UNCLE RALPH LETTER

DEC 2 2 1988

Mr. Ralph Stein, Associate Director
Office of Systems Integration and Regulations
Office of Civilian Radioactive Waste Management
U. S. Department of Energy RW-24
Washington, D. C. 20545

Dear Mr. Stein:

The purpose of this letter is to transmit the minutes from the U. S. Nuclear Regulatory Commission (NRC) staff's November 18, 1988 meeting with staff and representatives from the U. S. Department of Energy (DOE) and the State of Nevada. Discussed during the meeting were the NRC comments on the DOE Quality Assurance Program Description (QAPD) as well as other revisions to the QAPD, and DOE's proposed revision to the "Nevada Nuclear Waste Storage Investigation Quality Assurance Plan," (NNWSI/88-9). As a result of the meeting, several of the DOE responses to NRC comments on the QAPD were found acceptable. Some staff comments were removed, and DOE needs to revise some of its responses. The NRC staff did not have any comments on the other changes to the QAPD, but committed to contact DOE once the staff had completed its review.

With respect to NNWSI/88-9, the staff did not have any comments on the DOE changes to address the open items identified in the staff safety evaluation, but did agree to inform DOE of any concerns it may have once the NRC completes its review. Besides those changes needed to address the six open items, DOE plans to make additional changes to NNWSI/88-9. Contained in the enclosure are the detailed minutes from the meeting along with copies of the information discussed during the meeting.

If you need any additional assistance, feel free to contact the NRC project manager for the meeting Mr. Joe Holonich, who can be reached at (301) 492-3403 or FTS 492-3403.

Sincerely,

ORIGINAL SIGNED BY

John. J. Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

cc: C. Gertz, DOE/Nevada
R. Loux, State of Nevada
D Bechtel, Clark County
M. Baughman, Lincoln County
J. Bradhurst, Nye County

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ENCLOSURE

Meeting Summary

On November 18, 1988, members of the U. S. Nuclear Regulatory Commission (NRC) staff met with representatives from the U. S. Department of Energy (DOE), and the State of Nevada. The purpose of the meeting was to discuss the NRC staff comments on the DOE Quality Assurance Program Description (QAPD) and to have DOE provide its responses to those comments. These comments had been previously discussed with DOE in a conference call on November 4, 1988. Attachment 1 is a list of attendees. The NRC staff concerns, the DOE responses, and the disposition of the comments are contained in Attachment 2. Besides providing its responses to the NRC comments, DOE also presented several changes to the QAPD that resulted from changes precipitated by the NRC review of the DOE Quality Assurance Requirements Document (QARD). These are also contained in Attachment 1. The NRC staff agreed to review these QARD required changes and to inform DOE if there were any major problems by November 23, 1988.

In addition to discussing the NRC review of the QAPD, DOE presented changes that were being made to the "Nevada Nuclear Waste Storage Investigation Quality Assurance Plan," (NNWSI/88-9). These changes were of two types. One set of changes was being made to address the open items in the NRC safety evaluation of NNWSI/88-9. The second set was just additional changes being made by DOE. All of the proposed changes to NNWSI/88-9 are contained in Attachment 3. The staff stated at the beginning of the meeting that although it was prepared to listen to the additional changes proposed by DOE, it did not intend to provide any feedback on the acceptability of the changes during the meeting. DOE stated that it understood and that it did not expect acceptance during the meeting. When DOE had completed its presentation, the NRC staff noted that before NRC could perform a review of the additional changes to NNWSI/88-9, DOE would have to formally request an NRC review and in that request identify the priority of the NNWSI/88-9 review with respect to other ongoing NRC reviews. DOE agreed to provide a letter. Attachment 4 is a draft copy of the revised NNWSI/88-9 document.

Joseph J. Holonich, Sr. Project Manager
Office of Nuclear Material Safety
and Safeguards
U. S. Nuclear Regulatory Commission

Linda Desell, Licensing Branch
Office of Civilian Radiactive Waste
Management
U. S. Department of Energy

James E. Kennedy, Section Leader
Office of Nuclear Material Safety
and Safeguards
U. S. Nuclear Regulatory Commission

Lake Barrett, Director
Office of Quality Assurance
U. S. Department of Energy

ATTACHMENT 1

List of Attendees

NRC

J. Holonich
W. Belke
J. Kennedy

State of Nevada

S. Zimmerman

Newman & Holtzinger

K. Unnerstall

Nye County, Nevada

E. Holstein

Others

P. Wade, (SAIC/Reston)

DOE

L. Barrett
J. Blaylock
J. Jones
S. Echols
L. Desell

DOE/SAIC

J. Estella
S. Ailes

DOE/Weston

A. Kimmins
G. Faust

DOE/CER

N. Frank

Attachment 2

NRC Comments on QAPD and DOE Responses

GENERAL

NRC Comment

A. Paragraph 2.0 in Section 2 of the QAPD indicates the OCRWM quality assurance program will comply with the requirements in the QAR. The NRC staff interprets this commitment as one which totally applies the commitments in the QAR, without exception, to the QAPD. This includes the QAR commitments to ANSI/ASME NQA-1-1986 and the NRC NUREGs 1297, 1298, 1318 and 0856. Consequently, the NRC staff has not asked all or parts of the NRC Review Plan criteria 1.1, 1.4, 1.11, 2.2, 2.8(c)&(e), 3.1, 3.2, 3.4, 3.6, 3.7, 3.8, 3.9, 6.1, 7.2, 7.3, 16.3, 17.3, 17.4, 18.2, 18.3, and 18.6. Should this interpretation be incorrect, the DOE should provide sufficient description in equivalent detail for those instances where the QAPD takes exception to the QAR.

Additionally, although acceptable, the NRC staff believes this is a somewhat cumbersome system whereby the user of the DOE QA documents must refer to the QAR, QAPD, and NQA-1. It would appear that the DOE consider incorporating the QA requirements for the waste repository program into a single document to facilitate its use and avoid misinterpretations or reduce error in the documents use.

DOE Response

- Revise 2nd sentence of 1st paragraph of QAPD Sect. 2, Para. 2.0 to read:

  "The OCRWM quality assurance program will comply with the requirements specified in the QAR which are applicable to headquarter's activities."

- Insert the words "applicable requirements of the" between the words "the" and "QAR" in the second line of the 1st sentence of Section 2.1.2.

- The NRC's above comment that they read the QAPD to say that the requirements of the QAR apply without exception to the QAPD is a correct interpretation. However, only the sections of the QAR under which OCRWM is doing work can be applied to the QAPD.

RP 1.1 - This is covered by QAR Introduction and Section 1 and by QAPD paragraph 1.1.1.

RP 1.4 - This is covered by QAR Introduction and paragraph 18.5 and QAPD paragraphs 4.2, 7.1.1, and 18.1.3.

RP 1.11 - This is covered by the DOE response to NRC comments to the QAR. QQA participation is defined in the QAR and QAPD. The philosophy is described in the QAR "Introduction and QAPD Policy."

RP 2.2 - Software control, including a commitment to NUREG 0856, is covered by QAR Subsection 3.3 and QAPD Paragraph 3.1.5

RP 2.8c - This is covered by QAR Subsection 2.6 which references NQA-1 Supplements 2S-1 and 2S-4 and Appendix 2A-1. QAPD Paragraph 2.1.9 specifies how OCRWM meets the QAR.

RP 2.8e - Section 2 of the QAR commits to NQA-1, BR, Supplements 2S-1, 2S-2, 2S-3, and 2S-4 and Appendix 2A-1 which meets this RR comment. Paragraph 2.1.9 of the QAPD describes how OCRWM meets QAR

RP 3.1 - Addressed in QAR's Glossary, which incorporates definitions of NQA-1 Supplement S-1 and adds other definitions including design and design activities. Design change, design input, design output, design process, and final design are included in NQA-1 Supplement S-1.

RP 3.2 - NQA-1 B.R.3 and Supplement 3S-1 Paragraphs 2 and 3; QAR Section 3, Paragraph 3.0; and QAPD Section 3 Paragraphs 3.0 and 3.1.1 address the design input and design process phases of design control.

QAR Paragraph 2.5.1 and QAPD Paragraph 2.1.8 address the identification and classification of items important to waste isolation.

QAR Paragraph 2.5.2 and QAPD Paragraph 2.1.8 address the application of a graded QA approach.

QAR Paragraph 3.6.1, 3.6.2, 3.6.3, 3.6.4, and 3.6.5 and QAPD Paragraph 3.1.3 address data gathering and analysis.

RP 3.4 - QAR Paragraph 3.1 and 3.5, and QAPD Paragraph 3.1.10 address the control of design error and deficiency control and control of erroneous data

RP 3.6 - NQA-1 Basis Requirement 6 requires that documents that specify quality requirements or prescribe activities affecting quality (which includes design drawings, specs, criteria and analyses) be reviewed by authorized personnel.

NQA-1 and the OCRWM approach to quality does not require this review, which is considered a line function of the design organization, to be done by QA personnel.

RP 3.7 - NQA-1 Supplement 3S-1 Paragraph QAR Section 3 Paragraphs 3.4.3 and 3.5.1; QAPD Section 3 Paragraphs 3.1.7 and 3.1.8 address design verification and the independence of the design verification personnel.

RP 3.8 - QAR 3.5.1 and QAPD 3.1.7 address use of Peer Reviews. The QAR and QAPD require compliance with NUREG-1297 for peer reviews.

RP 3.9 - NQA-1 Supplement 3S-1 Paragraphs 4, 4.1, 4.2, 4.2.1, 4.2.2, and 4.2.3 address design verification, responsibilities related to verification of design, extent, and methods.

RP 6.1 - QAPD Section 6, Paragraph 6.0; NQA-1 Basic Requirement 6 and Supplement 6S-1 Section 1 address the scope of the document control program

RP 7.2 - NQA-1 Supplement 7S-1 Paragraphs 3.1, 5, 5.2, 8.2.3 address source evaluation and selection, supplier performance evaluation, and receipt inspection. QAPD Section 7.1.1 also addresses these topics.

RP 7.3 - NQA-1 Supplement 7S-1 Paragraph 8.2.1, and Paragraph 9; QAPD Paragraphs 7.1.1 (c), (d), and (f) (3&4) address supplier documentation.

RP 16.3 - NQA-1 Basic Requirement 16; QAR Subsection 16.2; QAPD Paragraph 16.1.3 address follow-up verification of proper implementation of corrective action.

RP 17.3 - NQA-1 Supplement 10S-1 Section 8, 10.1; NQA-1 Supplement 11S-1 Section 5; QAR Paragraphs 3.6.6 and 10.2 address the required content of inspection and test records.

RP 17.4 - NQA-1 Supplement 17S-1 Paragraphs 4.4, 4.4.1, 4.4.2 and 4.4.3 address records storage facilities.

RP 18.2 - NQA-1 Supplement 18S-1 Sections 2 and 3.1; QAR Subsections 18.2, 18.4 and 18.5; QAPD 18.0, 18.1.1, 18.1.2(a), (c) and 18.1.3 address audit scheduling and use of audit plans.

RP 18.3 - NQA-1 Supplement 18S-1 Section 4; QAR Paragraphs 18.3 and 18.5.4; QAPD 18.1.2(d), 18.1.3(d) addresses conduct of audits

RP 18.6 - NQA-1 Supplement 18S-1 Section 7; QAR Subsection 2.9 and 16.1; QAPD Section 2.1.12, 16.1.2, and 18.1.2(g) address tracking, follow-up action, and trending.

Disposition

1st Paragraph: The staff will review the response and provide DOE with feedback.

2nd Paragraph: DOE will provide in its letter transmitting the revision to the QAPD, Rev. 1 a discussion of why it chose this approach.

NRC Comment

B. Paragraph 15.1 of Section 15 in the QAR dates that,

"The work associated with identification and control of nonconforming items will be delegated by OCRWM to other PROGRAM participants because OCRWM neither directly produces nor directly procures hardware items."

This appears inappropriate since paragraph 16.1.3 of QAR Section 16 states in part, "Significant conditions adverse to quality identified within or by OCRWM..." A description should be provided in the QAR to explain the system of how significant conditions adverse to quality are identified if other than by the nonconformance system identified in Section 15 of the QAR.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

Change/replace the 1st sentence of 16.1.3 to read as follows:

"Significant conditions adverse to quality cited within OCRWM will be reported to the cognizant Associate Directors and the Director, OQA by using a Corrective Action Report (CAR). Nonconformances, deficiencies, and significant conditions adverse to quality identified by OCRWM personnel at other participants' facilities will be brought to the attention of the participant and handled using the participant's nonconformance or corrective action system."

Disposition

The DOE response is acceptable to the staff.

NRC Comment

C. Paragraph 1.1.2(f) in Section I of the QAR states that, "The responsibilities of the Director OQA are:

"Review the quality assurance program documents of the Project Offices and OCRWM-managed PROGRAM participants for compliance with established PROGRAM quality assurance policies and requirements, develop a recommendation for approval or disapproval, obtain concurrence of the cognizant Associate Directors, and submit the recommendation to the Director, OCRWM for approval or disapproval action."

This may be interpreted to mean that the OQA reviews all the QA program documents including the implementing procedures. Clarification should be provided to delineate what is exactly meant here and the degree of review required for the implementing procedures.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

QAPD Section 2.2 states that the quality assurance program descriptions will be reviewed and approved by the next higher PROGRAM-participant organization level. For OCRWM the responsibilities are delineated in Paragraphs 1.1.1(e)0, 1.1.2(f), 1.1.3(g), 1.1.4(f), 1.1.5(f), and 1.1.6(d).

QAPD Paragraphs 2.1.1, 2.1.2, and 2.1.3 state that the Director, OQA reviews the OCRWM QAR, QAPD, and QAAP's. QAPD Paragraph 2.1.4 states that Implementing Line Procedures are reviewed and approved by the OCRWM Branch (line organization) that performs the activity to which the procedure applies.

Disposition

DOE will add the following sentence to Section 2.4 of the QAPD:

"The Office of Quality Assurance will support and assist in the development of implementing line procedures, as appropriate."

NRC Comment

D. For Sections 8 through 15 in the QAR it is stated that the work associated with these sections will be delegated by OCRWM to Project Offices and other Program Participants. In the footnote for Figure 2.2 in the QAR, it is stated that:

"OCRWM will normally delegate the work of establishing and implementing these criteria to Project Offices and other PROGRAM participants, however OCRWM retains responsibility for assuring that these activities are established and appropriately implemented, and carries out this responsibility through review and approval of Project Office and other PROGRAM participants procedures and through audits and surveillances of the activity."

The QAPD should specifically explain and justify in equivalent detail, exactly what the DOE involvement will be in these areas and why appropriate QA description for these areas is unnecessary.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

Add the following to Subsection XX.1 in Sections 8 thru 15:

"OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. This overview will include audits, surveillances, reviews, [redacted] by the OCRWM OQA." (2)

Disposition

The word "normally" will be removed, and DOE will state that the Office of Civilian Radioactive Waste Management has delegated responsibility for Sections 8 through 15.

1. NRC REVIEW PLAN CRITERION

1.7 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.

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

NRC Comment

Paragraph 1.1.14 on page 28 of the QAPD references a contracting officer. This position is not identified on the organizational charts and the responsibilities of this position are not described.

DOE Response

Delete the 2nd sentence of the 1st Paragraph of Section 1.1.14. Refer to response to Question #7, 3rd bullet.

Disposition

This response is dependent upon DOE satisfactorily addressing Item 7.

2. NRC REVIEW PLAN CRITERION

1.10 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 Manual(s), changes thereto, and interpretations thereof.

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

NRC Comment

The QAPD should describe the management and QA knowledge and experience for the management position that retains overall authority and responsibility for the QA program.

DOE Response

OCRWM's approach is to specify knowledge and experience requirements for the various positions in job descriptions, not in the QAPD.

Disposition

DOE will add the sentence similar to the following one to Section 1.1.2 of the QAPD and provide the Director of Quality Assurance's job description and resume' as supplemental information when it submits revision 1 of the QAPD.

"This position will be occupied by an individual with appropriate management and QA knowledge."

3. NRC REVIEW PLAN CRITERION

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

NRC Comment

This does not appear to be addressed in QAPD.

DOE Response

While the QAPD does not specifically use the word "mandatory", the concept is covered by the Policy Statement (p. ix) and Section 2.0 - Quality Assurance Program (p. 30)

Disposition

This comment is acceptable to the staff.

4. NRC REVIEW PLAN CRITERION

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

NRC Comment

Paragraph 2.1.3 in Section 2 of the QAPD contains provisions whereby the Director OQA approves the QAAPs. Paragraph 2.1.4 of the QAPD indicates the implementing line procedures will be prepared, reviewed and approved by the OCRWM Branch performing the activities. A description should also be provided to assure the QA organization reviews and documents concurrence with the implementing line procedures to assure appropriate quality requirements are incorporated.

DOE Response

This comment was deleted by the NRC during the 11/3/88 telephone conversation.

5. NRC REVIEW PLAN CRITERION

3.1 The definitions of design, design information, and design activities used in the design control program are as defined in this section.

NRC Comment

In paragraph 3.1.1 of Section 3 of the QAR, the term "Systems Engineering" is used. This term should be defined to assure there are no misunderstandings between the NRC staff's interpretation as opposed to the DOE interpretation in the use of this term.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

"Systems engineering is a structured, formal method of managing the design process. It specifies:

"(a) the iterative engineering process which defines the technical baseline and the development of the PROGRAM design to that baseline. The system-engineering design process is iterative, cycling between the definition of requirements (design, development, siting), evaluations of the design and siting against the requirements, and optimization of the design, leading to further definition and refinement of the requirements.

"(b) the procedures for integrating the disciplines involved in the system design development, interface between the various levels of the PROGRAM, control of revisions to the technical baseline, review of that baseline, and periodic review of the system development.

"(c) the documentation requirements to record the system baseline and provide a traceable record of the design and siting process."

Disposition

The NRC staff will review this comment and identify any concerns to DOE.

6. NRC REVIEW PLAN CRITERION

3.3 Organizational responsibilities are described for preparing, reviewing, approving, verifying and validating design and design information documents.

NRC Comment

The QAR should identify the specific organizational responsibilities for developing, reviewing, approving, verifying and validating the requirements documents for systems engineering activities.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

Add the following as Paragraph 1.1.5(b) for OSIR:

(b) Develop the Systems Engineering Management Plan for each system element of the PROGRAM.

Reletter current Subsections (b) through (k) as (c) through (l)

Disposition

DOE will add the words similar to the following ones to the Systems Engineering Management Plan.

"...reviewing, approving, verifying and validating the requirements documents for system engineering activities."

7. NRC REVIEW PLAN CRITERION

4.2 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.

NRC Comment

Paragraph 4.1.1 of Section 4 in the QAPD states that the above criterion will be done but does not identify the positions responsible to perform the procurement activities or the QA organizational involvement.

DOE Response

OCRWM has a liaison with the Procurement and Assistance Management Directorate. This will be clarified by the following changes.

- Add the following to the end of the 2nd sentence of the 1st Paragraph of Section 1.1.3 (OPARM):

  "..., establishing OCRWM's annual procurement plan, and coordinating the preparation, review, approval, and control of procurement documents with the DOE's Procurement and Assistance Management Directorate."

- Revise Figure 1-1A to show "dotted-line" coordination and matrix support between OCRWM and the Procurement and Assistance Management Directorate.

- Add the following at the beginning of the 3rd Paragraph of QAPD Subsection 4.1.1:

  "Procurement documents are prepared, issued, and controlled for OCRWM by the Procurement and Assistance Management Directorate."

Disposition

DOE will amend the response to make the QAPD changes and identify them section by section.

8 NRC REVIEW PLAN CRITERION

6.2 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.

NRC Comment

The QAPD does not appear to address whether procedures are reviewed for technical adequacy and whether the QA organization concurs with these documents for quality-related aspects.

DOE Response

This comment was deleted by the NRC during the 11/3/88 telephone conversation.

Disposition

This comment has been removed.

9. NRC REVIEW PLAN CRITERION

6.6 When documents which require verification are released prior to verification, they are so identified and controlled.

NRC Comment

The above criterion does not appear to be addressed other than for design (Section 3, paragraph 3.1.7).

DOE Response

Add the following to Paragraphs 6.1.2(a) and 6.1.3(a)(1) of the QAPD.

"including documents released prior to completion of the approval process" (2)

Disposition

This response is acceptable to the staff.

10. NRC REVIEW PLAN CRITERION

16.1 Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

NRC Comment

Paragraph 1.1.2(b) in Section 1 of the QAR indicates QA coordinates the development of the quality assurance procedures, and paragraph 6.1.1(a) in Section 6 of the QAR indicates procedures will identify the individuals or organizations responsible for preparation, review and approval of procedures. The QAR does not appear to address whether the QA organization reviews and documents concurrence with the procedures.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

Line organizations are responsible to prepare their own procedures. Each QAAP has a "4.0 Responsibilities" section that includes who is responsible for preparation of the QAAP. For QAAP 16.1, Director OQA is responsible for preparation. Procedure QAAP 16.1 "Corrective Action" will receive review and concurrence from the Associate Directors of OPARM, OFSD, OSIR, OERAP, and OQA. The Director, OCRWM approves all QAAPs for use.

Disposition

This comment is acceptable to the staff.

11. NRC REVIEW PLAN CRITERION

18.5 Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.

NRC Comment

Paragraph 18.1.2 of the QAR indicates the audit team leader will be a certified lead auditor and independent of having direct responsibility for the work being audited. The QAR should also address whether the audit team members are independent of having direct responsibility of the area being audited.

DOE Response

As noted during the 11/3/88 telecon, all references to the QAR have been interpreted to mean the QAPD.

Add the following between the 2nd and 3rd sentences of QAPD 18.1.2(b):

> "Audit team members may be from the same organization which was responsible for accomplishing the work being audited but they cannot be the individuals who actually performed or directly supervised the performance of the work being audited." (2)

Disposition

This response is acceptable to the staff. DOE will note that team independence will be covered in the administrative procedure.

LISTING OF CHANGES TO THE QAPD
Revision 0 dated September 16, 1988

Page ix, Policy

Add the following paragraph to the end of the Policy statement:

> The OCRWM quality assurance program will emphasize individual achievement of quality. Line organizations have the responsibility for the achievement of quality and the inspections, tests, and reviews, within the organization. The quality assurance organization has the responsibility to overview and assess the achievement of quality and report the results to management.

Page 1, 1.0 General

Add the following to the end of the 1st paragraph:

> The assignment of responsibilities reflects the philosophy that the line organization achieves quality and the quality organization overviews to assess the achievement of quality.

Page 1, 1.1 OCRWM Organization, sixth line:

> Change "AND" to lower case "and".

Page 2, 1.1.1 (i), 1st line:

> Replace "regular" with "annual".

Page 3, 1.1.2 Director, Office of Quality Assurance (OQA), 2nd paragraph:

1st line:

> Delete "execution,"

4th line:

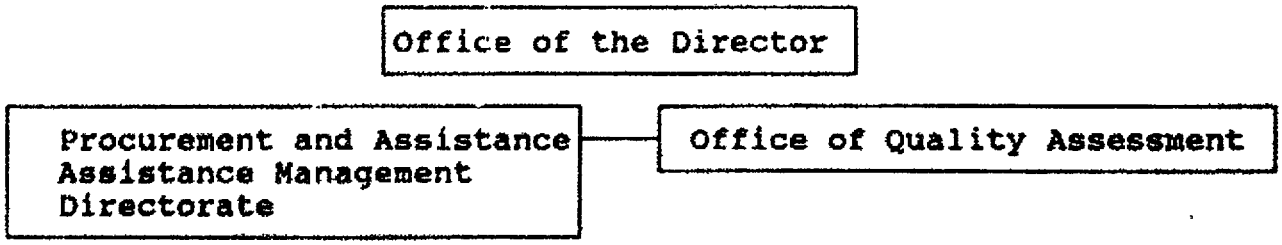
> Delete "training,"

Page 4, 1.1.2 (f), 1st line:

> Add between "documents" and "of" the following:
>
> "(including revisions to and interpretations thereof)"

Page 12, Figure 1-1A

Add the following:



Add the following legend to the Figure:

Dotted line [----]: Matrix support

Solid line [____]: Direct line of authority

Page 32, 2.1.6b, 2nd paragraph, 1st line:

Add "normally" between "will" and "be"

Page 33

Replace 2.1.6c in its entirety with the following:

Verification personnel shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When verification personnel are part of the line organization, the quality assurance organization shall overview and monitor the verification activities by conducting independent QA assessments, audits, and surveillances.

Page 34, 2.1.8, last paragraph, 1st sentence

Replace "develop" with "develops"
Replace "maintain" with "maintains"

Page 36, 2.1.11, Title

Delete "Independent"
1st paragraph, 1st sentence

Replace "continually" with "periodically"

Page 40, 3.0, 1st paragraph, 2nd sentence:

Insert "from conceptual design through final design" between "activities" and "are"

Page 43, 3.1.7, last paragraph:

Add the following to the end of the paragraph:

Peer reviews will be performed in accordance with the guidance provided in NUREG-1297, Peer Review for the High-Level Waste Repositories Generic Technical Position, February 29, 1988 as provided in the applicable QAAP.

Page 43, 3.1.8, 1st paragraph:

Add the following to the end of the paragraph:

Peer reviews will be performed in accordance with the guidance provided in NUREG-1297, Peer Review for the High-Level Waste Repositories Generic Technical Position, February 29, 1988 as provided in the applicable QAAP.

Page 44, 3.1.9

Add the following paragraph:

The impact of design changes on procedures and training will be evaluated. The changes will be communicated to all affected groups or individuals.

Page 46, 4.1.1

Add:

"(h) Acceptance criteria"

Page 51, 6.1.2 (a):

Add"

"including documents released prior to completion of the approval process"

Page 51, 6.1.3 (a)(1):

Add:

"including documents released prior to completion of the approval process"

Page 54, 7.1.1 (d)

Insert the following as the 1st paragraph:

When required by procurement documents, suppliers' QA PROGRAMS shall be reviewed and accepted prior to initiation of activities affected by the quality assurance program.

Page 55, 7.1.2

Delete "is:" and replace with "are:"

Add "QAAP 2.5 Quality Assurance Document Review" above "QAAP 7.1..."

Page 64, 16.1.1, 2nd sentence:

Replace 1st "of" with "for"

Page 64, 16.1.3, Title

Delete "and Corrective Action"

Page 66, 17.1.1, 2nd paragraph, 2nd sentence

Replace "Resource" with "Resources"

Page 68, 18.1.1, 1st paragraph, last sentence

Add "on" between "audited" and "at"
Replace "annually" with "a triennial basis"

Page 69, 18.1.2

Add the following paragraph after the first paragraph:

The scope of each audit will be based on an evaluation of the activities to be audited. The evaluation will consider:

(a) Results of previous internal audits

(b) Results of previous extrinsic audits

(c) Impact of significant changes in personnel, organization, or quality assurance program

Page 70, 18.1.2 (e), 1st sentence

Replace "Documentation of audit" with the following:

Analysis by the OQA of data from the performance of the audit and documentation of the _____

Page 70, 18.1.2 (e), 2nd sentence

Replace 1st "and" with "for review, assessment, and appropriate action with copies"

Page 71, 18.1.2 (g), 1st sentence

Replace 1st "that" with "who"

Page 71

Change "18.1.3" to "18.1.4" and add new paragraph that follows:

18.1.3 External Audits

The following amplifies the program as applied to external audits

(a) After award of the contract and based on the determination of the quality classification of each item or service to be procured, the need for external audits will be evaluated. A determination may be made that external audits are not necessary for procuring items that are (a) relatively simple and standard in design, manufacturing, and testing or (b) adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. The rationale for not performing an external audit will be documented.

(b) When external audits are determined to be necessary, audits of suppliers' quality assurance program swill be conducted on at least a triennial basis. External audits of the suppliers' quality assurance programs may be performed by a third party for PROGRAM participants. The triennial period begins when an audit is performed. The need for more frequent external audits of a supplier will be evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first triennial audit if the scope of the preaward is similar to the scope of other triennial audits.

(c) Audits conducted on a supplier by an external organization for the PROGRAM participant or for a group of purchasers that includes the PROGRAM participant are an acceptable alternative to a PROGRAM-participant conducted audit provided that the scope of the audit meets the needs of the PROGRAM and the audit report is provided to the PROGRAM participant. The PROGRAM participant remains responsible for the adequacy of these audits.

(d) Annual evaluations of suppliers will be performed or arranged for. Evaluations will be documented. These evaluations will assess:

(1) Supplier-furnished documents and records
(2) Previous verification results
(3) Supplier's operating experience with identical or similar products provided to others
(4) Extrinsic verification results

Attachment 3

Changes to NNWSI/88-9

NNWSI/88-9
ADDITIONAL CHANGES

1) REVIEW/APPROVAL OF PROCEDURES/QAPPS

Changes made to clarify reviews and approvals of lower tier implementing procedures and QA Program Plans.

CHANGE REFERENCE

Introduction (pg. xxii) para. 2.2.2 - Removes requirement for OCRWM review/approval of QA administrative procedures (AP-"Q")

Section II (pg. II-1) para. 1.0 - Removes requirement for Project Office submittal of AP-Q's to OCRWM for review/approval.

Section II (pg II-2) para. 1.2 - Removes requirement for Project Office review/approval of participant QA administrative procedures.

Section II (pg II-2) para. 1.2 - Removes requirement for Project Office approval of QAPPs prior to implementation.

These changes are fully consistent with the OCRWM QAR therefore no reduction in commitment has occurred.

2) GRADED QA

Changes made to clarify graded QA requirements as they specifically relate to QA Level I items and activities.

CHANGE REFERENCE

Section II (pg. II-4) para. 2.1.1
(pg. II-5) para. 2.1.4
(pg. II-9) para. 2.2.4

3) SOFTWARE QA

Changes made to clarify software QA requirements and to focus on the flexibility for selective application of these requirements.

CHANGE REFERENCE

Section III (pg. III-18) para. 3.1.6

- New paragraph to provide for use of unverified/unvalidated software

Section III (pg. III-18) para. 3.1.9

- Edited and revised to remove reference to NNWSI AP Manual

Appendix H - Various

4) TERMS AND DEFINITIONS

Changes made to Appendix A to clarify and add definitions.

CHANGE REFERENCE

Appendix A (pg. A-3) - Title Clarification
(pg. A-2) - Authentication, New
(pg. A-12) - Validation, New

5) MISCELLANEOUS

Section II (pg. II-1) para. 1.0 - higher-tier documents CFRs
Section III (pg. III-2) para. 1.3.1 - cursory reviews
Section III (pg. III-5) para. 1.6.2 -methods of data reduction
Section III (pg. III-7) para. 1.6.4.2
1.6.4.4 - S.I. final results
Section III (pg. III-19) para. 3.2 - Editorial
Section V (pg. V-1) para. 1.0 and 3.0 - Scientific notebooks QA records
Section XII (pg. XII-2) para. 2.1 - tolerance
Section XV (pg. XV-3) para. 1.4.4 - root cause for NRCs
Section XVIII (pg. XVIII-3) para. 1.2.2 - joint audits

NRC SAFETY EVALUATION (SE) - NNWSI/88-9

OCRWM RESPONSE TO OPEN ITEMS

1) NRC Comment
The definition of "Corroborative Data" found in Appendix A of the 88-9 QA Plan should be consistent with the definition contained in NUREG-1298.

OCRWM Response
The definition of "Corroborative Data" contained in Appendix A of NNWSI/88-9 has been revised. It is now fully consistent with the definition contained in NUREG-1298 as well as Appendix G of the 88-9 QA Plan.

Change Reference
Appendix A, Page A-4

2) NRC Comment
Section 6 of Appendix J in the 88-9 QA Plan should state that each individual member should sign the peer review report, to be consistent with NUREG-1297

OCRWM Response
The 88-9 QA Plan has been revised to require that the peer review report be prepared under the direction of the peer review group chairperson and signed by each peer review group member. An additional change was made to indicate that the technical qualifications of the peer reviewers shall be the primary consideration in the selection of peer reviewers. This change was made to ensure full consistency with NUREG-1297.

Change Reference
Appendix J, page J-2, para. 4.1 - "primary consideration."
Appendix J, page J-3, para 6.1 - "peer review report."

3) NRC Comment
Paragraph 1.6.4.1 of Section III of the 88-9 QA Plan should contain provisions for precision and accuracy for initial entries in the records for experiments or research.

OCRWM Response
The subject paragraph has been revised to require that the initial entries for scientific notebooks include identification of required levels of precision and accuracy, where appropriate.

Change Reference
Section III, page III-6, para. 1 6.4.1, 9th bullet.

4) NRC Comment

Appendix I of the 88-9 QA Plan should be consistent with Section 4 of NUREG-1318 for Q-List items and activities.

OCRWM Response

Various changes have been made to Appendix I as well as the remainder of the 88-9 QA Plan to ensure full consistency with NUREG-1318.

Change Reference

Appendix I, page I-1, para. 1.0 - Incorporate Quality Activities List
Appendix I, page I-1, para. 2.1 - Title change to include Quality Activities List
Appendix I, page I-1 and 2, para. 2.2 - Incorporate protection of worker health and safety.
Appendix I, page I-3 and 4, para. 3.4/3.5/3.6 - Number change
Appendix I, page I-5, para. 4.0 (last part) - Editorial correction
Appendix I, page I-5 and 6, para. 5.0 - Incorporate submittal requirements
Appendix I. page I-6, para 6.0 - Incorporate graded QA measures
Appendix A, page A-8, - Revise "Q-List" definition
Appendix A, page A-9, - Add "Quality Activities List" definition
Section II, page II-3, para. 1.5 - Revise title and remove "Q-List" definition and revise text for consistency with Appendix I.

5) NRC Comment

The control of nonconformances generated by surveillance should be addressed in greater detail, e.g., by indicating that Section XV of the 88-9 QA Plan "Control of Nonconforming Items", applies to surveillances.

OCRWM Response

Surveillance requirements have been revised to specifically require that nonconformances be handled in accordance with the requirements of Section XV or XVI of the 88-9 QA Plan, as applicable.

Change Reference

Section XVIII, page XVIII-6, para 2.3, 5th bullet.

6) NRC Comment

The section on scientific investigation should be revised to better address changes to procedure and use of lab notebooks, as discussed in Section 3.3 of this SE.

OCRWM Response

A number of changes have been made to various sections of the 88-9 QA Plan to address the NRC concerns expressed in Section 3.3 of the SE.

a. The first concern related to the need for controls to assure that investigation conducted with scientific notebooks be controlled so that tests which could affect the waste isolation capabilities of the site, interfere with other site characterization tests, or

which are not repeatable are appropriately controlled. Appropriate changes have been made to the 88-9 QA Plan, Section III, Section V, and Section VI, to focus on the fact that the study plan is the controlling document for the investigation when the scientific notebook system is used to document the work, and to clarify that reviews of these study plans, as well as changes thereto, shall specifically consider whether the activities are not repeatable, have the potential to impact the waste isolation capability of the site, or interfere with other site characterization activities.

b. The second concern related to what the NRC staff believed to be unnecessarily restrictive criteria for technical implementing procedures. Appropriate changes were made to Section III, para. 1.6.2 to provide for modifications to technical implementing procedures.

c. The third NRC concern related to the initial entries in scientific notebooks and the NRC staff's belief that a "general procedure" should also be included as an initial entry. Appropriate changes have been made to Section III, para. 1.6.4.1 to resolve this concern.

d. The final NRC concern related to this issue involved an apparent conflict between the 88-9 QA Plan and the NRC/DOE agreement of May 7-8, 1986. As a result, a new Appendix K was created which is based on the SCP Management Plan requirements for format and content of SCP study plans. This appendix is fully consistent with the May 7-8, 1986, NRC/DOE agreement.

Change Reference

Section III, para. 1.1.1.1	Item a) above
Section III, para. 1.1.2	Item d) above
Section III, para. 1.6.1	Item a) above
Section III, para. 1.6.2	Item b) above
Section III, para. 1.6.4.1	Items a and c) above
Section V, para. 2.0	Item a) above
Section VI, para. 2.1	Item a) above
Appendix K	Item d) above

Attachment 4

Draft of Revised NNWSI 88-9

NEVADA NUCLEAR WASTE STORAGE

INVESTIGATIONS

FOR INFORMATION ONLY

QUALITY ASSURANCE PLAN

NNWSI/88-9

REVISION 2

SIGNATURE PAGE

YMP PROJECT QUALITY MANAGER _____ DATE _____

PROJECT MANAGER, YMP _____ DATE _____

OCRWM DIRECTOR, OFFICE OF QUALITY ASSURANCE _____ DATE _____

DRAFT 11/14/88

DRAFT

NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT

QUALITY ASSURANCE PLAN

REVISION 2

DRAFT

UNITED STATES DEPARTMENT OF ENERGY
NEVADA OPERATIONS OFFICE
LAS VEGAS, NEVADA

PREFACE

This document is the eighth revision of the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Quality Assurance (QA) Plan. This document was previously designated as NVO-196-17 but has been renumbered as NNWSI/88-9.

This NNWSI Project QA Plan is a requirements document which was developed from QA requirements imposed on the NNWSI Project by the Office of Civilian Radioactive Waste Management (OCRWM), the U.S. Department of Energy (DOE), and the U.S. Nuclear Regulatory Commission (NRC). Accordingly, this document establishes the QA requirements that are applicable to the NNWSI Project participants.

Note that the term Nevada Nuclear Waste Storage Investigations (NNWSI) Project is superseded by Yucca Mountain Project and the term Waste Management Project Office (WMPO) is superseded by Yucca Mountain Project Office (Project Office). These changes will be reflected in a future revision to this document.

This revision reflects changes made to the Introduction, Sections II, III, V, VI, XII, XV, XVIII, Appendix A, Appendix H, Appendix I, and Appendix J. In addition, Appendix K was added. The changes made to this document are noted with line-by-line revision indicators throughout. In addition, the changes are summarized as follows:

- The signature page and title page were revised to correspond to the revision level of the document.
- The Preface was revised to indicate the basis for the changes to NNWSI/88-9, Rev. 1 and to provide a revised summary of the changes.
- The Table of Contents was updated to revise page numbers as necessary.
- The List of Effective Revisions was updated to reflect the current revision level of each section of the NNWSI QA Plan and to correct editorial errors.
- The Introduction, para. 2.2.2 was revised to remove the requirement for OCRWM review and approval of Project quality-related administrative procedures. This is consistent with the OCRWM QA Requirements document. In addition, editorial corrections were made to para. 2.8.1.
- Section II, para. 1.0, first subparagraph, was revised to remove requirements relative to Project Office submittal of quality-related administrative procedures to OCRWM for review and approval (see above bullet). In addition, the scope of the Quality Assurance Program was clarified.
- Section II, para. 1.0, third subparagraph was revised to insert "higher-tier" before "documents" in the third line for clarification and to exclude the CFRs.

- Section II, para. 1.2 was revised to remove the requirement for NNPO review and approval of NNWSI Project Participant non-technical implementing procedures based on OCRWM direction.

- Section II, para. 1.2, second paragraph was revised to be consistent with the OCRWM QAR.

- Section II, para. 1.5.1 was deleted to eliminate redundancy. (i.e. Appendix A contains a definition of "Q-List). In addition the heading for para. 1.5.2 was deleted, and the heading for para. 1.5 was revised to be consistent with the remaining text.

  → and para. 1.5.2 was revised for consistency with Appendix I.

- Section II, paras. 2.1.1/2.1.4/2.2.4. Changes were made to these paragraphs to clarify that QA requirements can be selectively applied to Level I items and activities commensurate with its importance to safety and/or waste isolation.

- Section III, para. 1.1.1.1 was revised to require that scientific investigation planning documents describe the proposed methodology for performing the work and that these planning documents provide identification, explanation, and justification for areas where scientific notebooks will be used.

- Section III, para. 1.1.2 was revised to clarify control of site characterization activities and to provide reference to Appendix K for study plan requirements.

- Section III, para. 1.3.1 was revised to remove the statement regarding cursory supervisory reviews since the definition of technical reviews in Appendix A adequately precludes a cursory review.

- Section III, para. 1.6.1 was revised to clarify the controls for scientific investigations when scientific notebooks are used to document the work. In addition, provisions were made for modifications to technical implementing procedures and the first sentence was revised for editorial clarity.

- Section III, para. 1.6.2 was revised to add requirements for the modification of technical implementing procedures. In addition, the parenthetical notation "as required" was removed from the fourth bullet since it was redundant with the lead in sentence which contains the words "as appropriate" and applies to all the bullet items.

- Section III, para. 1.6.2, seventh bullet was changed to "methods of data reduction" since data analysis is adequately covered by paragraph 1.4 of Section III.

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- Section III, para. 1.6.4.1 was revised to provide additional requirements for the initial entries to scientific notebooks and to clarify that these initial entries are considered to be the "general procedure" for performing the work. Additionally, provisions were established for modifications to these initial entries.

- Section III, para. 1.6.4.2. The last bullet was revised to clarify documentation of the final results of scientific investigations and renumbered as para. 1.6.4.4.
- Section III, para. 2.4.6.1, last bullet was revised to remove
- Section III. A new paragraph 3.1.6 was inserted to provide for the use of computer software which has not been verified or validated. Subsequent paragraphs were renumbered accordingly. Paragraph 3.1.9 (old paragraph 3.1.8) was modified to remove reference to the NNWSI Project Administrative Procedures Manual. reference to the NNWSI Project Administrative Procedures Manual.
- Section III, para. 3.2, last sentence was revised for editorial clarity.

- Section V, para. 1.0 and 3.0, were revised to clarify that requirements for work performed using the scientific notebook method are contained in Section III, para. 1.6. In addition, para. 3.0 of this section was modified to reflect that scientific notebooks are subject to QA records requirements.

- Section V, para 2.0 was revised to clarify review criteria for instructions, procedures, plans and drawings.

- Section VI, para. 2.1 was revised to clarify review criteria for changes to documents.

- Section XII, para. 2.1 was revised to clarify the control of M&TE when used to determine specified tolerance requirements.

- Section XV, para. 1.4.4. The last two bullets were deleted since para. 3.0 establishes requirements for periodic trending of nonconformances for root cause determination.

- Section XVIII, para. 1.2.2. The last portion of the paragraph was renumbered as para. 1.2.3 and titled "Joint Audits". In addition, requirements for external audits were strengthened.

- Section XVIII, para 2.3. The fifth bullet was modified to clarify nonconformance control requirements for surveillances.

- Appendix A. The term "Computer Code Validation" was changed to "Computer Model Validation" to correspond more accurately with the definition.

- Appendix A. The terms "Authentication" and "Validation" are new and were added to enhance understanding of QA Records

- Appendix A. The term "Q-List" was modified and the term Quality Activities List was added for consistency with Appendix I.

- Appendix A. The definition of "Corroborative Data" was revised for consistency with Appendix G and NUREG-1298.

- Appendix H, paragraph 1.0 was revised to clarify software QA requirements. Requirements for verification and/or validation of computer software were revised and relocated to paragraph 5.0. Paragraph 2.0 was revised to clarify applicability. Paragraphs 4.0, 4.1 and 4.1.2 were revised to clarify that flexibility exists for the selective application of software QA requirements. Editorial clarifications were made to Section 5.1, 5.2 and model validation approaches were enhanced. In Sections 6.1, 6.2 and 6.3, configuration management controls were revised and clarified. Section 7.0 was revised to accommodate participant software QA development documentation plans and Section 7.3 and 7.4 were clarified. Section 8.0, 8.1, 8.3 and 8.4 were also edited to improve review activities. In addition, editorial enhancements were made to paragraphs 11.0 and 12.0.

- Appendix I was revised for consistency with NUREG-1318 requirements.

- Appendix J, paragraphs 4.1 and 6.1 were revised for consistency with NUREG-1297.

- Appendix K is a new appendix which was added to establish requirements for the format and content of study plans. These requirements were extracted from the SCP management plan.

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LIST OF EFFECTIVE REVISIONS

Title	Revision No.	Effective Date
Signature Page	2	
Title Page	2	
Preface	2	
Table of Contents	2	
List of Effective Revisions	2	
Policy Statement	0	5/19/88
Introduction	2	
Section I - Organization	0	5/19/88
Section II - Quality Assurance Program	2	
Section III - Scientific Investigation and Design Control	2	
Section IV - Procurement Document Control	0	5/19/88
Section V - Instructions, Procedures, Plans, and Drawings	2	
Section VI - Document Control	2	
Section VII - Control of Purchased Items and Services	0	5/19/88
Section VIII - Identification and Control of Items	0	5/19/88
Section IX - Control of Processes	0	5/19/88
Section X - Inspection	0	5/19/88
Section XI - Test Control	1	8/26/88
Section XII - Control of Measuring and Test Equipment	2	
Section XIII - Handling, Shipping and Storage	0	5/19/88
Section XIV - Inspection, Test, and Operating Status	0	5/19/88

Section XV - Control of Nonconforming Items	1	
Section XVI - Corrective Action	0	5/19/88
Section XVII - Quality Assurance Records	0	5/19/88
Section XVIII - Audits	2	
Appendix A - Terms and Definitions	2	
Appendix B - Design Inputs	0	5/19/88
Appendix C - Requirements for Inspection and Test Personnel	0	5/19/88
Appendix D - Requirements for NDE Personnel	0	5/19/88
Appendix E - List of Typical QA Records	0	5/19/88
Appendix F - Requirements for Audit Personnel	0	5/19/88
Appendix G - Requirements for Qualification of Existing Data not Generated Under the Control of the NNWSI Project QA Plan	1	8/26/88
Appendix H - Requirements for Computer Software	1	
Appendix I - Requirements for Q-List	1	
Appendix J - Requirements for Peer Review	1	
Appendix K - Format and Content Requirements for SCP Study Plans	0	

POLICY

It is the policy of the U.S. Department of Energy, Nevada Operations Office (DOE/NV) that the achievement of quality in fulfilling the responsibilities for the NNWSI Project is essential to success. To meet this objective, we must establish effective networks of management plans and procedural controls and take the necessary actions to demonstrate to the public our ability to safely and efficiently handle and dispose of spent nuclear fuel and high-level radioactive waste. Concurrently, we must demonstrate compliance with legislative, regulatory, and DOE requirements for control and documentation of quality.

In order to meet our management responsibilities for achieving and assuring quality, the DOE/NV has established the Waste Management Project Office (WMPO) and delegated appropriate authority to the Project Manager, WMPO for the management and direction of the NNWSI Project. The Project Manager, WMPO has direct primary responsibility and accountability for the execution and implementation of the NNWSI Project in accordance with the NNWSI Project Plan, Project Charter, and Project Management Plan.

Consequently, the WMPO has developed this Quality Assurance Plan. Its requirements establish a framework for consistency in the continuing development of quality assurance plans and implementing procedures at all levels of the NNWSI Project.

Nick C. Aquilina
Manager, Nevada Operations Office

INTRODUCTION

1.0 OVERVIEW OF THE NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT

The NNWSI Project was established by the U.S. Department of Energy, Nevada Operations Office (DOE/NV) to evaluate planned and systematic actions to provide sufficient information to expand the public's confidence in the suitability of a geologic repository site and its subsystems and components for high-level radioactive waste isolation. The location of the potentially acceptable geologic repository site that is currently under evaluation is on and adjacent to the Nevada Test Site (NTS). Evaluation of the site includes all systems, structures, and components important to safety for the design, construction, and characterization of barriers important to high-level waste isolation and to related activities.

It is possible that the results of these DOE activities will support the U.S. Nuclear Regulatory Commission (NRC) licensing decisions and will assess risks to public radiological health and safety with regard to the geologic repository. Therefore, the establishment of quality assurance requirements is essential in order to specify the method of control for quality aspects of the work. The Quality Assurance Program applies to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto. These activities include: site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Figure 1 details the hierarchy of Quality Assurance (QA) criteria to be applied to the NNWSI Project. The QA requirements placed on the NNWSI Project are established from three main sources:

U.S. Nuclear Regulatory Commission (NRC)

- 10CFR60 Subpart G, Disposal of High Level Radioactive Wastes in Geologic Repositories - Quality Assurance
- 10CFR50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories (June, 1984)

U.S. Department of Energy (DOE)

- DOE 5700.6B (9/23/86), Quality Assurance
- NV 5700.6-6 (3/13/87), Quality Assurance

CRITERIA FOR QUALITY ASSURANCE

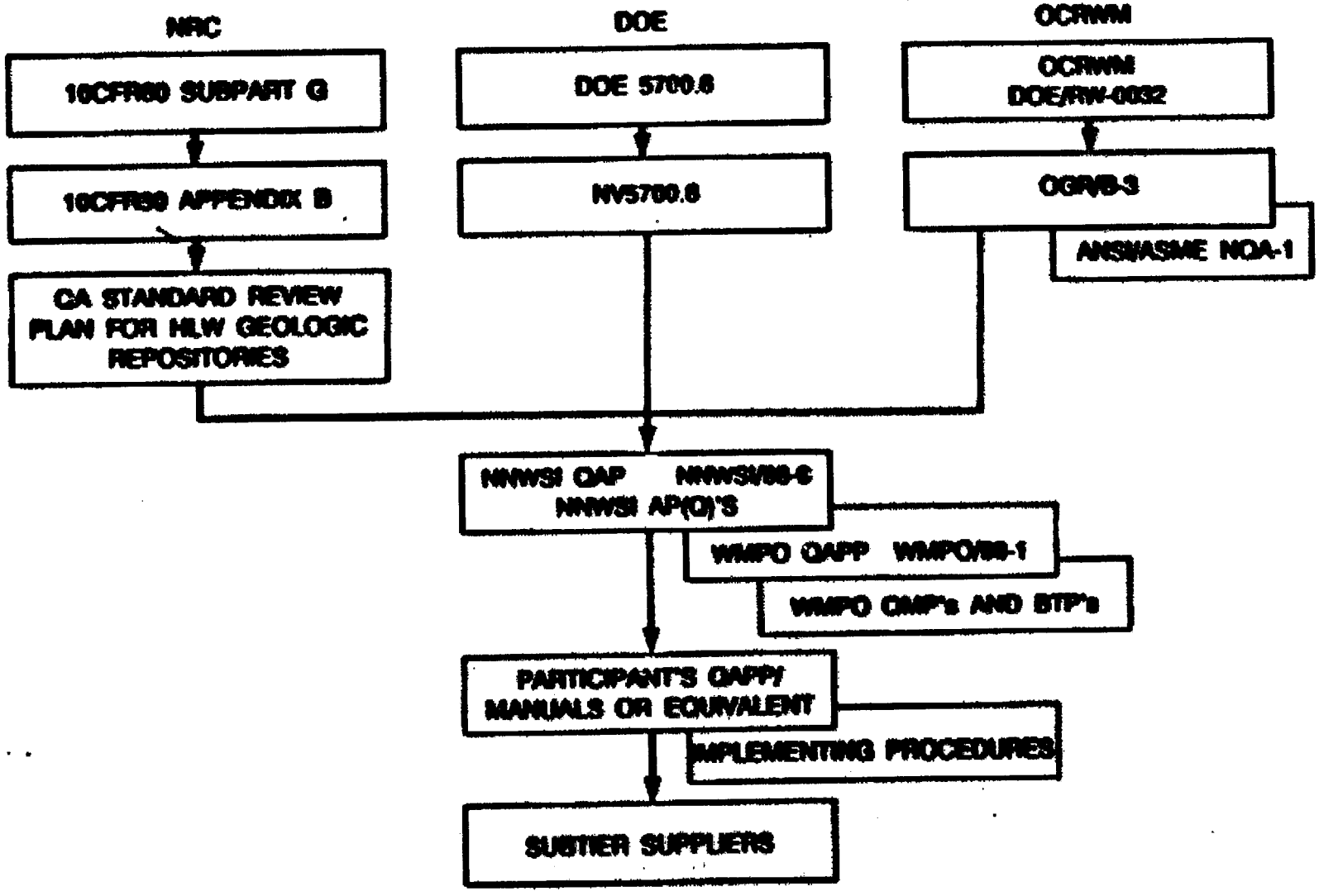


Figure 1

NNWSI PROJECT QA PLAN

N-QA-040
1/88

Office of Civilian Radioactive Waste Management (OCRWM)

- OCRWM Quality Assurance Management Policies and Requirements (October, 1985)
- OGR/B-3, OGR Quality Assurance Plan for High Level Radioactive Waste Repositories (August, 1986)
- ANSI/ASME NQA-1, American National Standard for Quality Assurance Program Requirements for Nuclear Facilities (ANSI/ASME NQA-1-1986)

The Waste Management Project Office (WMPO) has used the QA criteria from these documents, plus any additional criteria deemed necessary by the WMPO, to develop the NNWSI Quality Assurance Plan. The NNWSI Quality Assurance Plan is used by the WMPO to establish the QA requirements for the NNWSI Project Participants. A detailed description of the criteria applicable to each investigative phase of the Project is contained in individual Quality Assurance Program Plans (QAPPs) prepared by each organization that is responsible for directing or conducting an assigned task, or both.

The WMPO has been assigned responsibility for administering and coordinating Project activities. The WMPO requires each NNWSI Project participant to prepare and submit a QAPP that covers their task activities. All QAPPs prepared by the NNWSI Project participants shall meet the requirements set forth in this plan.

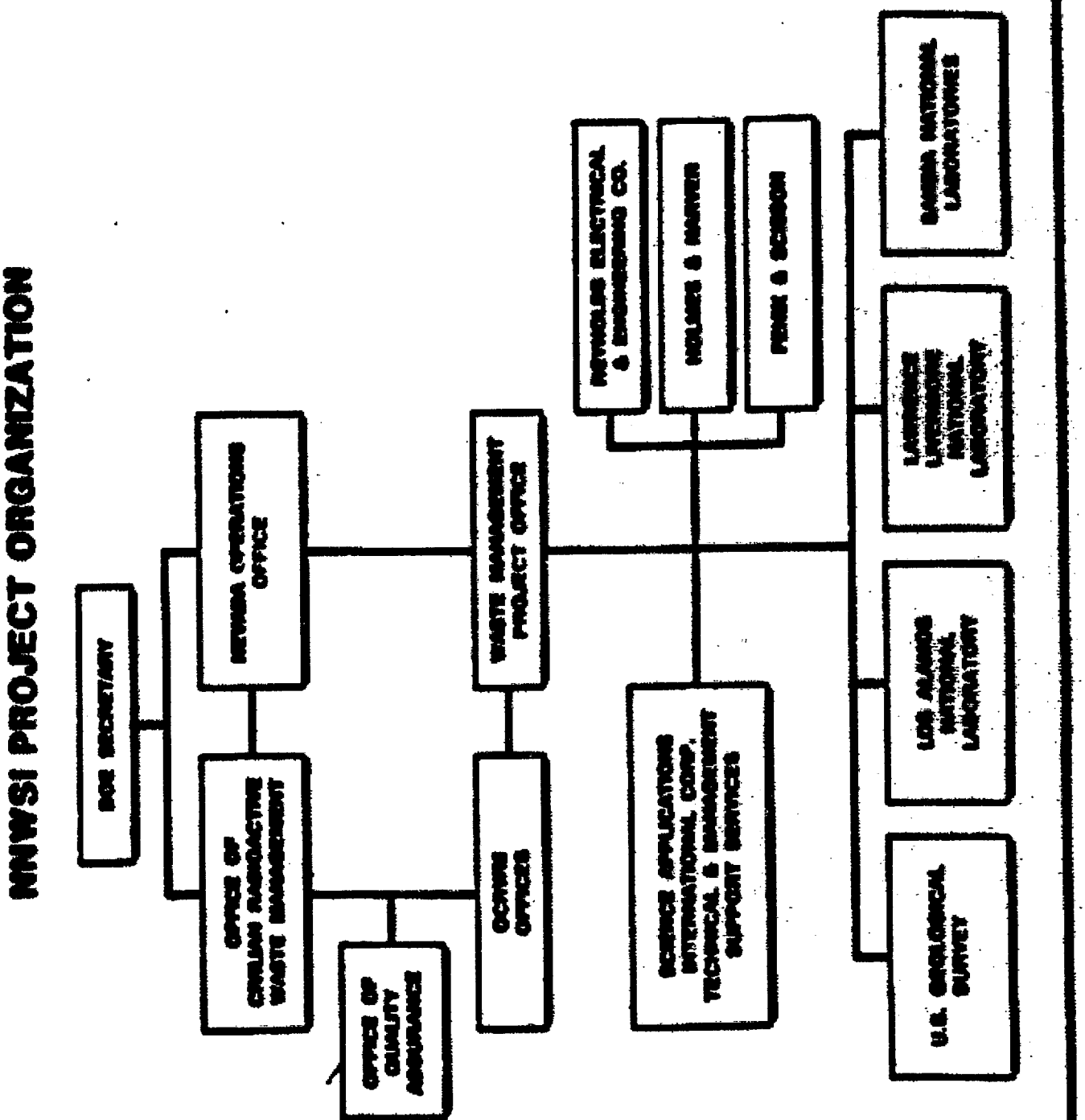
2.0 ORGANIZATION OF THE PROJECT WITH RESPECT TO QUALITY ASSURANCE

These paragraphs describe organizational responsibilities and interfaces with the Nevada Nuclear Waste Storage Investigations (NNWSI) Project with respect to Quality Assurance. The organization of the Project is shown in Figure 2. The NNWSI Project Work Breakdown Structure Dictionary (WBS) provides the technical and management responsibilities of each Participating Organization and Nevada Test Site (NTS) Support Contractor. A definitive description of the Quality Assurance (QA) responsibilities are contained in the Quality Assurance Program Plans (QAPPs) of each NNWSI Project participant. Specific organization requirements which must be addressed in the QAPPs of each NNWSI Project participant are contained in Section I of this document.

2.1 DEPARTMENT OF ENERGY (DOE)

The Secretary, U.S. Department of Energy Headquarters (DOE/HQ), was given the responsibility to carry out the Nuclear Waste Policy Act (NWPA) of 1982. This responsibility has been delegated by the DOE Secretary to the Office of Civilian Radioactive Waste Management (OCRWM) for the integration of QA and management policies and requirements for the overview of the activities performed by DOE field operations offices. The DOE/NV operations office has been delegated the responsibility for the implementation of the technical and QA activities of the NNWSI Project.

Figure 2


NNWSI PROJECT ORGANIZATION
DOE SECRETARY
NEVADA OPERATIONS OFFICE
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
WASTE MANAGEMENT PROJECT OFFICE
OCRWM OFFICES
RAYMOND ELECTRICAL & ENGINEERING CO.
HOLMES & NARVER
FENIX & SCISSON
SCIENCE APPLICATIONS INTERNATIONAL CORP. TECHNICAL & MANAGEMENT SUPPORT SERVICES
SANDIA NATIONAL LABORATORIES
LAWRENCE LIVERMORE NATIONAL LABORATORY
LOS ALAMOS NATIONAL LABORATORY
U.S. GEOLOGICAL SURVEY

2.2 DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

The U.S Department of Energy Headquarters (DOE/HQ), Office of Civilian Radioactive Waste Management, provides programmatic and policy guidance to the WMPO to assure that adequate QA and technical objectives of the program are achieved.

2.2.1 OCRWM OFFICES

The OCRWM is comprised of the following offices: Program Administration and Resources Management, Facilities Siting and Development, Systems Integration and Regulation, and External Relations and Policy. These OCRWM offices provide direction to WMPO for the implementation of the OCRWM program objectives.

2.2.2 OCRWM OFFICE OF QUALITY ASSURANCE

The OCRWM Office of Quality Assurance provides QA guidance and overview to the NNWSI Project by (1) review and approval of the NNWSI Quality Assurance Plan and the WMPO QAPP; (2) specifying applicable requirements which are contained in the OCRWM Quality Assurance Plan; and (3) performance of QA audits and surveillances of the WMPO. 2

2.3 DOE/NV OPERATIONS OFFICE

The DOE/NV Manager has the ultimate responsibility and accountability for the NNWSI Project in the Nevada Operations Office. The Waste Management Project Office (WMPO) has been established within the DOE/NV organization for the management of the NNWSI Project. The WMPO operates as a part of the DOE/NV under the programmatic direction of the DOE/HQ Office of Civilian Radioactive Waste Management (OCRWM). In matters of Department policy, DOE/NV works and cooperates with DOE/OCRWM in establishing a consistent QA approach for accomplishing the objectives of the Geologic Repository Program managed by the DOE/OCRWM.

2.4 WASTE MANAGEMENT PROJECT OFFICE (WMPO)

The WMPO has sole responsibility for authorization of work and management and technical direction of the activities of the Participating Organizations and NTS Support Contractors through the issuance of technical and programmatic guidance, technical integration of the Project, Project planning and documentation, and QA programmatic guidance. Technical adequacy of the work performed shall be determined via audits, design reviews, technical reviews, management assessments, etc., as appropriate. In addition, the WMPO is responsible for conducting the technical activities described under the responsibilities of the appropriate WMPO Branch Chief. An organizational chart depicting the WMPO organization is provided in Figure 3.

Figure 3

WMPO ORGANIZATION
WMPO PROJECT QUALITY MANAGER (PQM)
DOE/NV MANAGER
WASTE MANAGEMENT PROJECT OFFICE
PROJECT MANAGER
SYSTEMS & PROJECT CONTROL (S&PC) BRANCH CHIEF
STAFF PERSONNEL
TECHNOLOGY DEVELOPMENT & ENGINEERING (TD&E) BRANCH CHIEF
STAFF PERSONNEL
REGULATORY & SITE EVALUATION (R&SE) BRANCH CHIEF
STAFF PERSONNEL
MATRIX SUPPORT PERSONNEL
HEALTH PHYSICS & ENVIRONMENTAL DIVISION (HP&E) DIRECTOR
SAFETY & HEALTH DIVISION (S&HD) DIRECTOR
CONTRACTS & PROPERTY DIVISION (C&PD) DIRECTOR
DIRECT REPORTING
MATRIX REPORTING

The Project Manager, WMPO is responsible for the NNWSI Project management which encompasses: (1) planning and directing activities; (2) establishing goals and objectives, and assessing progress toward the attainment of those goals; (3) administration of procurement of materials and services; (4) preparation and issuance of technical and programmatic guidance; (5) organization and conduct of peer reviews; (6) compliance with laws, regulations, and DOE policies; and (7) other administrative duties. In addition, the Project Manager, WMPO is responsible to ensure implementation of the WMPO QA Program for the conduct of WMPO quality related activities and the implementation of corrective actions.

The technical responsibilities of the WMPO focus in three areas, each under the direction of a Branch Chief. Each Branch Chief is responsible for implementing the QA program in his/her area of responsibility. The QA responsibilities of the WMPO are accomplished through the efforts of the WMPO Project Quality Manager (PQM) and his organization. The overall responsibility to assure that quality assurance control and documentation is maintained throughout the Project is retained by the WMPO.

The WMPO utilizes a matrix management organizational concept to support NNWSI Project activities. The administrative responsibility for DOE/NV personnel supporting the NNWSI Project remains with the respective DOE/NV organizational element, while the functional responsibility of DOE/NV personnel performing NNWSI Project activities is to the WMPO. Personnel from Participating Organizations and NTS Support Contractors may also be matrixed to the WMPO. The organization of WMPO with respect to Quality Assurance is shown in Figure 3 as one organization with the major DOE/NV divisions that provide matrix support staff. The DOE/NV staff assists the Project Manager, WMPO by providing reviews, recommendations, and expertise on various aspects of the NNWSI Project in terms of their respective responsibilities as established in accordance with the matrix management approach. Matrix support personnel work under the implementing procedures of the WMPO QAPP.

SAIC/T&MSS provides broad technical, operational, and managerial support for NNWSI Project activities and performs these functions in accordance with the requirements of the WMPO QA Program Plan. SAIC/T&MSS efforts involve both the direct provision of technical, scientific, and institutional expertise and the management and integration of support provided by all Project participants in connection with planning, design, field investigations, laboratory work, construction, and regulatory licensing and institutional activities related to the NNWSI Project. SAIC/T&MSS assists the WMPO in such areas as (1) the identification and analysis of, and compliance with, applicable statutory, regulatory, and program requirements, (2) the development and execution of project management plans and strategies, (3) the monitoring and coordination of work performed by project participants, including the review of their work for completeness, technical sufficiency, and compliance with project requirements, (4) the preparation of assigned management, technical, and scientific reports and studies, (5) the presentation to the public, the program office, and affected federal, state, and other agencies of project positions, plans, and other project related information, (6) the execution, on an assigned basis, of any of the activities specified by the OCRWM approved work breakdown structure, and (7) quality assurance.

2.5 REGULATORY AND SITE EVALUATION BRANCH

The Regulatory and Site Evaluation Branch is responsible for (1) Site Characterization in field and laboratory activities (including geology, hydrology, geochemistry, geophysics, drilling, seismology, radiation safety, climate, meteorology, in-site testing in the Exploratory Shaft Facility (ESF), and sample management facilities); (2) performance assessment (including code development, analysis, and radionuclide release calculations); (3) Nuclear Regulatory Commission (NRC) interactions (including site visits, work shops, Appendix 7 meetings, and reviews of regulations); (4) preparation of project documents required by the Nuclear Waste Policy Act and the NRC (including preparation of the Site Characterization Plan (SCP), SCP updates, study plans, technical input to the Environmental Impact Statement (EIS) and license application, project position papers, and prelicensing topical reports for use in the license application to NRC); (5) site investigation documents - evaluation and approval of reports that contain data and interpretations from site characterization; and (6) review and approval of NNWSI Project quality related documents as defined in WMPO QMP-06-03, "Document Review/Acceptance/ Approval."

2.6 TECHNOLOGY DEVELOPMENT AND ENGINEERING BRANCH

The Technology Development and Engineering Branch is responsible for (1) systems description, analysis, and integration; (2) waste package design and development; (3) design, construction and operation of major test facilities; (4) operational safety; (5) repository engineering including conceptual design, rock mechanics, and borehole sealing; (6) instrument and equipment development; (7) exploratory shaft design, construction, and operation; (8) engineering and technical support for Project plans, reports, and presentations; and (9) review and approval of NNWSI Project quality related documents as defined in WMPO implementing procedures.

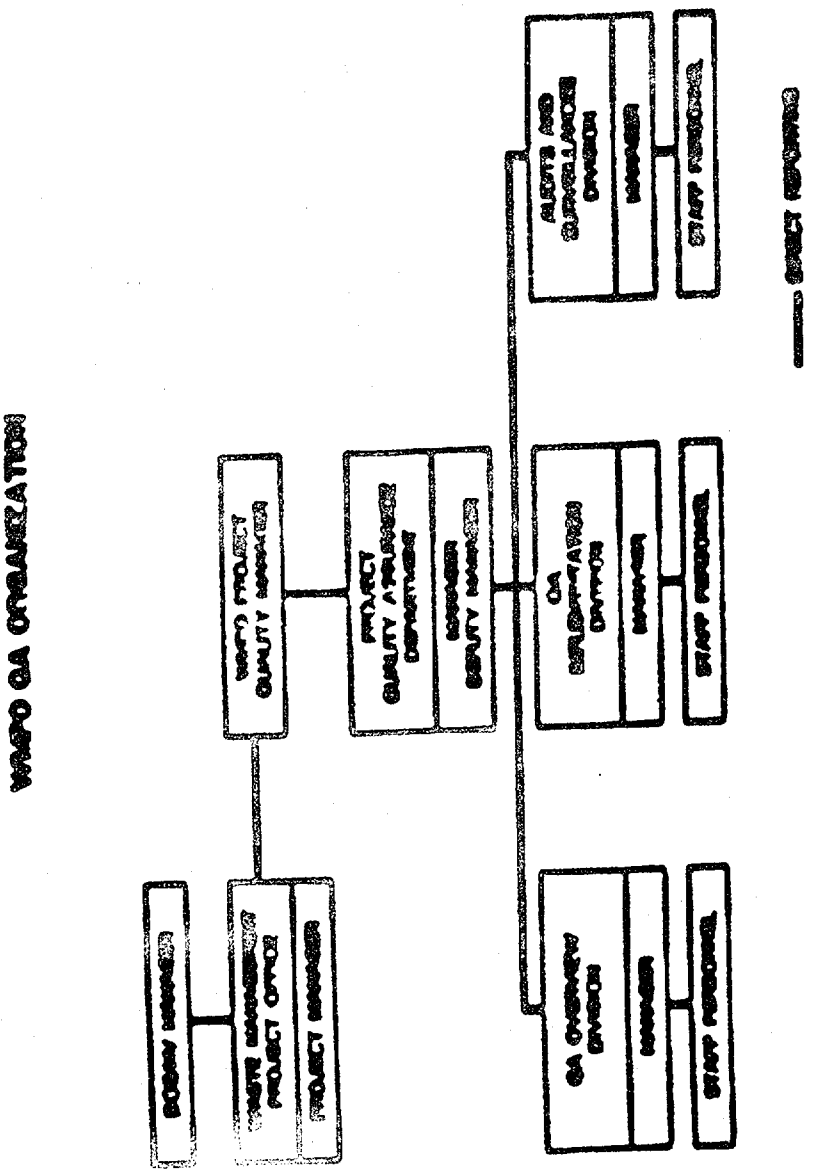
2.7 SYSTEMS AND PROJECT CONTROL BRANCH

The Systems and Project Control Branch is responsible for (1) administration and management support to integrate and control the NNWSI Project including preparation of networks, monitoring milestones, and overseeing issuance of Project documentation, (2) records management/information management system; (3) quality assurance records administration; (4) configuration management; (5) transportation; (6) socioeconomics; (7) institutional liaison; (8) Project training; (9) review and approval of NNWSI Project quality related documents as defined in WMPO implementing procedures; and (10) environmental analysis and support.

2.8 PROJECT QUALITY MANAGER (PQM)

The WMPO PQM is responsible for directing and managing the overall NNWSI Project QA Program and has appropriate organizational position,

Figure 4


WMPO QA ORGANIZATION
DIRECT REPORTING
AUDITS AND SURVEILLANCE DIVISION
MANAGER
STAFF PERSONNEL
WMPO PROJECT QUALITY MANAGER
PROJECT QUALITY ASSURANCE DEPARTMENT
SUPERVISOR QUALITY MANAGER
QA SURVEILLANCE DIVISION
MANAGER
STAFF PERSONNEL
QA OVERVIEW DIVISION
MANAGER
STAFF PERSONNEL
SUBCONTRACTOR
ONSITE SUPERVISORY PROJECT OFFICE
PROJECT MANAGER

2.10 SAFETY AND HEALTH DIVISION (S&HD)

Upon the request of WMPO, the Safety and Health Division (S&HD) may provide matrix support personnel to WMPO and are responsible for review of procedures, facility designs, and operations plans applicable to the occupational health and industrial and fire safety of site workers and facilities. The S&HD acts on requests for support submitted by participating organizations through WMPO and provides document reviews, advice, and assistance to the WMPO.

2.11 CONTRACTS AND PROPERTY DIVISION (CPD)

Upon the request of WMPO, the Contracts and Property Division (CPD) may provide matrix support personnel to the WMPO and are responsible for preparing and negotiating contracts and other agreements with the national laboratories and other federal agencies (except the NRC for which DOE/HQ is responsible) on behalf of the DOE/NV in support of the NNWSI Project. The CPD acts on requests for support submitted by WMPO and provides procurement package reviews, advice, and assistance to WMPO.

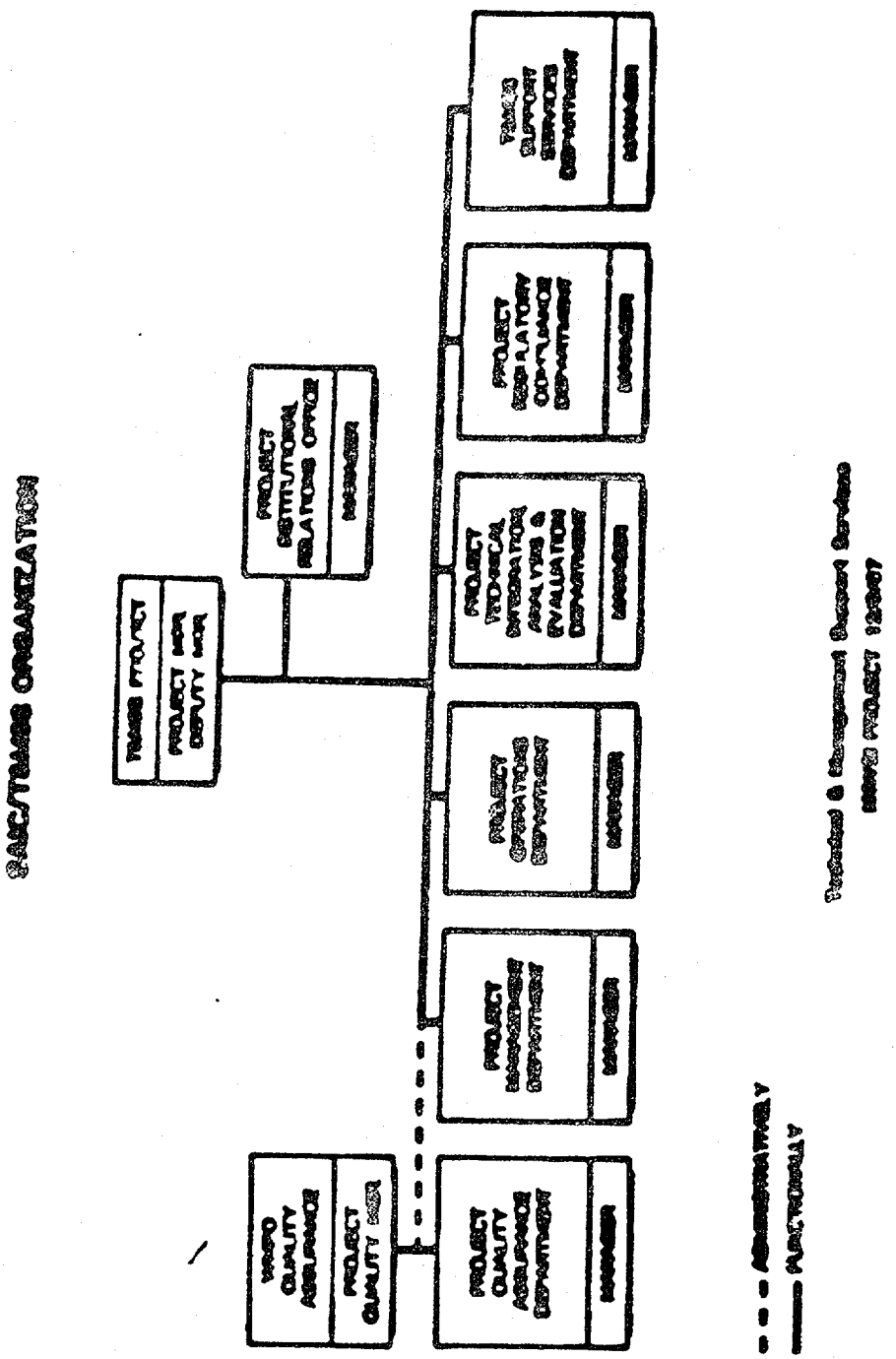
3.0 SAIC/T&MSS ORGANIZATION

The SAIC/T&MSS organization is comprised of six major operating departments and a Project Institutional Relations Office reporting to the Project Manager. In addition, the Project QA Department reports administratively to the Project Manager (T&MSS) and functionally to the WMPO Project Quality Manager to assure independence. The following section describes the organization, relationships, responsibilities, and authorities of the T&MSS organization in its role as the integrating contractor for the WMPO in support of the NNWSI Project. An organization chart depicting the SAIC/T&MSS organization down to the department level is shown in Figure 5.

3.1 The Project Manager (T&MSS) reports directly to the Project Manager, WMPO. He has authority over all T&MSS personnel assigned to the NNWSI Project and is responsible for the management and performance of T&MSS activities in support of the WMPO.

The Project Manager (T&MSS) is responsible to ensure implementation of the WMPO QAPP and its implementing procedures for the conduct of all T&MSS quality related activities. He is also responsible for meeting the requirements of tasks performed by T&MSS for the WMPO. These requirements include staffing, control of costs, meeting schedules, and approval of deliverables. The Project Manager (T&MSS) is the primary contact with the WMPO and the primary spokesman for T&MSS. He is also responsible for the implementation of corrective actions in cases of deficiencies in the quality of T&MSS activities or items, as documented in audits and surveillances by WMPO QA or other organizations.

Figure 5


RASC/TRW/M&O ORGANIZATION
PROJECT INSTITUTIONAL RELATIONS OFFICE
PROJECT TECHNICAL INTEGRATION ANALYSIS & EVALUATION DEPARTMENT
PROJECT OPERATIONS DEPARTMENT
PROJECT QUALITY ASSURANCE DEPARTMENT
TRW/M&O QUALITY ASSURANCE
PROJECT QUALITY MGR
MANAGER
ADMINISTRATIVELY
AUTHORITATIVE

3.2 The Deputy Manger (T&MSS) reports to the Project Manager (T&MSS) and is delegated to act for the Project Manager (T&MSS) in his absence. He is responsible to assist the Project Manager (T&MSS) in the implementation of the NNPO QAPP and its implementing procedures thru coordination of the activities of the six SAIC/T&MSS Department Managers in the performance of their respective functions.

3.3 Project Management Department

The Project Management Department provides (1) overall management and integration for NNWSI Project management and Project Control WBS elements, management of T&MSS and Project plans and procedures, training of staff in both Project and T&MSS procedures and technical subject matter, and quick response support to client requests (e.g., briefings to outside organizations and DOE Headquarters); (2) management analysis and evaluation, including performance evaluation/reporting and performance measurement; (3) information management (including system operations, information integration, information systems development, and technical data management); and (4) Project configuration management support.

3.4 Project Operations Department

The Project Operations Department provides (1) engineering documentation and design reviews specifically related to waste package, repository, and exploratory shaft facility designs; (2) geotechnical services, including operation of the NNWSI Project Sample Management Facility and various field studies; (3) regional studies, including transportation, land access, and socioeconomics; and (4) environmental programs, including environmental and radiological field programs.

3.5 Project Technical Integration, Analysis, and Evaluation Department

The Project Technical Integration, Analysis, and Evaluation Department provides (1) technical integration across the NNWSI Project in systems, waste package, site, repository, regulatory, and institutional, exploratory shaft facility, and test facilities; and (2) technical evaluation and analysis of the site characterization plans and other technical documents.

3.6 Project Regulatory Compliance Department

The Project Regulatory Compliance Department provides (1) nuclear regulatory compliance support, including regulatory interaction and planning and regulatory review; and (2) environmental regulatory compliance support, including permitting and planning.

3.7 Project Quality Assurance Department

The Project Quality Assurance Department provides (1) quality assurance overview; (2) quality assurance implementation support, including development of plans and procedures; and (3) audits and surveillances of all Project activities. The department's functions are further described in paragraph 2.8.1 of this section.

3.8 T&MSS Support Services Department

The T&MSS Support Services Department provides (1) T&MSS administrative support, including personnel services and support to and coordination with sector contractor administration; (2) computer services, including software development and support, operations, and systems support; and (3) publication services, including technical editing, word processing, and graphics.

3.9 Project Institutional Relations Office

The Project Institutional Relations Office provides support in DOE interactions with the State of Nevada and other affected public parties.

4.0 PARTICIPATING ORGANIZATIONS AND NTS SUPPORT CONTRACTORS

This section identifies the major organizations participating in the Project, the designated functions of these organizations and their relationship with the WMPO. Participating organizations and NTS support contractors are responsible to the WMPO for technical activities assigned to them as specified in the NNWSI Project WBS Dictionary and Project specific technical plans. The technical activities are to be accomplished in accordance with the QA requirements in the NNWSI Project QAP, NNWSI/88-9, (formerly NVO-196-17) and their respective QAPPs when approved by the WMPO.

4.1 NTS Support Contractors

4.1.1 Fenix and Scisson, Inc. (F&S)

Fenix and Scission, Inc. is the Exploratory Shaft Facility (ESF) architect-engineer (A-E) for drilling and mining for the NNWSI Project. Responsibilities also include field surveillance and inspection of drilling and mining, and subsurface facilities construction and testing.

4.1.2 Holmes and Narver, Inc. (H&N)

Holmes and Narver, Inc. is the ESF A-E responsible for the design of the underground support systems and the above-ground facilities. Responsibilities include field surveillance and inspection of facilities construction. Additionally, they provide Material Test Laboratory support, nondestructive examination services, and field surveying services, microfilming, and archival storage of NNWSI Project records.

4.1.3 Reynolds Electric and Engineering Company (REECo)

Reynolds Electric and Engineering Company is the prime support contractor providing support for subsurface and surface construction, drilling, and mining. REECo assists in the operation and maintenance of the site facilities and provides procurement and logistical activities for the NNWSI Project when requested.

4.2 PARTICIPATING ORGANIZATIONS

4.2.1 Lawrence Livermore National Laboratory (LLNL)

Lawrence Livermore National Laboratory is responsible for the development of the waste package for emplacement in tuff, which includes the definition of the package environment, material development and testing, package design, performance analysis, and testing; and provides assistance to other NNWSI Project participants in areas of specialized expertise.

4.2.2 Los Alamos National Laboratory (LANL)

Los Alamos National Laboratory is responsible for nuclide migration, geochemistry, mineralogy, and petrology studies. Los Alamos acts as the lead technical organization for the coordination and scheduling of the ES testing program. Los Alamos also provides assistance to other NNWSI Project participants in areas of specialized expertise.

4.2.3 Sandia National Laboratories (SNL)

Sandia National Laboratories is responsible for (1) repository systems development; (2) data management and analysis; (3) systems performance assessment of the repository; (4) conceptual design of the repository; (5) determining the thermal and mechanical properties of the host rock; (6) repository sealing performance requirements, materials, evaluation, design, and testing; and provides assistance to other NNWSI Project participants in areas of specialized expertise.

4.2.4 United States Geological Survey (USGS)

The United States Geological Survey is responsible for (1) site characterization of geology, hydrology, tectonism, volcanism, and seismicity; (2) acts as lead technical participant for the site characterization drilling activities; and (3) provides assistance to other NNWSI Project participants in areas of specialized expertise.

DRAFT

SECTION II

QUALITY ASSURANCE PROGRAM

1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM

The Quality Assurance (QA) Program for the NNWSI Project consists of the NNWSI Quality Assurance Plan (QAP), the QA Program Plans of the Waste Management Project Office (WMPO), the Participating Organizations, and the Nevada Test Site (NTS) Support Contractors, and the QA and technical procedures required to implement these documents. The NNWSI Project Office will submit this QAP and the WMPO QAPP to the OCRWM Director, Office of Quality Assurance for approval. Pending receipt of this approval, QA plans may be issued by WMPO for interim use. When any QA plan is issued for interim use, the transmittal record shall be appropriately marked to indicate that it is for interim use. Final QA plans will include a signature block for approval by the Director, Office of Quality Assurance.

Each NNWSI Project Participant shall develop a Quality Assurance Program Plan which shall provide the description of the organization's QA program and indicate the commitment to the applicable NNWSI Project QA requirements given herein. Each Quality Assurance Program Plan (QAPP) shall include consideration of the technical aspects of the activities affecting quality and shall be generated by the respective QA organization with assistance from the technical staff. The QAPP shall provide instruction to implement and apply the QA requirements to the technical activities of the NNWSI Project. It shall be planned, implemented, and maintained in accordance with this document and be consistent with and address all of the applicable requirements of this NNWSI QA Plan. Management above or outside of the QA organization shall regularly receive information as to the scope, status, adequacy, compliance, etc. of the QA Program. Management shall perform readiness reviews, as deemed appropriate. Readiness reviews shall apply to major scheduled/planned activities which could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified prior to starting a major activity.

The hierarchy of criteria applicable to the Project are shown in Figure 1 of the Introduction of this document. With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in that Figure and this QAP exist, the requirements of this document shall prevail.

1.1 QA CRITERIA

The QA Criteria and specific requirements associated with these criteria have been adapted to the NNWSI Project activities through this QA plan and shall be addressed in the QAPPs of the WMPO, the Participating Organizations, and NTS Support Contractors. When a specific criteria is not applicable to an organization's activities, it shall be noted in the QAPP and recorded on the checklist required in paragraph 1.2 below with justification of its exception.

APPENDIX I

REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS AND ACTIVITIES SUBJECT TO QUALITY ASSURANCE REQUIREMENTS

1.0 GENERAL

This Appendix provides requirements for identification of structures, systems and components important to safety in the pre-closure phase and for identification of the barriers important to waste isolation in the post closure phase which are to be listed on the "Q-List"; and for identification of those major activities conducted during site characterization, construction, operation or closure that relate to natural barriers important to waste isolation and which are to be listed on the Quality Activities List.

2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste. In order to obtain a license for receipt and possession of radioactive material at the geologic repository, it must be demonstrated that the repository system will function as required to protect health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and long-term isolation of waste following permanent closure of the geologic repository. The QA Level I requirements of this QA Plan specify the QA program for these items and related activities important to safety and/or waste isolation to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

2.1 QUALITY ASSURANCE CRITERIA FOR THE Q-LIST AND QUALITY ACTIVITIES LIST

The QA Level I requirements of this QA Plan apply to items and activities important to safety and/or waste isolation. As derived from 10 CFR Part 60 (60.152), this QA program is based on the 18 criteria of 10 CFR Part 50 Appendix B. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria are supplemented as necessary to meet the specific requirements of the repository program. In addition to the QA Level I requirements of this QA Plan, items important to safety and waste isolation are subject to the design criteria of 10 CFR 60.131(b) and 60.135 respectively.

2.2 CRITERIA FOR NON-Q-LIST ITEMS

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health

1.2 CONTENTS OF THE QAPP

The Quality Assurance Program of each organization shall consist of the QAPP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. The control shall be consistent with the importance of the activity. These procedures shall be developed by qualified personnel and be reviewed and approved by the cognizant QA organization prior to implementation to assure that they meet all the requirements of their QAPP.

The QAPP of each Participating Organization and NTS Support Contractor shall be submitted to the WMPO for review prior to implementation and shall include a checklist based on this NNWSI QAP which identifies how and where each requirement of this document is addressed. The WMPO is also required to complete a checklist based on NNWSI/88-9 (formerly NVO-196-17) for the preparation of the WMPO QAPP. The QAPP of each Project Participating Organization and NTS Support Contractor shall be reviewed, comments resolved, and the document approved by the WMPO within a timely manner.

1.3 QAPP VERIFICATION

Assurance that the QA requirements have been adequately addressed and effectively implemented will be provided by the WMPO with support from the SAIC/T&MSS Project QA Department during the review and approval of each organization's QAPP, monitoring and surveillance operations, and audits of activities. The Participating Organizations' and NTS Support Contractors' management shall also monitor their respective QAPPs through internal audits to assess the adequacy of their program and assure its effective implementation.

1.4 USE OF DATA NOT GENERATED UNDER QA CONTROLS

The QA program for the NNWSI Project provides for the acceptance of existing data for use in licensing activities that were not generated under the controls of a QA Program which meets the requirements of 10 CFR 60, Subpart G. Specific methods for acceptance of this information are contained in NNWSI Project Administrative Procedure 5.9Q. This procedure shall meet the requirements of NUREG - 1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories" (February, 1988). These requirements are contained in Appendix G to this QA Plan. Once accepted, this existing data is classified as "primary data" for licensing purposes.

1.5 METHODOLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST

The WMPO shall prepare the appropriate NNWSI AP or APs for determining the items and activities to be placed on the Project Q-List and Quality Activities List. ~~This~~ procedure shall meet the requirements of NUREG - 1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (April, 1988). These requirements are contained in Appendix I to this QA Plan. ~~This procedure shall describe the Probabilistic Risk Assessment (PRA) techniques and performance allocation methods used for identifying Q listed items and activities.~~

1.6 APPROACH TO QA

The NNWSI Project uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation and those that do not. The approach is designed to ensure that each item or activity is assigned a QA level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. The Participating Organizations or WMPO shall identify the appropriate quality assurance levels for all items and activities that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Once assigned, the QA level for a particular item or activity shall be applied by all NNWSI Project participants involved in the activity.

1.7 APPLICATION OF QA

A QAPP that complies with the requirements of this document, NNWSI/88-9 (formerly NVO-196-17), shall be established by each NNWSI Participant at the earliest practicable time consistent with the schedule for accomplishing the activities. Each QAPP shall assure that procedures required to implement the requirements of this document are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official. The QAPP shall be applied throughout the life of the NNWSI Project in accordance with the established policies, procedures, and instructions. The QAPP shall apply to all items and activities affecting quality. It also shall identify the major organizations participating in the project and the designated functions of these organizations. The QAPP shall provide control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance.. The activities that affect quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the

activity, and assurance that all prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. The program shall provide for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

The WMPO shall regularly assess the status and adequacy of the QA Programs of the Participating Organizations and NTS Support Contractors by means of overview, surveillance, and audit activities.

2.0 APPLICATION OF GRADED QUALITY ASSURANCE

2.1 SCOPE

2.1.1 EXTENT OF APPLICATION

The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. The preparation of administrative and management planning documents shall not require QA level assignments, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA level assignments. The WMPO shall develop a Project administrative procedure for the application of graded QA. The procedure shall be in consonance with the QA requirements specified herein. It may be necessary to exempt certain NNWSI items and activities from QA Level assignment. Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions shall be approved by the WMPO PQM.

2.1.2 PURPOSE OF A GRADED QA PROGRAM

The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Repository Program consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of QA applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY

This approach involves (1) identifying those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses, or both, and (2) ensuring that these items and activities are covered by a commensurate QA program. Alternatively, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon the delivery of the item. Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.

2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION

The graded approach set forth here provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.

2.2 REQUIREMENTS

The requirements specified in this section are to be used to apply the graded quality philosophy to all NNWSI Project items and activities.

2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

The appropriate Quality Assurance Level for any item or activity shall be determined by the application of decision criteria as provided by the NNWSI Administrative Procedures. The basis for the selection of the Quality Assurance Level and assigned QA requirements shall be documented. The assigned Quality Assurance Levels and QA requirements must be submitted to the WMPO for review, resolution of comments, and approval prior to implementation or use. This review and approval shall be performed by the WMPO PQM and appropriate WMPO Branch Chiefs.

2.2.2 SELECTION OF SPECIFIC QA LEVELS

This approach incorporates three quality assurance levels (QA level) of which one will be assigned to each technical task that affects the quality of the NNWSI Project. The definition, application, and assignment to each of the three QA levels are described in the following discussion.

2.2.2.1 QA Level I - are those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public.

items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

2.2.2.2 QA Level II - are those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and WMPO concerns, and the environment.

2.2.2.3 QA Level III - are those activities and items not classified as QA Levels I or II.

2.2.3 APPLICATION OF LEVELS

2.2.3.1 QA LEVEL I

QA Level I is the most stringent level of quality assurance. It is to be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. QA Level I activities which are on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard.

To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety as well as long term isolation as per the following:

- Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.

- Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. This data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance.

- Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.

- Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.

- Where items and activities that, having failed, could cause a failure of a QA level I item, or irretrievable loss of QA level I data.

- The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationalships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.

2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to the NNWSI Project activities, and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled.

Therefore, Quality Assurance Level II must be applied to activities and items as follows:

- Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.

- Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.

- Where items and activities could affect the retrievability of waste up to the time of repository closure.

- Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.

- The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, shall be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.

- Where items and activities that, having failed, could result in a major cost overrun.

- Where items and activities that, if failed, could result in a major schedule slippage.

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with NNWSI AP 5.9Q "Acceptance of Data and Data Interpretations Not Developed Under the NNWSI Project QA Program."

2.2.3.3 QA LEVEL III

QA Level III is the least stringent level of Quality Assurance. Level III Quality Assurance items and activities are such that they have no major function in the characterization of the site and design of the repository, but they require good practices for the intended use. Design phases which are purely preliminary and are conducted to define the range of alternatives/ methods/equipment which are felt to be worthy of more detailed study shall be assigned a QA level of III prior to execution. Those activities controlled in accordance with a Quality Assurance Level III program cannot subsequently be used to directly support Quality Assurance Level I activities.

In some cases, data or data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the NNWSI Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.

2.2.4 GENERAL

The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by the organizations participating in the NNWSI Project.

3.0 QA ACTIVITIES

3.1 OVERVIEW

Each NNWSI Project Participant shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. Overview is to include the following as appropriate:

- The review and approval of QAPPs.
- Surveillance of activities affecting quality to verify compliance with requirements.
- Performance of quality audits to verify the adequacy and compliance of QA programs.

3.2 REVIEW AND APPROVAL OF QA PROGRAMS

Procedures are to be established by each NNWSI Project Participant for the review of QA program documentation of those organizations under their purview for adequacy, completeness and relevance.

The procedures shall identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action. Reviews of QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

4.0 MANAGEMENT ASSESSMENT

4.1 FREQUENCY OF MANAGEMENT ASSESSMENTS

Management assessments are to be conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) the adequacy of resources and personnel provided to the QA program. Management is to verify that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program.

4.2 PERFORMANCE OF MANAGEMENT ASSESSMENTS

Management assessments are to be performed by the WMPO and each NNWSI Project Participant. Each organization is to develop its internal procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are to be provided to the Project Manager, WMPO and the WMPO PQM. The Project Manager, WMPO will make appropriate submittals of management assessment reports to OCRWM. Management above or outside the QA organization shall be responsible for the management assessment activity.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 ESTABLISHMENT OF REQUIREMENTS

All NNWSI Project participants shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. The requirements shall establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) shall be certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.

5.1.1 POSITION DESCRIPTION

Minimum education and experience requirements shall be established and documented in position descriptions for each position involved in the performance of activities that affect quality.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience shall be verified. This verification shall be documented. The initial capabilities of an individual shall be based upon an evaluation of their education, experience, and training and compared to those established for the position. Evaluations shall be documented by managers or supervisors responsible for the activities to be performed.

5.1.3 INDOCTRINATION

Prior to assigning personnel to perform activities affecting quality, they shall be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.

- QAPP's
- Implementing Procedures and Work Instructions (applicable to the individual's responsibilities).
- Regulations
- Project level Documents

5.1.4 TRAINING

Prior to assigning personnel to perform quality affecting activities training, if needed, shall be conducted to gain the required proficiency. The training (in-depth instruction) shall include the principles, techniques, and requirements of the activity. Such in-depth instruction may be internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.

5.1.5 PROFICIENCY EVALUATION

After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality shall be evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations. Proficiency evaluations shall be performed by managers or supervisors who have responsibility for the activities being performed or verified.

5.1.6 RECORDS

Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations shall be retained as lifetime QA records. These records shall include, as a minimum, the items listed below.

5.1.6.1 Personnel Qualification Evaluation Records

Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.

5.1.6.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.

5.1.6.3 Training Records

Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.

5.1.6.4 Proficiency Evaluation Records

Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

SECTION III

SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

1.0 SCIENTIFIC INVESTIGATION CONTROL

1.1 PREPARATION OF PLANS

1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Prior to the start of any scientific investigation, the responsible Principal Investigator (PI) shall develop a scientific investigation planning document for that investigation. Scientific investigations categorized as site characterization activities as defined in the Nuclear Waste Policy Act (as amended) shall utilize study plans as the scientific investigation planning document. The WMPO shall conduct a technical, QA, and management review of scientific investigation planning documents and approve the document prior to implementation. Study plans shall also be reviewed and approved by OCRWM prior to implementation. Such planning documents shall contain or shall reference the following:

1.1.1.1 Description of Work to be Performed

A description of the work to be performed in the scientific investigation and the proposed methodology for accomplishing the work including a discussion of the overall purpose for the work shall be provided in the scientific investigation planning document. References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items, for which the work is to be performed shall also be provided. This discussion shall identify all of the factors and concerns that are important for the planning or the performance of the scientific investigation including identification, explanation, and justification for areas where scientific notebooks are to be used.

1.1.1.2 Description of previous work

A description of any previous work which will be used in support of the scientific investigation, including the identification of the Quality Assurance Levels, or Quality Assurance (QA) controls, under which that previous work was performed. Note: This requirement does not apply to study plans.

1.1.2 PLANNING DOCUMENTS

The scientific investigation planning document shall contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. For Site Characterization activities, the purpose and key milestones of study plans is described in the SCP. The format and content of study plans shall meet the requirements of Appendix K of this QA Plan.

1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a scientific investigation planning document, as specified in Paragraph 1.1.1 of this section has been developed, the Quality Assurance Levels for all of the items and activities which are associated with that work, may be assigned. It may be necessary in some cases to assign Quality Assurance Levels to the items and activities within a plan that was prepared earlier.

Therefore, the Quality Assurance Level assignments are not a part of the planning documents themselves, even though they would normally accompany those planning documents and go through the same review and approval process.

1.2.2 CONFORMANCE

Scientific investigation planning documents shall be prepared and Quality Assurance Levels shall be assigned in accordance with the methods specified in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Administrative Procedures Manual.

1.3 REVIEW AND APPROVAL PROCESS

1.3.1 RESPONSIBILITY

The responsible Participating Organization shall conduct a technical review of the scientific investigation planning document. This review shall be performed by any qualified individual(s) other than those who developed the original planning document. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the QA manager of the originating organization. The results of this technical review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and shall become a part of the QA records.

1.3.2 ~~WASTE~~ PROJECT OFFICE REVIEW
MANAGEMENT

The WMPO Project Quality Manager and the appropriate WMPO Branch Chief shall review and approve the scientific investigation planning document prior to implementation. The WMPO PQM shall return the planning document to the responsible organization's TPO upon completion of the WMPO review and approval cycle. Study plans shall also be reviewed and approved by OCRWM prior to implementation.

1.3.3 PEER REVIEW

A peer review of the scientific investigation planning document will be conducted when deemed necessary by the WMPO.

1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS

1.4.1 INTERPRETATION/ANALYSIS DOCUMENTS

Interpretation/analysis shall be performed in a planned, controlled, and documented manner. Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.

1.4.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS

Documentation of interpretation/analysis shall include the following:

- Definition of the objective of the interpretation/analysis.
- Definition of input and their sources.
- A listing of applicable references.
- Results of literature searches or other background data
- Identification of assumptions
- Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.
- Signatures and dates of review and approval by appropriate personnel.

1.5 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subsection 3.0 and Appendix H of this QA Plan. The documentation and control measures shall be consistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

1.6 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES

1.6.1 DOCUMENTATION

There are two methods which can be used for the quality assurance, documentation and control of scientific work. These are the scientific notebook system and the technical implementing procedure system.

The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. Alternatively, the technical implementing procedure system will generally be used when qualified personnel are performing repetitive work which does not include the use of a high-degree of professional judgment or trial and error methods in the performance of the work. Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. Modifications may be made to these procedures as detailed in Para. 1.6.2. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work. → by the individual utilizing the procedure.

1.6.2 TECHNICAL IMPLEMENTING PROCEDURES

Detailed technical implementing procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. Such technical implementing procedures shall be developed in accordance with the requirements given in Section V of this document and reviewed for compliance with the requirements of this section of the QA Plan. Modifications may be made to the technical aspects of technical implementing procedures ~~with the approval of an appropriately qualified reviewer~~ if the change or modification is within the scope of the study plan or scientific investigation plan, ~~and can be repeated, providing it does not potentially impact the waste isolation capability of the site~~ or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer. not

Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.

Technical procedures utilized for scientific investigations shall provide for the following as appropriate:

- Requirements, objectives, methods and characteristics to be tested or observed.
- Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.
- Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the scientific investigation.

Could the investigation is not repeatable, the change could potentially impact the site isolation capability of the site

- Mandatory verification points.
- Acceptance and rejection criteria, including required levels of precision and accuracy (NOTE: "Accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)
- Methods of documenting or recording data and results, including precision and accuracy.
- Methods of data reduction.
- Provision for ensuring that prerequisites have been met.
- Special training or qualification requirements for personnel performing the scientific investigation.
- Personnel responsibilities.

1.6.2.1 Procedures shall be complete to the extent that another qualified individual may, at a later date, reproduce the results.

1.6.2.2 The potential sources of uncertainty and error in technical implementation procedures which must be controlled and measured to assure that scientific investigations are well controlled shall be identified. Parameters that need to be measured and/or controlled to minimize such uncertainties or error, and to ensure adequate control, shall be addressed explicitly in test procedures.

1.6.2.3 For instrumentation and/or equipment used in data collection consideration shall be given to whether failure or malfunction of the instrumentation during scientific investigation will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, procedures will include any special provisions for equipment/instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.

1.6.2.4 Any procedural deviations or nonconformances, encountered during activities shall be documented, reported, and evaluated for significance.

1.6.3 SCIENTIFIC NOTEBOOKS

Scientific notebooks along with other appropriate documents may be used to document scientific investigations and experiments. In such cases, this documentation shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI.

1.6.4 FORMAT FOR DOCUMENTATION

Documentation of scientific work i.e. experiments and research shall be performed using bound logbooks or notebooks to provide written record of the experiment or research.

1.6.4.1 Initial Entries

Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, shall be made | 2

- o Title of the experiment or research.
- o Name of the qualified individual or individuals performing the experiment or research.
- o Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work. | 2
- o Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- o Calibration requirements.
- o Dated signature of the individual or individuals making the initial entries.
- o Special training or qualification requirements.
- o Documentation of suitable and controlled environmental conditions, if applicable.
- o Required levels of precision and accuracy shall be identified. | 2
- o The potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are well controlled shall be identified. | 2

The initial entries described above are considered to be a "general" procedure and shall be entered into the scientific notebook prior to beginning an investigation. Modifications may be made by the individual performing the investigation. If the change or modification is not within the scope of the study plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.

→ or scientific investigation plan,

1.6.4.2 In-process Entries

Entries to be made during the experiment or research, daily or as appropriate, shall be sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and shall include:

- Date and name of individual making the entry.
- Provisions for assuring prerequisites have been met.
- Description of the experiment or research attempted, including detailed step-by-step process followed: either by reference to implementing procedure or by actual entry into the notebook.
- Description of any conditions which may adversely affect the results of the experiment or research.
- Identification of samples used and any additional equipment and materials not included as part of the initial entries prescribed by Paragraph 1.6.4.1 of this section.
- All data taken and a brief description of the results, to include notation of any unaccepted results.
- Any deviations from the planned experiment or research.
- Any interim conclusions reached, as appropriate.

1.6.4.3 Final Entries

The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

1.6.4.4 Final Results /

Final results and a summary of the outcome of the experiment or research shall be documented (e.g. in a technical report). This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Paragraph 1.6.4.1) were achieved. This documentation shall become part of the QA records of the activity.

1.7 CHANGE CONTROL

All changes in scientific investigation planning documents shall go through the same review and approval process as specified in Paragraph 1.3 of this section. The Participating Organization shall be responsible for evaluating the impacts of such changes on the associated Quality Assurance level assignments.

1.8 INTERFACE CONTROL

1.8.1 COORDINATION

Internal and external scientific investigation interfaces shall be identified and scientific investigation efforts shall be coordinated among and within Participating Organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within Participating Organizations for the review, approval, release, distribution and revision of documents involving scientific investigation interfaces. Interfaces within a participating organization shall be coordinated according to procedures developed by that participating organization. Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, shall be coordinated among Project participants in accordance with administrative procedures established by the NNPO. Interfaces between Participating Organizations and their suppliers shall be controlled in accordance with procedures established by the Participating Organization. Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatability. Such identification shall be clearly evident at the location at which the scientific investigation is being performed. Field investigations shall identify the location of the investigation.

1.8.2 TRANSMITTAL

The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces shall be documented.

1.9 VERIFICATION OF SCIENTIFIC INVESTIGATIONS

1.9.1 VERIFICATION PLANNING

Planning for verification activities shall be accomplished and documented via verification procedures, instructions, or checklists. Verification procedures, instructions, or checklists shall provide for following:

- o Identification of characteristics and activities to be verified.
- o A description of the method of verification.
- o Identification of the individuals or groups responsible for performing the verification.

- o Acceptance and rejection criteria.
- o Identification of required procedures, drawings, and specifications (including revisions).
- o Recording identification of the verifier and the results of the verification.

1.9.2 VERIFICATION HOLD POINTS

Mandatory verification hold-points shall be established as necessary. When such hold points are established, work may not proceed without the specific consent of the responsible representative. These hold points shall be indicated in appropriate documents controlling the activity. Consent to waive any specified hold point shall be documented before work can be continued beyond the designated hold point.

1.9.3 REPORTING INDEPENDENCE OF PERSONNEL

Verification shall be performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being verified. If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When these persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the verification activity.

1.10 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

1.10.1 LOGISTICS OF SURVEILLANCE

The QA organization within the Participating Organization shall perform surveillances of all scientific investigations, as may be deemed appropriate for the purposes and the complexity of the work. The QA surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel. The timing and the number of surveillances shall be determined by the QA surveillance team that is formed for this work. Surveillances will be performed in accordance with the requirements specified in Section XVIII of this document.

1.10.2 SURVEILLANCE TEAM

The technical member or members of the QA surveillance team shall be familiar with the plan for the scientific investigation.

1.11 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS

The Participating Organization shall have implementing procedures for the technical review and approval of the results of scientific investigations. These procedures shall include the WMPO in the review and approval cycle of the Final report.

1.12 CLOSE-OUT VERIFICATION

The Participating Organization shall perform a close-out verification upon the completion of any scientific investigation to assure that the QA records for that investigation are adequate and complete. This will be done because it may be a considerable period of time after the work is completed and before the investigation is used in the licensing process. Close-out verifications shall be performed by a team consisting of qualified technical personnel as well as QA personnel.

2.0 DESIGN CONTROL

2.1 GENERAL

2.1.1 DEFINITION

The design shall be defined, controlled, and verified. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. 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 implementing procedures for data collection and analyses and related information such as test results and analysis. The data collection activities result from scientific investigations and produce design input. 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.

It is the policy of the NNWSI Project that a completed or final design of a facility or item evolves from a sequential order of design activities (or phases) wherein each phase becomes more detailed in nature than the preceding phase. It is recognized that the number and length of design phases required to produce a completed or final design of any particular item or facility may vary, among organizations responsible for design, according to the timeliness and availability of pertinent information and the complexity of the item or facility. It is also recognized that all Project design activities, although undertaken by different organizations, which may progress at different rates, are dependent on and require an interface with each other to produce a unified facility design.

2.1.2 QUALITY ASSURANCE LEVEL ASSIGNMENT

All design phases shall be assigned a Quality Assurance Level prior to execution in accordance with the methods specified in the NNWSI Project Administrative Procedures Manual.

2.1.3 QUALIFICATION OF PERSONNEL

Personnel performing design work shall be indoctrinated, trained, and qualified in accordance with the requirements of Section II of this document. Instructions, procedures and drawings for design work shall be in accordance with the requirements of Section V of this document.

2.1.4 PEER REVIEW

For design activities including design output documents which involve use of untried or beyond state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review shall be conducted. The peer review shall meet the requirements of Paragraph 4.0 of this section of the NNWSI Project Quality Assurance Plan (QAP).

2.2 DESIGN INPUT

2.2.1 IDENTIFICATION, REVIEW AND APPROVAL OF INPUT

Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

2.2.2 CHANGES TO DESIGN INPUT

Changes to approved design input, including the reason for the changes, shall be identified, documented, approved, and controlled by the responsible design organization.

2.2.3 CONSIDERATIONS FOR DESIGN INPUT

Considerations for design inputs as they apply to specific items or systems are contained in Appendix B of this document.

2.3 DESIGN ANALYSIS

2.3.1 DESIGN ANALYSIS DOCUMENTS

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, design input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject (including structure, system, or component) originator, reviewer, and date.

2.3.2 DOCUMENTATION OF DESIGN ANALYSES

Documentation of design analysis shall include the following:

- Definition of the objective of the analysis.
- Definition of design input and their sources.
- A listing of applicable references.
- Results of literature searches or other background data.
- Identification of assumptions and indication of those which require verification as the design proceeds.
- Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.
- Signatures and dates of review and approval by appropriate personnel including QA Personnel. The purpose of the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.3.3 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subparagraph 3.0 and Appendix H of this QA Plan.

2.4 DESIGN VERIFICATION

2.4.1 IDENTIFICATION AND DOCUMENTATION

Design control measures shall be applied to verify the adequacy of design and verification shall be performed in a timely manner. The responsible design organization shall identify and document the verification method used, the results of the verification, and the verifier.

2.4.2 TIMING OF VERIFICATION

Verification of the adequacy of design shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities. In those cases, where this timing can not be met, the portion or portions of design which have not been verified shall be identified and controlled. In all cases, the verification shall be completed prior to relying on the component, system, or structure to perform its function.

2.4.3 EXTENT OF VERIFICATION

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with Paragraph 2.4 of this section, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

2.4.4 CHANGES TO VERIFIED DESIGNS

Changes to previously verified designs shall require verification including evaluation of the effects of those changes on the overall design.

2.4.5 PERSONNEL PERFORMING VERIFICATION

Design verification shall be performed in accordance with the requirements of Paragraph 2.4.6 of this Section by any competent, certified individual or individuals or certified group or groups other than those who performed the original design. This includes the following:

2.4.5.1 Individuals or groups from the originator's same organization.

2.4.5.2 Individuals or groups from other organizations contracted for this purpose.

2.4.5.3 The originator's supervisor providing all of the following requirements are met:

- The supervisor is the only individual in the organization competent to perform verification.
- The supervisor did not establish the design input used, specify a singular design approach, or rule out certain design considerations.

- The rationale for satisfying the two requirements above is documented and approved by management superior to the supervisor. The QA manager shall also concur with this rationale.

2.4.6 METHODS OF DESIGN VERIFICATION

Design verification shall be accomplished by any one or a combination of the following: design reviews, alternate calculations, qualification testing, or peer review.

2.4.6.1 Design Reviews

Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. At a minimum, the items below shall be considered during the review and the results of such deliberations shall be documented.

- Were the design inputs correctly selected?
- Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- Was an appropriate design method used?
- Were the design inputs correctly incorporated into the design?
- Is the design output reasonable compared to design inputs?
- Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- Are computer programs used for analysis identified and verified in accordance with the methods specified in ~~the NNWSI Project Administrative Procedures Manual~~ paragraph 3.0 of this Section.

2.4.6.2 Alternate Calculations

Alternate calculations are a form of analysis which may be used to determine the adequacy of the original analyses. The use of alternate calculations shall include a review of the assumptions, inputs and computer programs or other calculation method used.

2.4.6.3 Qualification Tests

Qualification tests that involve actual physical testing of systems, structures, or components may be used to verify the adequacy of design. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented.

Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mock-ups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design work.

2.4.6.4 Peer Review

Peer review is an acceptable method of design verification when the design is beyond state-of-the-art and other methods of design verification are not feasible.

2.5 DESIGN CHANGE CONTROL

2.5.1 CHANGES TO APPROVED DESIGNS

Changes to approved designs, including field changes, shall be justified and subjected to design control measures commensurate with those applied to the original design and approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the M&O shall designate a new responsible organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. Errors and deficiencies in approved design and design information documents shall be documented, and action taken to assure that all errors and deficiencies are corrected. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.6 DESIGN INTERFACE CONTROL

2.6.1 IDENTIFICATION AND RESPONSIBILITY

Internal and external design interfaces shall be identified and controlled and design efforts shall be coordinated among and within responsible design organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within responsible design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

2.7 DESIGN OUTPUT REQUIREMENTS

2.7.1 DESIGN OUTPUT DOCUMENTS

Design output documents shall:

2.7.1.1 Relate to the design input by documentation in sufficient detail to permit design verification.

2.7.1.2 Identify assemblies or components or both that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.7.1.3 Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. As a minimum, the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the WMPO. The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.8 DESIGN DOCUMENTS AS QA RECORDS

Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification and records confirming interface control shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section [illegible] of this document.

3.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

3.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL

For a geologic repository, computer software used to perform analysis in support of the license application shall be controlled to the same level of

requirements as software used to perform direct design analysis. Auxiliary software used to support primary analysis software shall be controlled at a level commensurate with the complexity of that software.

Where commercial auxiliary software is used, all available documentation from the software supplier shall be obtained. It is recognized that source code is generally not available and controls are limited to unique version identification and user-related manuals. Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the life cycle model are contained in Appendix H to this QA Plan.

3.1.1 Each organization participating in the NNWSI Project shall prepare a description of their software design, test and configuration management system, and submit it to the next higher program organizational level for review and approval. The description shall:

- Provide criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.
- Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.
- Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.
- Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
- Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analysis.
- Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

3.1.2 Software shall be placed under configuration management as each baseline element is approved. Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.

3.1.3 Changes to software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations.

Changes to computer software shall be subject to the same level of approval, verification, and validation as the original software.

3.1.4 Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.

3.1.5 Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.

3.1.6 Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application for repository structures, systems and components. 2

3.1.7 Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system. 2

3.1.8 Existing software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. Software that has not been developed in accordance with this QA Plan may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section. 2

3.1.9 Methods for determining the applicability of requirements and managing interfaces involving ~~software~~ documentation, configuration management, change, qualification, verification, and validation of software shall be described in each organizations software QA Plan and procedures. 2

3.2 DOCUMENTATION OF COMPUTER SOFTWARE

Documentation of scientific and engineering software shall include the following, as a minimum:

- Software requirements specification;
- Software design and change documentation;

- Description of mathematical models and numerical methods;
- Software verification and validation documentation;
- User documentation;
- Code assessment and support;
- Continuing documentation and code listings; and
- Software summary.

This documentation is considered to be a QA Record and is subject to the requirements of Section XVII of this QA Plan. Appendix H to this QA Plan provides detailed requirements on the content of the documentation for this software and other computer software used on the NNWSI Project. 2

3.3 SOFTWARE CONFIGURATION MANAGEMENT

All Participating Organizations and NTS Support Contractors shall institute a software configuration management program appropriate to the projects they conduct and shall provide documentation of this program to the Records Management System (RMS). The minimum requirements for this configuration management program shall be: (1) the inclusion of a unique identification, including software version numbers whenever feasible, in the output; (2) listings of the software; and (3) a brief chronology of the software versions, including descriptions of the changes made between versions.

4.0 PEER REVIEWS

All Participating Organizations and NTS Support Contractors shall institute a peer review process, when applicable, to provide adequate confidence in the work being reviewed. Peer reviews shall meet the requirements of NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988). These requirements are contained in Appendix J to this QA Plan.

5.0 TECHNICAL REVIEWS

When technical reviews are required, they shall be conducted in accordance with procedures that contain specific criteria for the performance of the technical review.

SECTION V

INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS

1.0 GENERAL

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings, of a type appropriate to the circumstances except as noted in paragraph 3.0 of this Section. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Instructions and procedures shall include a section which identifies the QA records which are generated during implementation of the document. If plans are used in lieu of procedures, then these plans shall also include or reference appropriate acceptance criteria and identify the QA records which are generated. These documents, including drawings, shall be controlled as required in Section VI of this document. 2

2.0 REVIEWS

An independent review of all instructions, procedures, plans and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of appropriate quality requirements. If applicable, this review shall consider whether the activities have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities. 2

are not repeatable,

3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

The Participating Organizations shall prepare instructions for the control of scientific notebooks, plans and the other documentation that will be used in scientific investigations. When scientific notebooks are used to document scientific investigations, the requirements of Section III, paragraph 1.6 shall prevail over the requirements of this Section. Scientific notebooks shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document. 2

4.0 DISTRIBUTION

Each Participating Organization and Nevada Test Site (NTS) Support Contractor shall maintain and provide the NNPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager with controlled distribution of all implementing procedures, plans and instructions used for QA Level I and II activities.

SECTION VI

DOCUMENT CONTROL

1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

1.1 METHODS

The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

- Documents containing or specifying quality requirements.
- Documents that prescribe activities affecting quality.

The document control system shall be documented, and the QA organization shall provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.

1.2 IMPLEMENTATION

Implementation of document control shall provide for the following:

- Identification of documents to be controlled.
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
- Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance.
- A method for the removal or marking of obsolete or superseded documents to prevent inadvertent use.
- A method for assuring that the correct and applicable documents are available at the location where they are to be used.
- A master list or equivalent to identify the correct and updated revisions of documents.
- Coordination of interface documents.

2.0 DOCUMENT CHANGES

2.1 MAJOR CHANGES

Changes to documents, other than those defined below as minor changes are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organization shall have access to pertinent background data or information upon which to base their approval and, if applicable, shall specifically consider whether the changes have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities. 2

are not repeatable,

2.2 MINOR CHANGES

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

3.0 DISTRIBUTION OF DOCUMENTS

3.1 DOCUMENT CONTROL SYSTEM

The document control system shall assure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Paragraph 1.2 of this section. A master list or equivalent used to identify the correct, current and updated versions of documents shall be submitted to the NNPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager.

SECTION XII

CONTROL OF MEASURING AND TEST EQUIPMENT

1.0 GENERAL

1.1 MAINTAINING ACCURACY OF EQUIPMENT

Measures shall be established to ensure that tools, gages, instruments, and other measuring and test equipment used in activities that affect quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

1.2 SCOPE OF CONTROL PROGRAM

The Quality Assurance Program Plans (QAPPs) of the Participating Organizations and Nevada Test Site (NTS) Support Contractors shall define the scope and methodology of their program for the control of measuring and test equipment. This shall include all measuring and test equipment or systems used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

1.3 DESCRIPTION OF RESPONSIBILITIES

The responsibilities of all organizations shall be described for the establishment, implementation and assurance that the calibration program is effective.

2.0 PURPOSE OF EQUIPMENT

Measuring and test equipment are devices or systems used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

Specific requirements for control of measuring and test equipment are listed below:

2.1 SELECTION

Selection of measuring and test equipment shall be controlled to assure that such equipment is of proper type, range, and accuracy, to accomplish the function of determining conformance to specified tolerance requirements. The type, range, and accuracy of a measuring device shall be documented in test and inspection documents. Each device shall have a unique identification number. This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability to the measurement of the device that was used to take the measurement.

2.2 CALIBRATION

Measuring and test equipment shall be calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and shall be calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration shall be documented. Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function shall be identified.

2.3 CONTROL

The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. Measuring and test equipment must be labeled, tagged, or otherwise documented in a fashion which indicates the due date of the next calibration and to provide traceability to calibration data. If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous results obtained and of the acceptability of items previously inspected, tested or data gathered since the last calibration. Devices that are out of calibration shall be tagged or segregated and shall not be used until they have been recalibrated. If any measuring or test equipment is found to be out of calibration consistently, then it shall be repaired or replaced. A calibration shall be performed when the accuracy of equipment is suspect.

2.4 COMMERCIAL DEVICES

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

2.5 HANDLING AND STORAGE

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

2.6 RECORDS

Records shall be maintained and equipment shall be marked suitably to indicate calibration status. Calibration records shall identify the calibration procedure (including revision) utilized to perform the calibration.

SECTION XV

CONTROL OF NONCONFORMING ITEMS

1.0 GENERAL REQUIREMENTS

Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use. These measures shall include documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All personnel involved in Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities are responsible for reporting nonconformances in accordance with their established nonconformance control procedures. These procedures shall be consistent with the minimum requirements listed below.

1.1 IDENTIFICATION

1.1.1 METHOD OF IDENTIFICATION

Identification of nonconforming items shall be made by marking, tagging, or other methods that shall not adversely affect the end use of the item. The identification shall be legible, easily recognizable, and shall contain the nonconformance report number. The nonconformance report number shall be a sequential number preceded by an organizational acronym (e.g, LLNL-1, USGS-6, etc). If tags are used, they shall be securely attached to avoid loss during handling.

1.1.2 EXCEPTIONS

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

1.1.3 CONDITIONAL RELEASE

Work on the nonconforming item shall be stopped until completion of the action specified in the Nonconformance Report (NCR) disposition. If only a specific portion of the item is in nonconformance, then that specific area shall be identified and work may proceed on the remaining areas. If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the Waste Management Project Office (WMPO) shall approve such continuance. Requests for conditional releases on nonconforming items shall include documented justification that the following conditions are met:

- The nonconforming item can be removed or corrected at a later date without damage to, or contamination of the associated permanent facility equipment or structures.

- The nonconforming item remains accessible for inspection.
- The nonconforming item is evaluated and limitation(s) for use of the equipment or system is established.
- Traceability and identification of the nonconforming item are maintained.

1.2 LOGGING

1.2.1 NONCONFORMANCE CONTROL LOG

Each NNWSI Project participant shall maintain a nonconformance control log to track nonconforming items. This log shall contain the following information:

- The nonconformance report number.
- A brief description of the nonconforming condition.
- Identification of the person or organization responsible for determining and carrying out the nonconformance disposition.
- The status of each nonconformance report (open or closed).

1.3 SEGREGATION

1.3.1 HOLD AREA

When practical, nonconforming items shall be segregated by placing them in a clearly identified and designated hold area until they are dispositioned properly.

1.3.2 ALTERNATIVE

When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

1.4 DISPOSITION

1.4.1 NONCONFORMANCE CHARACTERISTICS

Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel. Distribution of nonconformance documentation shall be to all affected organizations.

1.4.2 RESPONSIBILITY AND AUTHORITY

The responsibility and authority for the evaluation, disposition, and close-out of nonconforming items shall be defined and documented. Those personnel assigned signature approval of the disposition shall be identified. Quality Assurance (QA) responsibilities relating to nonconformances shall be described.

1.4.3 PERSONNEL

Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area that they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

1.4.4 DISPOSITIONING OF NCR

The person or organization assigned the responsibility of dispositioning the NCR shall ensure the following:

- Nonconformance documentation adequately identifies and describes the nonconformance.
- Appropriate justification for the disposition has been documented. In the case of use-as-is or repair dispositions, technical justification is required. The as-built records, if such records are required, shall reflect the accepted deviation.
- The disposition has referenced any approved design documents, procedures, plans, work orders, etc., that are to be used for the correction of the nonconforming condition.
- The technical details for correction of the nonconforming condition are adequate for the recommended disposition.
- If continuance has been requested, justification for the activity to continue has been documented and approved by the appropriate NNPO Branch Chief and the NNPO PQM.
- The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.
- If a change to reflect the as-built condition is appropriate, then the disposition addresses action to change the existing design documents, test plans or procedures, reports, etc. Any documents changed shall also be cross referenced on the NCR.
- Disposition has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.
- Disposition has identified the people or organization responsible to implement the disposition.

1.4.5 WMPO APPROVAL

In those cases where the responsible organization proposes a disposition of "repair", WMPO shall approve the proposed disposition prior to implementation. In the case of a proposed disposition of "use-as-is", the NCR shall be forwarded to WMPO for approval after all actions necessary to support technical justification of the disposition have been completed. The appropriate WMPO Branch Chief and the WMPO PQM shall approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.

1.4.6 CORRECTIVE ACTION

The action taken to correct the nonconforming item shall be verified and documented. Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.

1.4.7 INTERFACES

Internal interfaces between organizational units and external interfaces between NNWSI Project participants shall be clearly described.

2.0 REPETITIVE NONCONFORMANCES

When repetitive or recurring nonconforming conditions are identified, an evaluation shall be made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition on the existing NCRs and shall be processed in accordance with corrective action procedures developed by each NNWSI Project participant.

3.0 TRENDING

Nonconformance reports shall be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances. Results shall be reported to upper management for review and assessment.

4.0 DISTRIBUTION OF DOCUMENTS

Copies of nonconformance reports for items shall be sent to the WMPO PQM and the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and upon closure. The original nonconformance reports shall be sent to the WMPO for approval as required by Paragraph 1.4.5 of this section.

SECTION XVIII

AUDITS

1.0 GENERAL REQUIREMENTS

All Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall Quality Assurance (QA) program and to determine their effectiveness. Each NNWSI Project participant shall include in their Quality Assurance Program Plan (QAPP) a system of planned, periodic audits to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records to ensure that the QA program is effective and properly implemented. The audits shall be performed in accordance with written procedures using checklists by appropriately trained personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented, reported to, and reviewed by responsible management. Tracking systems shall be instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies, nonconformances, and potential quality problems identified during the audit are to be documented and monitored until verification of effective corrective action is made. The audited organization shall describe in a formal report the corrective action to be taken to address findings, and shall submit the report to the auditing organization and their own responsible management.

Followup action, including verification of corrective action or reaudit of specific areas, shall be performed.

1.1 NNWSI PROJECT AUDITS

The NNWSI Project audit program will be executed at the Project level by the Waste Management Project Office (WMPO) and at the activity level by individual Participating Organizations and NTS Support Contractors.

1.1.1 WMPO AUDITS

The SAIC/T&MSS Project QA Department shall develop a schedule defining the WMPO audits planned for each fiscal year. This schedule shall be approved and issued by the WMPO as an annual planning document. As a minimum, WMPO shall audit all NNWSI Project participants annually. The audits shall cover the entire scope of the participants' QAPP. Additional audits may be conducted when a unique need arises or when an audit is requested by a Participating Organization or NTS Support Contractor. Participating Organizations and NTS Support Contractors shall be audited to verify the effectiveness and adequacy of implementation of all elements of their respective QAPPs and this QA Plan. These audits will eliminate the need for Participating Organizations or NTS

Support Contractors to conduct audits of each other. Representatives of the Participating Organizations, or NTS Support Contractors, or both may be invited to participate in a WMPO audit when the audited organization's activities are of mutual interest. Copies of audit documents for the WMPO audits shall be sent to the audited organization. The WMPO shall also conduct internal audits, which cover the complete WMPO QAPP and this QAP, on an annual basis.

1.1.2 PARTICIPATING ORGANIZATION AND NTS SUPPORT CONTRACTOR AUDITS

Each Participating Organization and NTS Support Contractor shall conduct internal (covering their entire QAPP, on an annual basis) and external (direct subcontractor) audits of activities under its direct control, but they will not conduct audits of each other. These audits will be scheduled, planned, conducted, and reported as described in their respective QAPPs and this Quality Assurance Plan (QAP). External and internal audit schedules, dates, and changes thereto, shall be sent to the SAIC/T&MSS Project QA Department (QA Verification Division Manager). Audit schedules shall identify the date of the audit, the activities to be audited, and the requirements to which the activities are to be audited.

1.2 SCHEDULING

Internal and external QA audits, shall be scheduled in a manner that shall provide coverage and coordination with ongoing QA program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity and shall be initiated early enough to assure effective QA. Each NNWSI Project Participant shall perform or arrange for annual evaluations of suppliers. This evaluation shall be documented and shall take into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

1.2.1 INTERNAL AUDITS

Applicable elements of an organization's QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of the audit shall be established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA program.

1.2.2 EXTERNAL AUDITS

Elements of an external organization's QA program shall be audited at least annually or once during the life of the activity, whichever is the shorter period, with the following exception: If the activity is less than four months in duration, an audit is not required to be performed unless an audit is necessary due to the complexity or importance of the activity being performed.

The justification for not performing audits of vendors whose activities are less than four months in duration shall be documented and approved by the responsible QA Manager prior to implementation of the activity. A copy of the documented justification shall be provided to the Yucca Mountain Project Office PQM.

1.2.3 JOINT AUDITS

If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit shall satisfy the needs of all of the purchasers, and the audit report shall be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

1.3 PREPARATION

Preparation for an audit shall include the items listed below.

1.3.1 AUDIT PLAN

The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

1.3.2 PERSONNEL

The auditing organization shall select and assign auditors who are independent of any direct responsibility for the performance of the activities that they are to audit. If the audit is to be an internal one, then the personnel who have direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA audit personnel.

1.3.3 SELECTION OF AUDIT TEAM

An audit team shall be identified before the beginning of each audit. This team shall contain one or more auditors and shall have an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses. The audit team leader shall identify the technical specialists, if any, who will participate in the audit and include this information in the audit plan. Audit team members selected to participate in audits for technical consideration purposes shall have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit teams shall be employed when activities to be audited involve more than a single technical area. The audit team leader shall ensure that the audit team is prepared before the audit begins.

1.4 PERFORMANCE

Audits shall be performed in accordance with written procedures using checklists as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements including a review of corrective actions taken on deficiencies in the area being audited that were identified during previous audits. Objective evidence shall be examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively. The audit results shall be documented by audit personnel and shall be reviewed by management having responsibility for the area audited. Conditions that require prompt corrective action shall be reported immediately to the management of the audited organization. Audit findings will be reviewed with the audited organizations at a closing meeting.

1.5 REPORTING

The audit report shall be signed by the audit team leader and should be issued within 30 calendar days. This report shall include the following information, as appropriate:

- Description of the audit scope.
- Identification of the auditors.
- Identification of persons contacted during audit activities.
- Summary of audit results, including a statement of the effectiveness of the QA program elements that were audited.
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

1.6 RESPONSE

Management of the audited organization or activity shall investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and, within thirty calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

1.7 FOLLOW-UP ACTION

Follow-up action shall be taken to determine whether or not corrective action has been accomplished as scheduled and shall be verified by the auditing organization.

An analysis of audit results shall be performed by the QA organization to identify quality trends. The results of the analysis shall be reported to responsible management for review, assessment, and appropriate action.

1.8 RECORDS

1.8.1 AUDITS

As a minimum, audit records shall include the following:

- Identification of the organization(s), activities, or items audited and the individual(s) contacted during the audit(s).
- Description of any deficiencies, nonconformances, and potential quality problems identified.
- Audit plans, audit reports, written replies, and the record of completion of corrective action, and close-out of the audit.

1.8.2 PERSONNEL RECORDS

Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. Records for each Lead Auditor shall be maintained and updated annually.

2.0 SURVEILLANCES

The NNWSI Project audit program shall be supplemented by independent surveillance activities. The purpose of a surveillance is to monitor or observe items or activities to verify conformance to specified requirements. These surveillances shall be conducted by the M&PO, the Participating Organizations and the NTS Support Contractors, and shall be either scheduled or implemented on a random basis.

Measures for the surveillance of site investigation activities shall be established and executed in accordance with procedures prepared by the organization performing the activity. Surveillances shall be scheduled and conducted based on the activity's relative impact or importance, or both, to the NNWSI Project. All deficiencies, nonconformances, and potential quality problems identified during surveillances are to be documented and monitored until verification of effective corrective action is made. Specific requirements applicable to surveillance activities are as follows:

2.1 PLANNING

Surveillances are to be performed to written checklists or surveillance plans whenever practical. The documentation shall identify characteristics, methods, and acceptance criteria, shall provide for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance.

The specification of acceptance criteria related to surveillances may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements".

2.2 REPORTING INDEPENDENCE

Surveillance personnel shall not report directly to the immediate supervisors who are responsible for the work being surveilled.

2.3 RECORDS

As a minimum, surveillance records shall identify the following:

- o Item or activity.
- o Date of surveillance.
- o Name of individual performing the surveillance.
- o Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.
- o Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section XV or XVI, as applicable. 2
- o Surveillance criteria.
- o Equipment used during the surveillance.
- o Results.
- o Acceptance statement.

APPENDIX A

TERMS AND DEFINITIONS

ACCEPTANCE CRITERIA: Specified limits defined in codes, standards, or other requirement documents placed on characteristics of an item, process, or service.

ACCESSIBLE ENVIRONMENT: (1) the atmosphere; (2) the land surface; (3) surface water; (4) oceans; and (5) the portion of the lithosphere that is outside the controlled areas.

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The NNWSI QA Program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation. The QA Level I requirements of this QA Program apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-list nor do they require QA level assignment. However, activities related to natural barriers important to waste isolation shall be identified and listed on a Q-list. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. Examples are site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.

ACTIVITY: Any time consuming effort (operation, task, function, or service) which influences or affects the achievement or verification of the objectives of the NNWSI Project as depicted in the WBS Dictionary.

AP - NNWSI Administrative Procedure: An implementing procedure which identifies the interface control methods which govern Project-wide systems and are implemented by all Project participants. Administrative procedures that implement QA requirements are identified with a "Q" suffix (i.e., AP 1.1Q).

AUDIT: A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, codes, standards, instructions, drawings, and other applicable requirements, and the effectiveness of implementation. An audit should not be confused with surveillance or

inspection activities performed for the sole purpose of process control or product acceptance.

AUTHENTICATION: Authentication is the act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by one of the following methods: (1) a stamped, initialed, or signed, and dated document; (2) a statement by the responsible individual or organization; or (3) issuing a document which is clearly identified as a statement by the reporting individual or organization. A document cannot become a Quality Assurance (QA) record until it has been authenticated.

AUXILIARY SOFTWARE: (1) Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format, or plotting of data in support of primary analysis software. (2) A stream of commands or sequence of streams of commands executed to utilize system maintained software in which the system maintained software generates reportable results. Auxiliary software does not generate primary data.

BARRIER: Any material or structure that prevents or substantially delays the movements of water or radionuclides.

BASELINE: As used for computer software: (1) The stage of computer software at a completed and reviewed phase of the software lifecycle; (2) Approved documentation generated within or as a result of completing a phase of the software life cycle.

CERTIFICATE OF CONFORMANCE: A document signed by an authorized individual that certifies the degree to which items or services meet specified requirements.

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

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

COMMERCIAL GRADE ITEM: An item satisfying all of the following requirements:

1) The item is not subject to design or specification requirements that are unique to Mined Geologic Disposal Systems;

2) The item is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description, i.e., catalog.

3) The item is used in applications other than Mined Geologic Disposal Systems.

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COMPUTER MODEL VALIDATION: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing code results to (1) physical data, or (2) a verified or validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for code validation if it is the only available means for validating a code.

COMPUTER CODE VERIFICATION: Assurance that a computer code correctly performs the operations specified in a numerical model (NUREG-0856). Usually accomplished by comparing code results to (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).

CONDITION ADVERSE TO QUALITY: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability.

CONFIGURATION MANAGEMENT: As used for computer software: (1) A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration.

CONSEQUENCE ANALYSIS: A method by which the consequence of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

CONTAINMENT: The confinement of radioactive waste within a designated boundary.

CONTAINMENT, PERIOD OF: Known as the period during the first several hundred years following permanent closure of the geologic repository in which radiation and thermal levels are high and the uncertainties of ensuring repository performance are great. During this time, special emphasis is placed upon the ability to contain the wastes by waste packages within an engineered barrier system.

CONTRACTOR: An organization under contract to provide supplies, construction, or services.

CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that extend horizontally no more than 5 kilometers in any direction from the outer boundary of the underground facility and the underlying subsurface, which is an area that has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure. The controlled area is also known as the site.

CONVERSION REPORT: A written description of all modifications made to the original code or an externally available existing code after it is acquired.

CORRECTIVE ACTION: Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition.

CORROBORATIVE DATA: Existing data used to support or substantiate other existing data.

CREDIBLE EVENT OR CREDIBLE ACCIDENT: An event or accident scenario which needs to be considered in the design of a geologic repository.

DESIGN: The act of developing designs for construction or of analyzing the performance of repository engineered structures, systems, components, and natural barriers. Design documentation includes, but is not limited to, drawings, specifications, test plans, design reports, test reports, system design descriptions, configuration status listings, design manuals, and manuals describing computer programs used for design or performance analysis.

DESIGN INPUT: Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based.

DESIGN OUTPUT: Documents, such as drawings, specifications, and others that define technical requirements of structures, systems, and components.

DESIGN PROCESS: Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

DEVIATION: A departure from specified requirements.

DISPOSITION: The action taken to resolve a nonconforming condition and to restore acceptable conditions.

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

DOE: The U.S. Department of Energy or its duly authorized representatives.

ENGINEERED BARRIER SYSTEM: The waste package and the underground facility.

ENGINEERED ITEM: Any structure, system, or component identified in design documents as being a functional part of the completed facility.

EXISTING DATA: Data developed prior to the implementation of a 10 CFR 60, Subpart G QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.).

EXTERNAL AUDIT: An audit of those portions of another organization's QA program that is neither under the direct control nor within the organizational structure for the auditing organization.

FINAL DESIGN: Approved design output documents and approved changes thereto.

FUNCTIONAL CHARACTERISTICS: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the OGR Program or other Federal regulatory documents.

GEOLOGIC REPOSITORY: A system that is either intended to be used for or may be used for the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the geologic repository operations area and the portion of the geologic setting that provides isolation of the radioactive waste.

GEOLOGIC REPOSITORY OPERATIONS AREA: A high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, in which waste handling activities are conducted.

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

IMPORTANT TO WASTE ISOLATION: The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment (i.e. for achieving the postclosure performance objectives in 10CFR60, Subpart E).

INDOCTRINATION: Instruction provided to personnel for familiarization with programmatic and work-oriented documents applicable to the assigned activity.

INSPECTOR: A person who performs inspection activities to verify whether or not an item or activity conforms to specified requirements.

INSPECTION: Examination or measurement to verify whether an item or activity conforms to specified requirements.

INTERNAL AUDIT: An audit of those portions of an organization's QA program that is retained under its direct control and within its organizational structure.

ISOLATION: Inhibiting the transport of radioactive materials so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

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ITEM: An all-inclusive term that is used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, and prototype hardware. This term includes magnetic media, and other materials that retain or support data.

LIFETIME RECORDS: Quality Assurance Records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All NNWSI Project QA Records are classified as Lifetime Records.

MATERIAL: A term that includes items plus any hardware or geologic samples either used in or resulting from research and development or site investigations on the NNWSI Project. Hardware and geologic specimens include but are not limited to test apparatus or equipment, special nuclear material, cores, geologic samples, water and gas samples, etc.

MEASURING AND TEST EQUIPMENT: Devices or systems used to calibrate, measure, gage, test, or inspect, in order to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

NNWSI PROJECT PARTICIPANTS: An all inclusive term used to describe (generically) the various organizations involved in the NNWSI Project. This term includes the WMPO, Participating Organizations, and NTS Support Contractors. These organizations are required to have a WMPO approved Quality Assurance Program Plan (QAPP) for the conduct of their activities.

NNWSI PROJECT PERSONNEL: All U.S. Department of Energy Participating Organizations, and NTS Support Contractor personnel involved in NNWSI Project activities.

NNWSI PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic quality assurance requirements that are applicable to the NNWSI Project.

NNWSI PROJECT WORK BREAKDOWN STRUCTURE (WBS) DICTIONARY: A controlled document which establishes a product oriented framework for organizing and defining work to be accomplished.

NONCONFORMANCE: A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

NON-MECHANISTIC FAILURES: Postulated failures which are not based on previously observed models or mechanisms but which are assumed to provide conservatism in safety assessments.

NTS: Nevada Test Site

NTS SUPPORT CONTRACTOR: Organizations that are directly under contract to DOE/NV for activities at the NTS and other locations.

OBJECTIVE EVIDENCE: Any documented statement of fact, other information, or record, either quantitative or qualitative, that pertains to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

OPERATIONS, PERIOD OF: Includes the time during which emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing of shafts.

OVERVIEW: An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

OWNER: The person, group, company, agency, or corporation that has or will have title to the repository.

PARTICIPATING ORGANIZATION: This term applies to the following: (1) the government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in NNWSI Project activities.

PEER: A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

PEER REVIEW: A documented critical review performed by personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art.

A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

PEER REVIEW GROUP: A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

PEER REVIEW REPORT: A documented in-depth report of the proceedings and findings of a peer review.

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PERFORMANCE ALLOCATION: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components.

PERFORMANCE ASSESSMENT: The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to determine compliance with the numerical criteria associated with 10 CFR Part 60.

PERMANENT CLOSURE: The sealing of shafts and boreholes. Permanent closure represents the end of active human intervention with respect to the engineered barrier system.

PERFORMANCE CONFIRMATION: The program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

PRINCIPAL INVESTIGATOR (PI): The individual who has the technical responsibility for a particular technical task. This responsibility includes, but is not limited to, planning and cost control, the day-to-day technical direction and control of the item or activity, and the assembly of a support team to accomplish the item or activity. This term may be synonymous with task leader or project engineer depending upon the NNWSI Project Participant.

PROCEDURE: A document that specifies or describes the way in which an activity is to be performed.

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60 in accordance with the NNWSI Project Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with NNWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NNWSI Project QA Program."

PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means by which to acquire possession or ownership of items, or right to the use of services by payment.

PURCHASER: The organization responsible for the establishment of procurement requirements and for the issuance or administration, or both, of procurement documents.

Q-LIST: A list of geologic repository engineered structures, systems, and components that have been determined to be important to safety, and engineered barriers important to waste isolation. ~~The items on this list are subject to the highest quality assurance level (QA level 1) requirements of the NNWSI Project QA Plan.~~ that must be covered under the QA requirements of 10 CFR 60, Subpart G.

QUALIFICATION (OF DATA): A formal process intended to provide a desired level of confidence that data are suitable for their intended use.

QUALIFICATION (PERSONNEL): The characteristics or abilities that are gained through education, training, or experience, which are measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

QUALIFICATION TESTING: Demonstration that an item meets design requirements.

QUALIFIED DATA: Data initially collected under a 10 CFR 60, Subpart G quality assurance program or existing data qualified in accordance with Appendix G of this QA Plan.

QUALIFIED PROCEDURE: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

QUALITY ACTIVITIES LIST: A list of those major activities conducted during site characterization, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the Quality Assurance program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

10 CFR 60, Subpart G

QUALITY ASSURANCE: All those planned and systematic actions that are necessary to provide adequate confidence that the geologic repository and its subsystems or subcomponents will perform satisfactorily in service.

QUALITY ASSURANCE RECORD: An individual document or other item that has been executed, completed, and approved and that furnishes evidence of (1) the quality and completeness of data (including raw data), items, and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of Quality Assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents such as plans, correspondence, documentation of telecons, specification, technical data, books, maps, papers, photographs, and data sheets; (5) items such as magnetic media; and (6) other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document or item (and documentation) that will receive no more entries, whose revisions would normally consist of a reissue of the document (or documentation), and that is signed and dated by the originator and, as applicable, by approval personnel.

QUALITY ASSURANCE LEVEL I: those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or

beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

QUALITY ASSURANCE LEVEL II: those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and WMPO concerns, and the environment.

QUALITY ASSURANCE LEVEL III: those activities and items not classified as QA Levels I or II.

QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document that describes the organizatic[illegible]uality Assurance Program, the applicable QA requirements, and defines how compliance with the QA criteria will be accomplished.

RADIOACTIVE WASTE: High-Level Waste (HLW) and other radioactive materials that are received for emplacement in a geologic repository.

READINESS REVIEW: An Independent, systematic documented review to determine and inform management of the readiness to advance from one phase, process, or activity into another. Readiness Reviews are used to coordinate many elements and provide attention to detail, to assure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of the project.

RECEIVING: Taking delivery of an item at a designated location.

RELIABILITY ANALYSIS: An analysis that estimates the reliability of a system or component.

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

REPOSITORY: See Geologic Repository Operations Area.

RETRIEVAL: The act of intentionally removing radioactive waste from the underground location at which the waste had been emplaced previously for disposal.

REWORK: The process by which a nonconforming item or activity is made to conform to the original requirements by completion or correction utilizing existing approved procedures.

RIGHT OF ACCESS: The right of a purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or Quality Assurance audit.

SCENARIO: An account or sequence of a projected course of action or event.

SCIENTIFIC INVESTIGATION: Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural barriers or the man-made aspects of the geologic repository, including the overall design of the facilities and the waste package. This will include, but will not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository.

SCIENTIFIC NOTEBOOK: A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods, or both. These notebooks may be used in lieu of a technical procedure.

SERVICE: The performance of activities that include but are not limited to site characterization, design, fabrication, investigation, inspection, nondestructive examination, repair, or installation.

SITE: Location of the controlled area.

SITE CHARACTERIZATION: The program of exploration and research both in the laboratory and in the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the procedures under 10 CFR Part 60. Site characterization includes borings, surface excavations, excavation or exploratory shafts, limited subsurface lateral excavations and borings, and in site testing at depth as needed to determine the suitability of the site for a geologic repository. It does not include preliminary borings and geophysical testing needed to decide whether or not site characterization should be undertaken.

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

SURVEILLANCE: The act of monitoring or observing to verify whether or not an item or activity conforms to specified requirements.

TECHNICAL REVIEW: A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluation of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

TESTING: An element of verification that is used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

TRACEABILITY: The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

TRAINING: In-depth instruction provided to personnel to develop and demonstrate initial proficiency in the application of selected requirements, methods, and procedures, and to adapt to changes in technology, methods, or job responsibilities.

UNDERGROUND FACILITY: The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.

USE-AS-IS: A disposition that is permitted for a nonconforming item or service when it can be established that the item is satisfactory for its intended use.

VERIFICATION: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether or not items, processes, services, or documents conform to specified requirements.

WAIVER: Documented authorization to depart from specified requirements.

WASTE MANAGEMENT PROJECT OFFICE (WMPO): The organization to which the U.S. Department of Energy, Nevada Operations Office (DOE/NV), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors associated with the NNWSI Project.

WASTE PACKAGE: The waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

VALIDATION: Validation is the act of reviewing a document or document package to ensure it is complete, authenticated, reproducible, and microfilmable.

APPENDIX H

REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE APPLICATION

This appendix provides detailed requirements for the development, maintenance, and security of computer software. It supplements Section III of this QA plan and shall be used in conjunction with that section.

1.0 OBJECTIVES

The purpose of this appendix is to establish requirements for the development, management, control, and documentation of software used to support the Yucca Mountain Project. The attainment of software quality is dependent on the control of the entire software development process, and is not assured solely by inspection and test of the end product. This appendix prescribes appropriate systematic practices that shall:

- Reduce the likelihood of defects entering executable code during development.
- Ensure that the end product answers the requirements of its intended application.
- Reduce the likelihood that defects will be introduced into executable code during later maintenance and modification.

2.0 APPLICABILITY

The detailed requirements set forth in this appendix apply to computer software used to produce or manipulate data which is used directly in site characterization, and the design, analysis, performance assessment, and operation of repository structures, systems, and components. The extent to which these requirements apply is related to the nature, complexity, and importance of the software application. The application of specific requirements shall be prescribed in plan(s) for software quality assurance and in written policies and procedures.

3.0 TERMS AND DEFINITIONS

Terms and definitions for NNWSI Project software are contained in Appendix A to this QA Plan.

4.0 SOFTWARE LIFE CYCLE

Organizations implementing software development activities shall adhere to a software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner. The relative emphasis placed on each phase of the software development cycle will depend on the nature and complexity of the software being developed.

Each phase of the software development cycle shall provide specific attributes that shall be incorporated into verification and validation activities. The documentation for each phase of the software development cycle shall be reviewed and approved as specified in each organization's software QA Plan. An example of one such model is described below:

Requirements

Design

Implementation

Test

Installation
and Checkout

Operation and
Maintenance

4.1 SOFTWARE QA PLAN

The application of the software life cycle to the development and/or use of the software shall be as described in the Software Quality Assurance Plan.

4.1.1 A software QA plan shall be prepared for each software development/application effort at the start of the software life cycle. This plan may be prepared individually for each piece of software or may exist as a generic document to be applied to all software prepared within an organization. The software QA plan shall identify:

- The software products to which it applies.
- The organizations responsible for software quality and their tasks and responsibilities.

- Required documentation.

- The required software reviews.

The software QA Plan should reference any standards, conventions, techniques, or methodologies which guide the software development, and describe methods to assure compliance to the same.

4.1.2 Within the software QA plan, software lifecycle management shall be described. Each participant shall present the specific software lifecycle controls for their organization in their software QA Plan. The following lifecycle elements shall apply, as appropriate, for the specific lifecycle model defined, interpreted, and described in each organizations software QA plan.

4.1.2.1 Requirements Phase

During this phase requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the completed software shall be specified, documented, and reviewed. These requirements shall possess the following characteristics:

- A format and language that is understood by the programming organization and the user.

- Enough detail to allow for objective verification.

- Adequate definition to provide for the response of the software to the identified input data.

- The information necessary to design the software without prescribing the software design itself.

4.1.2.2 Design Phase

During the design phase a software design based on the requirements shall be specified, documented, and systematically reviewed. The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation.

Design phase verification and validation activities during this phase shall consist of:

- The generation of design-based test cases.

- The review and analysis of the software design.

- The verification of the software design.

4.1.2.3 Implementation Phase

During this phase the design shall be translated into a programming language and the implemented software shall be debugged. Only minor, if any, design issues shall be resolved at this phase.

Verification and validation activities during this phase shall consist of:

- The possible modification of test cases necessary due to design changes made during coding.
- The examination of source code listings to assure adherence to coding standards and conventions.

4.1.2.4 Testing Phase

During the testing phase the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases may require the modification of the requirements, the design, the implementation, or the test plans and test cases.

Verification and validation activities during this phase shall consist of:

- The evaluation of the completed software to assure adherence to the requirements.
- The preparation of a report on the results of software verification and validation.

4.1.2.5 Installation and Checkout Phase

During this phase the software becomes part of a system incorporating other software components, the hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.

Testing activities during this phase shall consist of the execution of test cases for installation and integration. Test cases from earlier phases shall be enhanced and used for installation testing.

4.1.2.6 Operations and Maintenance Phase

During the operations and maintenance phase the software has been approved for operational use. Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested (including regression testing as appropriate), and controlled in accordance with Paragraph 5.0.

5.0 SOFTWARE VERIFICATION AND VALIDATION

Verification and validation plans by the responsible project organization shall employ methods such as inspection, analysis, demonstration, and test to assure that the software adequately and correctly performs all intended functions, and that the software does not perform any function that either by itself or in combination with other functions can degrade the entire system.

Verification and validation activities shall be planned and performed relative to specific hardware configurations. The amount of verification and validation activity shall be determined by the type and complexity of the software. The results of all verification and validation activities shall be documented.

Verification and/or validation of computer software should be performed in two stages:

1. By the individual generating or modifying the software

2. By an independent individual or organization, one who did not work on the original software.

The first stage should involve activities (i.e., iterations of tests and runs) to arrive at a final product. It is not required to document all of the activities performed to satisfy the software developer.

5.1 VERIFICATION

Verification activities shall be integrated into all applicable phases of the software life cycle and shall be performed to an extent proportional to the critical importance of the software. Software verification shall be performed to assure that the software requirements are implemented in the software design, and the software design is implemented in code. Appropriate methods such as inspection, analysis, test, or demonstration shall be applied to accomplish verification objectives.

5.2 VALIDATION

Validation activities are performed to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. This is accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in situ testing. Specific sets of data used in the validation process shall be identified and justification shall be made for their use.

When data are not available from the sources mentioned above, alternative approaches used shall be documented. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. The results of software validation shall be documented.

6.0 SOFTWARE CONFIGURATION MANAGEMENT

A software configuration management system shall be established to assure positive identification of software and control of all software baseline changes.

6.1 CONFIGURATION IDENTIFICATION

A configuration baseline shall be identified at the completion of each major phase of the software development cycle. Approved changes to a baseline shall be added periodically to the baseline as updates. A baseline plus updates shall specify the most recent software configuration. Updates shall be incorporated into subsequent baselines. Both baselines and updates shall be defined by their composition of software configuration items.

A labeling system for configuration items shall be implemented that:

- Uniquely identifies each configuration item or version number.
- Identifies changes to configuration items by revision.
- Places the configuration item in a relationship with other configuration items.

6.2 CONFIGURATION CHANGE CONTROL

Changes to baseline software configuration items shall be formally documented. This documentation shall contain a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The change should be formally evaluated by a qualified individual or organization with the ability to approve or disapprove the proposed change. Assurance shall be provided that only authorized changes are made to software baselines and software configuration items.

6.3 CONFIGURATION STATUS ACCOUNTING

The information that is needed to manage software configuration items shall be recorded and reported. This information shall include a listing of the approved configuration identification, the status of proposed changes to the configuration, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.

7.0 DOCUMENTATION

Minimum acceptable lifecycle documentation of computer software developed or modified for use on the Yucca Mountain Project shall be specified in each participants software QA plan(s). The documentation provided shall describe the following, as applicable. Additional documentation may also be identified in the software quality assurance plan for each Yucca Mountain Project participant's software project.

7.1 SOFTWARE REQUIREMENTS SPECIFICATION

A specific capability of software can be called a requirement only if its achievement can be verified by a prescribed method. Software requirements documentation shall outline the requirements that the proposed software must fulfill. The requirements shall address the following:

- Functionality - the functions the software are to perform.
- Performance - The time-related issues of software operation such as speed, recovery time, response time, etc.
- Design constraints imposed on implementation - any elements that will restrict design options.
- Attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.
- External Interfaces - interactions with other participants, hardware, and other software.

7.2 SOFTWARE DESIGN DOCUMENTATION

Software design documentation is a document or series of documents that shall contain:

- A description of the major components of the software design as they relate to the requirements of the software requirements specification.
- A technical description of the software with respect to control flow, data flow, control logic, and data structure.

- A description of the allowable and tolerable ranges for inputs and outputs.
- The design described in a manner that is easily traceable to the software requirements.
- Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.
- Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

7.3 SOFTWARE IMPLEMENTATION DOCUMENTATION

Any design changes made to the requirement and design phase documents shall be assessed as to the impact on the design. The revised requirement and design phase documents shall be reviewed to the same level of review as the original documents. The results of this phase should be the basis for the software verification and validation plan(s).

7.4 SOFTWARE VERIFICATION AND VALIDATION DOCUMENTATION (TEST)

Software verification and validation documentation shall include a plan that describes the tasks and criteria for accomplishing the verification of the software in each phase, and the validation of the software. The documentation shall also specify the hardware and system software configuration pertinent to the software. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. This documentation will also include a report on the results of the execution of the software verification and validation activities. This report shall include the results of all reviews, audits, and tests, and a summary of the status of the software.

7.5 USER DOCUMENTATION

User documentation shall be prepared in accordance with NUREG-0856 and shall include a description of:

- Program considerations, options, and initialization procedures.
- Anticipated error situations and how the user can correct them.
- Internal and external data files, their input sequence, structures, units, and ranges.
- Input and output options, defaults, and formats.

- o System interface features and limitations.
- o Information for obtaining user and maintenance support.
- o Sample problems.

8.0 REVIEWS

Reviews of software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each phase of development. The procedures used for reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review report.

The documentation for all reviews shall contain a record of review comments, a plan, and timetable for the resolution of the review comments, and the personnel responsible for this resolution.

After review comments are resolved, the approved documents shall be updated and placed under configuration management.

8.1 SOFTWARE REQUIREMENTS REVIEW

The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the requirements are complete, verifiable and consistent. The review shall also assure that there is sufficient detail available to complete the software design.

8.2 SOFTWARE DESIGN REVIEW

The software design review will be held at the completion of the software design documentation. This review shall evaluate the technical adequacy of the design approach, and assure that the design answers all the requirements in the requirements documentation. The complexity of the software design may require the performance of two design reviews; one at the completion of the overall software architecture, and the second at the completion of the total design.

8.3 SOFTWARE IMPLEMENTATION REVIEW

The software implementation review is an evaluation of the completed requirements, design, and implementation process prior to independent verification and validation.

8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW

The software verification and validation review is an evaluation of the adequacy of verification and validation plans or procedures and completed software verification and validation activities. The review results in an approval of verification and validation documentation.

9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

A formal procedure of software discrepancy reporting and corrective action shall be established. This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions.

Software discrepancy reporting and corrective action procedures shall assure that, as a minimum:

- Defects are documented and corrected.
- Defects are assessed for criticality and impacted as previous applications.
- Corrections are reviewed and approved before changes to the software configuration are made.
- Preventive and corrective actions provide for appropriate notification of affected organizations.

10.0 MEDIA CONTROL AND SECURITY

Physical media containing the images of software shall be physically protected to prevent their inadvertent damage or degradation.

11.0 ACQUIRED SOFTWARE

Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. Software transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QA Plan and the needs of the organization's computer system. Those requirements not met by the software received shall be completed by the organization in the relative phase of the software life cycle that is incomplete or, if that is not possible, the reason shall be documented and maintained with the software and distributed to the users.

Configuration management change controls shall be established for documenting the conversion of software to be used on a computer system, and/or peripheral hardware, other than that for which it was designed. Conversion includes all modifications and tests made to input/output or the source code or additional software written to run the original software on the new system. Software conversion shall be documented and maintained for the specific version of the software and the computer system on which it is installed. Software conversion changes shall be evaluated and activities performed in accordance with the appropriate configuration management system elements.

12.0 COMPUTER SOFTWARE APPLICATIONS

Organizations shall establish procedures for controlling the application of verified and/or validated computer software to technical calculations in support of site-characterization or design, analysis, performance assessment, and operation of repository structures, systems, and components.

Organizations shall establish procedures for documenting and reviewing software application and analyses and assuring that all results are accurate and reproducible. Requirements shall be established for identifying or otherwise marking record copies of all analyses and supporting documentation. Supporting documentation includes computer output (results), code input data including data bases and original sources/references of and assumptions used to obtain such data, code design, user's and/or operation manuals, verification/validation test results and/or hand calculations.

Technical calculations using software shall be performed with applicable computer codes and with software operating procedures defined sufficiently to allow independent repetition of the entire computation.

Controls shall be established for generating and documenting software used to perform technical calculations. All auxiliary software used should be included in documentation of technical calculations performed and should be included in independent review as part of the calculation.

All applications of computer software shall be independently reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

and safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

2.3 DATA NOT COLLECTED UNDER A 10 CFR 60 SUBPART G QA PROGRAM

All data collection, interpretations, analyses, and other work to be used to support findings related to important to safety and/or waste isolation in the licensing process shall be technically and procedurally defensible. "Existing data" shall be qualified in accordance with the requirements of Appendix G of this QA Plan. In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA Program. Supporting documentation on these materials (e.g. the technical specifications and QA records) shall be reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they shall be "qualified" for use to assure they will perform their intended function.

3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY

Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-List as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.

3.1 Probabilistic Risk Analysis (PRA) may be used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the HLW program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions shall be used. Conservative assumptions shall include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

3.2 Operator actions or errors which could initiate accidents shall be identified in PRAs or other analyses. These shall be controlled to minimize the probability of occurrence. Other activities which are subject to QA Level I requirements, such as designing, inspecting, and purchasing will not be identified in PRAs but shall be controlled in accordance with QA Level I requirements.

3.3 PRAS shall utilize the following techniques:

3.3.1 System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques which may be used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

An event-tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events shall be compiled to ensure that the event trees properly depict all important sequences.

A fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident shall be examined to determine how failures of components within that system could cause the failure of the entire system.

If failure of a mitigating system could contribute to an off-site dose, individual components within the mitigating system shall be reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

3.3.2 Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the HLW facility. The energy, magnitude, and timing of radiological releases resulting form various accidents shall be considered in this analysis.

3.3.3 Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

Additional guidance related to the assessment of pre-closure accidents can be found in NUREG 1318, (April, 1988), paragraph 5.2(a).

3.4 REDUNDANCY

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system shall not comprise or prevent the associated safety function from being performed.

For the high-level waste repository, 10 CFR 60 [60.131(b)(5)(ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the Q-List.

3.5 USE OF PREVIOUSLY ESTABLISHED GUIDELINES AND STANDARDS

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the Q-List. While some of these guidelines and standards may not be directly applicable to a geologic repository, they shall be considered to the extent practicable, to eliminate the need to develop new approaches.

3.6 RETRIEVAL

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations shall be conducted at that time, to identify Q-List items.

4.0 IDENTIFICATION OF ITEMS AND ACTIVITIES IMPORTANT TO WASTE ISOLATION

The term "important to waste isolation" refers to engineered and natural barriers that will be relied on to meet the containment and isolation performance objectives of 10 CFR 60 Subpart E. Four of the performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:

- ground water travel time
- waste package containment period
- maximum yearly release rate from the engineered barrier system
- the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the EPA standard in 40 CFR Part 191).

The items and activities important to waste isolation shall include:

- Components of the engineered barrier system relied on to meet the performance objectives.
- Elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives.

- Activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers.

- Activities in the preclosure phase that could effect post-closure performance.

The broad performance objectives for waste isolation provide some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. The initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocations of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities shall be controlled in accordance with the QA Level I requirements of this QA Plan. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated later in accordance with QA Level I requirements of this QA Plan and therefore would not have to be performed in accordance with the QA Level I requirements at this time. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed in accordance with the QA Level I requirements of this QA Plan. 1

5.0 SUBMITTAL REQUIREMENTS

5.1 LICENSE APPLICATION

A description of the QA program to be applied to items important to safety and/or waste isolation shall be submitted with the license application. The submittal shall identify the structures, systems, and components important to safety and describe the analyses used in this identification. It should also identify the barriers important to waste isolation falling under the QA program and describe the evaluations used to identify these barriers [10 CFR 60.21(c) (1)(ii)(C)]. A Quality Activities List, as defined in Section 1.0, should also be provided listing major site characterization, isolation, operation, and performance confirmation activities under the QA program.

5.2 SITE CHARACTERIZATION PLANS

The following information related to the Q-List should be submitted in the Site Characterization Plan:

- A description of the QA program to be applied to items and activities during the site characterization phase.
- A preliminary Q-List identifying major structures, systems, and components important to safety, engineered barriers important to waste isolation and the methodology used to develop the list.
- A list of major site characterization activities (Quality Activities List) and the QA requirements which apply to them.
- A general description of the process by which the preliminary Q-List will be revised as the design advances.

Plans for development and implementation of a QA program to demonstrate that non-Q-List licensing requirements are met should also be described in the Site Characterization Plan.

6.0 GRADED APPLICATION OF QA MEASURES

The 10 CFR 60 Subpart G requirements can be met using graded QA measures and should be applied to items and activities important to safety and/or waste isolation based on considerations such as the following:

- The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.
- The complexity of design or fabrication of an item, or design and implemen- tation of a test, or the uniqueness of an item of test.
- The special controls and surveillance needed over processes, tests, and equipment.
- The degree to which functional compliance can be demonstrated by inspection or test.
- The quality history and degree of standardization of the item or test.

Note: Additional guidance related to this subject can be found in NUREG-1318, "TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS" (APRIL, 1988).

APPENDIX J

REQUIREMENTS FOR PEER REVIEW

1.0 General

This appendix provides the requirements regarding the applicability of peer reviews, the structure of peer review groups, acceptability of peers, and the conduct and documentation of peer reviews.

2.0 APPLICABILITY OF PEER REVIEW

2.1 A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

2.2 In general, the following conditions are indicative of situations in which a peer review shall be considered:

a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

b. Decisions or interpretations having significant impact on performance assessment conclusions will be made.

c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized.

d. Detailed technical criteria or standard industry procedures do not exist or are being developed.

e. Results of tests are not reproducible or repeatable.

f. Data or interpretations are ambiguous.

g. Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.

2.3 A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

3.0 STRUCTURE OF PEER REVIEW GROUP

The number of peers comprising a peer review group shall vary commensurate with the following:

A. The complexity of the work to be reviewed.

B. Its importance to establishing that safety or waste isolation performance goals are met.

C. The number of technical disciplines involved.

D. The degree to which uncertainties in the data or technical approach exist.

E. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

3.2 The collective technical expertise and qualifications of peer review group members shall span the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. The potential for technical or organizational partiality shall be minimized by selecting peers to provide a balanced peer review group. Technical areas more central to the work to be reviewed shall receive proportionally more representation in the peer review group.

4.0 ACCEPTABILITY OF PEERS

4.1 The technical qualification of the peer reviewers, in their review areas, shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection of peer reviewers. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.

4.2 Members of the peer review group shall be independent of the original work to be reviewed. Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. In some cases (i.e. funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.

5.0 PEER REVIEW PROCESS

5.1 Since the peer review process may vary from case to case, a peer review plan shall be prepared prior to initiating a peer review. The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce a peer review report.

5.2 The peer review group shall evaluate and report on:

a. Validity of assumptions.

b. Alternate interpretations.

c. Uncertainty of results and consequences if incorrect.

d. Appropriateness and limitations of methodology and procedures.

e. Adequacy of application.

f. Accuracy of calculations.

h. Adequacy of requirements and criteria.

g. Validity of conclusions.

Documentation shall be prepared to indicate the results of meetings, deliberations, and activities of the peer review process.

6.0 PEER REVIEW REPORT

6.1 A report documenting the results of the peer review shall be prepared and issued under the direction of the peer review group chairperson and shall be signed by each peer review group member. The peer review report shall include the following: 1

a. A clear description of the work or issue that was peer reviewed.

b. Conclusions reached by the peer review process.

c. Individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate.

d. Listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

Note: Additional guidance related to this subject can be found in NUREG-1297, "PEER REVIEW FOR HIGH LEVEL NUCLEAR WASTE REPOSITORIES" (FEBRUARY, 1988).

APPENDIX K

FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLAN

1.0 Purpose and Objectives of Studies:

1.1 Describe the information that will be obtained in the study. Briefly discuss how this information will be used; and

1.2 Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

2.0 Rational for Selected Study:

2.1 Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and

2.2 Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference if available, reports which evaluate alternatives considered.

2.3 Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:

a) Potential impacts on the site from testing;

b) Whether the study needs to simulate repository conditions;

c) Required accuracy and precision of parameters to be measured with test instrumentation;

d) Limits of analytical methods that will use the information from the tests;

e) Capability of analytical methods to support the study;

f) Time required versus time available to complete the study;

g) The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;

h) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and

i) Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information)/

3.0 Description of Tests and Analyses:

3.1 Since studies are comprised of tests and analyses, provide for each type of test:

a) Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESF elements, repository layout, stratigraphic units, depth, and test location);

b) Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;

c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;

d) Indicate the range of expected results of the test and the basis for those expected results;

e) List the equipment required for the test and describe briefly any such equipment that is special;

f) Describe techniques to be used for data reduction and analysis of the results;

g) Discuss the representativeness of the including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;

h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and

i) Relationship of the test to the set performance goals and confidence levels.

3.2 For each type of analysis:

a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

b) Describe the methods of analysis including any analytical expressions and numerical models that will be employed;

c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA level 1. Reference the applicable QA requirements.

d) Identify the data input requirements of the analysis;

e) Describe the expected output and accuracy of this analysis; and

f) Describe the representativeness of the analytical approach (e.g. with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

4.0 Application of Results:

4.1 Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies)

4.2 For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;

4.3 For design uses, refer to , or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

4.4 For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

Schedule and Milestones:

5.1 Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;

5.2 Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and

5.3 Dates for activities or milestones including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5 of the SCP.