are established and described to identify and control samples. The description should include organizational responsibilities.
2. Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.
3. Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.
4. Correct identification of samples is verified and documented prior to release for use or analysis.

*Section VIII  
has standard  
dogma for items.*



*RBTC has no  
responsibility for the  
taking of samples and data.  
This section applies to  
items only.*

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IX. CONTROL OF PROCESSES

Activities related to control of special processes are acceptable to the NRC staff if:

1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.

*IX.2.2.1*

*Apply to engineered items only.*

2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

*2.2.2*

3. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.

*2.5  
2.3.1  
2.4.1*

4. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

*2.1*

5. Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.

*2.2.2  
2.6*

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X. INSPECTION

Activities

1. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.
2. Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.
3. A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.
4. Inspection procedures, instructions, or checklists provide for the following:
  - a. Identification of characteristics and activities to be inspected.
  - b. A description of the method of inspection.
  - c. Identification of the individuals or groups responsible for performing the inspection operation.
  - d. Acceptance and rejection criteria.
  - e. Identification of required procedures, drawings, and specifications and revisions.
  - f. Recording inspector or data recorder and the results of the inspection operation.

X. 1.0

2.1

2.2, 8.0, Appendix C

4.0

*Applies to engineered items only.*

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g. Specifying necessary measuring and test equipment including accuracy requirements.

*4.0*

5. Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

*3.0*

6. Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.

*6.0, 6.1, 6.2, 9.0*

*9.1*

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XI. TEST CONTROL

Activities related to test control are acceptable to the NRC staff if:

1. The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.
2. Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.
3. The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.
4. Test procedures or instructions provide the following:
  - a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.
  - b. Instruction for performing the test.
  - c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.
  - d. Mandatory inspection hold points (as required).
  - e. Acceptance and rejection criteria, including required levels of precision and accuracy.

*XI.1.0*

*2.0*

*3.1*

*XIII 1.2.1*

*3.3.1, 3.3.2,  
3.3.3*

*3.4*

*2.0*

*3.1*

*3.2*

*see X*

*2.0*

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- |   |                |  |
|---|----------------|--|
| f. Methods of data analysis.  | 4.0, 3.3.6.1   |  |
| g. Methods of documenting or recording test data and results. only required for   | 4.0<br>3.3.6.1 |  |
| h. Provisions for assuring test prerequisites have been met.  |                |  |
| 5. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3. | 4.0, 5.0       |  |

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XII. CONTROL OF MEASURING AND TEST EQUIPMENT

Activities related to control of measuring and test equipment are acceptable to the NRC staff if:

1. The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.
2. QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.
3. Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.
4. Measuring and test equipment is labeled, tagged, or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.
5. Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions which could affect measurement.
6. Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.
7. When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.

*XII.*

*1.2*

*1.3*

*1.0, 2.2, 2.3*

*2.3*

*2.3*

*2.2*

*2.3*

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XIII. HANDLING, STORAGE, AND SHIPPING

Activities related to sample handling, storage, and shipping are acceptable to the NRC staff if:

1. Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.
2. Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

*1.0*

*REEs not involved in samples*

*1.0, 1.1, 1.2*

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XIV. INSPECTION, TEST, AND OPERATING STATUS

Activities related to inspection, test, and operating status are acceptable to the NRC staff if:

1. Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.

1.0

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XV. CONTROL OF NONCONFORMING ITEMS

Activities related to nonconformances are acceptable to the NRC staff if:

- |  |       |
|--|-------|
| 1. Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. Procedures identify individuals authorized to dispose of and close out nonconformances | 1.0   |
| 2. QA responsibilities related to nonconformance control are described.  | 1.4.2 |
| 3. Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.   | 1.4.4 |
| 4. Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.                                   | 3.0   |

*audit data are analyzed by the QA organization and reported to mgt.*

3.0, 2.0

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XVI. CORRECTION ACTION

Activities related to corrective action are acceptable to the NRC staff if:

- |   |            |
|---|------------|
| <p>1. Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.</p>   | <p>1.0</p> |
| <p>2. Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.</p> | <p>1.1</p> |
| <p>3. Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.</p>  | <p>1.2</p> |
| <p>4. Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.</p>  | <p>1.1</p> |

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## XVII. QUALITY ASSURANCE RECORDS

Activities related to QA records are acceptable to the NRC staff if:

1. The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspection; tests; audits and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports; peer review reports; nonconformance reports; and corrective action reports. *Appendix E*
2. QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records. *III 1. 2. 1*
3. Inspection and test records contain the following where applicable: *Appendix E sections I and II*
  - a. A description of the type of observation.
  - b. The date and results of the inspection or test.
  - c. Information related to conditions adverse to quality.
  - d. Inspector or data recorder identification.
  - e. Evidence as to the acceptability of the results.
  - f. Action taken to resolve any discrepancies noted.
4. Suitable facilities for the storage of records are described and utilized. *6.0, 6.1, 6.2, 10.1*

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XVIII. AUDITS

Activities related to audits are acceptable to the NRC staff if:

- |   |                                  |
|---|----------------------------------|
| <p>1. Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program.</p> | <p>1.1.1<br/>1.2.1<br/>1.2.2</p> |
| <p>2. An audit plan is prepared identifying audits, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.</p>   | <p>1.2</p>                       |
| <p>3. Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.</p>   | <p>1.6</p>                       |
| <p>4. Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.</p>   | <p>1.7</p>                       |
| <p>5. Audits are performed in accordance with preestablished written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.</p>  | <p>1.3.1, 1.3.2</p>              |
| <p>6. A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.</p>   | <p>1.0</p>                       |
| <p>7. The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.</p>   | <p>1.6</p>                       |
| <p>8. In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.</p>  | <p>1.6</p>                       |

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REQUIREMENT	WHERE LOCATED IN REV. <u>3</u> OF PARTICIPANT QAPP	COMMENTS
<b>I. ORGANIZATION</b>		
<p>The organization elements responsible for the QA program are acceptable to the NRC staff if:</p>		
<p>1. The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.</p>	<p><i>POLICY STATEMENT SECT 1 PARA III B/C</i></p>	<p><i>1<sup>ST</sup> SENTENCE NOT APPLICABLE TO H&amp;N</i></p>
<p>2. DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</p>	<p><i>SECT 1 PARA I SECTS 4 &amp; 1</i></p>	<p><i>MADE APPLICABLE TO H&amp;N</i></p>
<p>3. DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.</p>	<p><i>SECT 1 PARA III B/C</i></p>	<p><i>ONLY 1<sup>ST</sup> SENTENCE MADE APPLICABLE TO H&amp;N</i></p>
<p>4. DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of the representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.</p>	<p><i>SECTS 7 AND 18</i></p>	<p><i>MADE APPLICABLE TO H&amp;N</i></p>
<p>5. Qualified individual(s) or organization elements are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.</p>	<p><i>SECT 1 PARA III B SECT 7 &amp; 18</i></p>	<p><i>MADE APPLICABLE TO H&amp;N</i></p>
<p>6. Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</p>	<p><i>SECT 1 PARA III B, ATTACHMENT B</i></p>	<p><i>MADE APPLICABLE TO H&amp;N</i></p>
<p>7. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.</p>	<p><i>SECT 1 ATTACHMENT B</i></p>	

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	REQUIREMENT	WHERE LOCATED IN REV. <u>3</u> OF PARTICIPANT QAPP	COMMENTS
8.	The QA organization is involved in the aspects of the high level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.	<i>SECTION 2 PARA II 6-5C SECTION 1 PARA III C</i>	
9.	DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.	<i>SECTION 1 PARA III 6 IV</i>	
10.	DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:  a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.  b. Has effective communication channels with other senior management positions.  c. Has responsibility for approval of QA manuals, changes thereto, and interpretations thereof.  d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.	<i>SECTION 1 PARA III C 1 &amp; 2 ATTACHMENT B</i>	
11.	Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for design (item 3.7) inspections (item 10.2) and test data evaluation (item 11.3) are outlined in these sections.	<i>SECTION 1 PARA III C 1 &amp; 2</i>	
12.	Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:	<i>SECTION 1 PARA III C 1 &amp; 2</i>	

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REQUIREMENT	WHERE LOCATED IN REV. <u>3</u> OF PARTICIPANT QAPP	COMMENTS
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- a. Identify quality problems.
- b. Initiate, recommend, or provide solutions through designated channels.
- c. Verify implementation of solutions.
- d. Stop unsatisfactory work.

The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

- 13. Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.
- 14. Policies regarding the implementation of the QA program are documented and made mandatory.
- 15. The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.

*SECTION 1 PARA III C 1  
SECTION 5 PARA III F*

*SECTION 1 PARA III A  
POLICY STATEMENT*

*SECTION 1 PARA III C*

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II. QUALITY ASSURANCE PROGRAM

Activities related to the QA program are acceptable to the NRC staff if:

1. The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.
2. The QA program includes a commitment that all development, control and/or use of computer programs will be conducted in accordance with the QA program. Requirements for the content of documentation of computer codes is provided by NUREG-0836, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."
3. Provisions are established to assure that technical and QA procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document consistent with QA program requirements and are properly documented and signed by a responsible official.
4. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.
5. The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities.

SECTION II PARA II C

BALANCE OF REQ  
NOT APPLICABLE TO  
HAN AS THEY DO  
NOT ASSIGN QA  
LEVELS.

SECTION 3 PARA III H 7

SECTION 2 PARA III A  
POLICY STATEMENT  
SECTION 1 PARA III A

SECTION 2 PARA III C

SECTION 2 PARA II B/C  
PARA III C  
SECTION 5 PARA III A, B, C

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<p>This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and other described in 10 CFR 50, Appendix B.</p>		
<p>6. Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR 50, Appendix B, appropriate to specific items and activities, will be met.</p>	<p>SECTION 2 PARA III A</p>	
<p>7. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR 50, Appendix B. These measures should include:</p> <ul style="list-style-type: none"> <li>A. Frequent contact with program status through reports, meetings, and/ or audits.</li> <li>B. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.</li> </ul>	<p>SECTION 2 PARA III E SECTION 1 PARA III C 4</p>	
<p>8. Indoctrination, training, and qualification programs are established such that:</p> <ul style="list-style-type: none"> <li>a. Personnel responsible for performing quality-related activities are instructed to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.</li> <li>b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.</li> <li>c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.</li> </ul>	<p>SECTION II PARA III D</p>	

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

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REQUIREMENT	WHERE LOCATED IN REV. <i>7</i> OF PARTICIPANT QAPP	COMMENTS
<p>III. DESIGN CONTROL</p>		
<p>Activities related to design control are acceptable to the NRC staff if:</p>		
<p>1. The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and components performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR 60 and the Atomic Energy Act of 1954.</p>	<p><i>SECTION III PARA II APPENDIX "B"</i></p>	<p><i>DEFINITION MADE APPLICABLE TO H&amp;N SCOPE OF WORK</i></p>
<p>2. The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.</p>	<p><i>SECTION 3 PARA III B+C</i></p>	<p><i>LAST SENTENCE NOT APPLICABLE TO H&amp;N</i></p>
<p>3. Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.</p>	<p><i>SECTION 1 PARA III B SECTION III PARA III A3</i></p>	
<p>4. Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.</p>	<p><i>SECTION 3 PARA III E 2</i></p>	

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <u>3</u>	COMMENTS
<p>5. Interface controls among organizations or groups involved in design development and other design activities are described.</p>	<p>SECTION 3 PARA III F</p>	
<p>6. Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.</p>	<p>SECTION 3 PARAG 29/63</p>	
<p>7. Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification provided:</p> <ul style="list-style-type: none"> <li>a. The supervisor is the only technically qualified individual.</li> <li>b. The need is individually documented and approved in advance with concurrence of the quality assurance manager.</li> </ul> <p>It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.</p>	<p>SECTION 3 PARA III A 3/06</p>	
<p>8. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.</p>	<p>SECTION 3 PARAG III D 5d/E, GLOSSARY, APPENDIX D</p>	

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<p>9. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.</p>	<p>SECTION 3 PARA III A 3/0</p>	
<p>10. Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.</p>	<p>SECTION 3 PARA III E SECTION 2 PARA III D 3</p>	

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## IV. PROCUREMENT DOCUMENT CONTROL

Activities related to procurement document control are acceptable to the NRC staff if:

1. Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants to provide an acceptable quality assurance program.
2. Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations, and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

*SECTION 4 PARA III D 1,3,4  
PARA III C / E*

*SECTION 4 PARA III D-E  
SECTION 7 PARA III A-B-C*

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V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities related to instructions, procedures, and drawings are acceptable to the NRC staff if:

1. Organizational responsibilities are described for assuring that quality related activities are (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described under verification in Section III of this document.
2. Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality related activities have been satisfactorily accomplished.

*SECTION 5 PARA III A.C  
POLICY STATEMENT  
SECTION 1 PARA III  
GLOSSARY*

*SECTION 5 PARA III B 1*

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## NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

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## REQUIREMENT

WHERE LOCATED IN REV. *3*  
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COMMENTS

## VI. DOCUMENT CONTROL

Activities related to document control are acceptable to the NRC staff if:

1. The scope of the document control program is described, and the types of controlled documents are identified.
2. Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality related aspects.
3. Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.
4. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.
5. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.
6. When documents which require verification are released prior to verification, they are so identified and controlled.

*SECTION 6 PARA II / III A 6**SECTION 6 PARA III A  
SECTION 3 PARA III B & G  
SECTION 4 PARA III I**SECTION 6 PARA III A 5 / C 2  
PARA I**SECTION 6 PARA III A 4 / D E C 2  
PARA I**SECTION 6 PARA III C 2**SECTION 6 PARA III C 1*

## NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

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10/88

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*RRR*

PARTICIPANT CONTRACTOR

*Holmes and Narver, Inc*

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OF PARTICIPANT QAPP

COMMENTS

## VII. CONTROL OF PURCHASED ITEMS AND SERVICES

Activities related to control of purchased materials, equipment, and services are acceptable to the NRC staff if:

1. Organizational responsibilities are described for the control of purchased material, equipment, and services.
2. Procedures governing procurement of items and services, including appropriate QA organization participation, provide for (a) evaluation and selection of supplier's; (b) verification of supplier's activities; and (c) receiving inspections.
3. The organization providing materials, equipment, or services furnishes the following records to the purchaser:
  - a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.
  - b. Documentation identifying any procurement requirements that have not been met.
  - c. A description of these nonconformances from the procurement requirements dispositioned "accept as is" or repair."

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

4. Supplier certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

*SECTION 7 PARA III A-1**SECTION 7 PARA III A-2**SECTION 7 PARA III G-11**SECTION 7 PARA III G-20*

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COMMENTS

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

SECTION 4 PARA III D2  
SECTION 11 PARA III B 2 A, 2

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WHERE LOCATED IN REV. 3  
OF PARTICIPANT QAPP

COMMENTS

## VIII. IDENTIFICATION AND CONTROL OF ITEMS

Activities related to sample identification and control are acceptable to the NRC staff if:

1. Controls are established and described to identify and control samples. The description should include organizational responsibilities.
2. Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.
3. Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.
4. Correct identification of samples is verified and documented prior to release for use or analysis.

SECTION 8 PARA III A

SECTION 8 PARA III A

SECTION 8 PARA III A 2a

SECTION 8 PARA III 2b

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WHERE LOCATED IN REV. 3  
OF PARTICIPANT QAPP

COMMENTS

IX. CONTROL OF PROCESSES

Activities related to control of special processes are acceptable to the NRC staff if:

1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.

*SECTION 9 PARA III C*

2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

*SECTION 9 PARA III A*

3. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.

*SECTION 4 PARA III C & E  
SECTION 18*

4. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

*SECTION 9 PARA III A  
SECTION 5 PARA III B*

5. Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.

*SECTION 9 PARA IV*

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REQUIREMENT	WHERE LOCATED IN REV. <i>2</i> OF PARTICIPANT QAPP	COMMENTS
X. INSPECTION		
Activities		
1. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.		<i>SECTION 10 PARA III A, C</i>
2. Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.		<i>SECTION 10 PARA III B 293</i>
3. A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.		<i>SECTION 10 PARA III B APPENDIX A</i>
4. Inspection procedures, instructions, or checklists provide for the following: <ul style="list-style-type: none"> <li>a. Identification of characteristics and activities to be inspected.</li> <li>b. A description of the method of inspection.</li> <li>c. Identification of the individuals or groups responsible for performing the inspection operation.</li> <li>d. Acceptance and rejection criteria.</li> <li>e. Identification of required procedures, drawings, and specifications and revisions.</li> <li>f. Recording inspector or data recorder and the results of the inspection operation.</li> </ul>		<i>SECTION 10 PARA III A</i>

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REQUIREMENT

WHERE LOCATED IN REV. 3  
OF PARTICIPANT QAPP

COMMENTS

- 4. Specifying necessary measuring and test equipment including accuracy requirements.
- 5. Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.
- 6. Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.

*SECTION 10 PARA III C*

*SECTION 10 PARA III*

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REQUIREMENT	WHERE LOCATED IN REV. OF PARTICIPANT QAPP <u>7</u>	COMMENTS
<p>XI. TEST CONTROL</p>		
<p>Activities related to test control are acceptable to the NRC staff if:</p>		
<p>1. The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.</p>	<p>SECTION 11 PARA II / III B 2 L PARA III B 3 SECTION 18</p>	
<p>2. Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.</p>	<p>SECTION 11 PARA B. 3</p>	
<p>3. The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.</p>	<p>SECTION 11 PARA III B 2 H</p>	
<p>4. Test procedures or instructions provide the following:</p> <ul style="list-style-type: none"> <li>a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.</li> <li>b. Instruction for performing the test.</li> <li>c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.</li> <li>d. Mandatory inspection hold points (as required).</li> <li>e. Acceptance and rejection criteria, including required levels of precision and accuracy.</li> </ul>	<p>SECTION 11 PARA III B 10 2 / D SECTION 5 PARA III B</p>	<p>REQ 4 F NOT ADDRESSED AS IT IS NOT A PART OF MAIN SCOPE OF WORK</p>

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REQUIREMENT	WHERE LOCATED IN REV. <u>J</u> OF PARTICIPANT QAPP	COMMENTS
f. Methods of data analysis.		
g. Methods of documenting or recording test data and results. only required for		
h. Provisions for assuring test prerequisites have been met.		
5. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.		SECTION 11 PARA III D 1

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REQUIREMENT	WHERE LOCATED IN REV. <i>3</i> OF PARTICIPANT QAPP	COMMENTS
<b>XII. CONTROL OF MEASURING AND TEST EQUIPMENT</b>		
Activities related to control of measuring and test equipment are acceptable to the NRC staff if:		
1. The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.	<i>SECTION 12 PARA II</i>	
2. QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.	<i>SECTION 18</i>	
3. Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.	<i>SECTION 2 PARA II B2 SECTION 12 PARA C8D</i>	
4. Measuring and test equipment is labeled, tagged, or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.	<i>SECTION 12 PARA III B162</i>	
5. Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions which could affect measurement.	<i>SECTION 12 PARA III C2</i>	
6. Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.	<i>SECTION 12 PARA III C1</i>	
7. When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.	<i>SECTION 12 PARA III C5</i>	

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REQUIREMENT

WHERE LOCATED IN REV. \_\_\_\_\_  
OF PARTICIPANT QAPP

COMMENTS

XIII. HANDLING, STORAGE, AND SHIPPING

Activities related to sample handling, storage, and shipping are acceptable to the NRC staff if:

1. Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.
2. Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

SECTION 8 PART A 1, 2  
SECTION 2 PART III D.I

SECTION 5 PART 1.1

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REQUIREMENT

WHERE LOCATED IN REV. 3  
OF PARTICIPANT QAPP

COMMENTS

## XIV. INSPECTION, TEST, AND OPERATING STATUS

Activities related to inspection, test, and operating status are acceptable to the NRC staff if:

1. Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.

*SECTION 14 PARA III R&G*

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REQUIREMENT	WHERE LOCATED IN REV. <u>2</u> OF PARTICIPANT QAPP	COMMENTS
XV. CONTROL OF NONCONFORMING ITEMS		
Activities related to nonconformances are acceptable to the NRC staff if:		
1. Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. Procedures identify individuals authorized to dispose of and close out nonconformances		<i>SECTION 15 PARA III A, G</i>
2. QA responsibilities related to nonconformance control are described.		<i>SECTION 15 PARA III A 8</i>
3. Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.		<i>SECTION 15 PARA III A / D</i>
4. Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.		<i>SECTION 15 PARA III 1</i>

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REQUIREMENT

WHERE LOCATED IN REV. 3  
OF PARTICIPANT QAPP

COMMENTS

## XVI. CORRECTION ACTION

Activities related to corrective action are acceptable to the NRC staff if:

1. Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.
2. Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.
3. Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.
4. Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.

*SECTION 2 PARA III B,C  
SECTION 5 PARA III A  
SECTION 16 PARA III C*

*SECTION 16 PARA III A+C*

*SECTION 16 PARA III B,C*

*SECTION 16 PARA III A+B*

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OF PARTICIPANT QAPP

COMMENTS

XVII. QUALITY ASSURANCE RECORDS

Activities related to QA records are acceptable to the NRC staff if:

1. The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspection; tests; audits and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports; peer review reports; nonconformance reports; and corrective action reports.

*SECTION 17 PARA I+II  
ATTACHMENT 1*

*NOTE. SAMPLE  
STORAGE ADDRESSED  
IN SECTION 8*

2. QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

*SECTION 18*

3. Inspection and test records contain the following where applicable:

*SECTION 10 PARA VI A  
SECTION 11 PARA III D*

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

4. Suitable facilities for the storage of records are described and utilized.

*SECTION 17 PARA III J*

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REQUIREMENT	WHERE LOCATED IN REV. <i>2</i> OF PARTICIPANT QAPP	COMMENTS
XVIII. AUDITS		
Activities related to audits are acceptable to the NRC staff if:		
1. Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program.	<i>SECTION 18 PARA III A 1, 2, 3, 4</i>	
2. An audit plan is prepared identifying audits, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.	<i>SECTION 18 PARA III A 1, 2, 3, 4</i>	
3. Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.	<i>SECTION 18 PARA III D 1</i>	
4. Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.	<i>SECTION 18 PARA III F 2</i>	
5. Audits are performed in accordance with preestablished written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.	<i>SECTION 18 PARA III B 1/D1</i>	
6. A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.	<i>SECTION 18 PARA III F.2</i>	
7. The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.	<i>SECTION 18 PARA III F.1</i>	
8. In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.	<i>SECTION 18 PARA III F.1 &amp; 2 SECTION 16 PARA III D</i>	