SAFETY EVALUATION

1. INTRODUCTION

The U.S. Department of Energy, Nevada Operations Office (DOE/NV) established the Nevada Nuclear Waste Storage Investigations (NNWSI) Project to investigate whether Yucca Mountain is a suitable site for the high-level radioactive waste repository. The NNWSI Project will perform investigations that will address items and activities which could affect the radiological health and safety of the public (i.e., those items and activities important to safety or waste isolation) and that the U. S. Nuclear Regulatory Commission (NRC) regulates.

To demonstrate compliance with legislative, regulatory, and DOE requirements for control and documentation of quality, DOE/NV has established the Waste Management Project Office (WMPO) to manage and to direct the NNWSI Project. To establish a framework for consistency in the development of quality assurance (QA) plans and implementation procedures at all levels of the NNWSI Project, WMPO has developed the NNWSI Project QA Plan, NNWSI/88-9 (hereafter 88-9 QA Plan). The 88-9 QA Plan establishes the QA requirements for the NNWSI Project organizations. All NNWSI organizations (i.e. WMPO, Nevada Test Site (NTS) Support Contractors and Participating Organizations) must meet the requirements described in the 88-9 QA Plan and incorporate them into their QA program plans and procedures.

NRC staff has prepared this Safety Evaluation (SE), which documents the NRC's review of the information that DOE/NV submitted in its 88-9 QA Plan, Revision 1. The 88-9 QA Plan addresses NRC's regulations, positions, and guidance documents on QA. This SE describes the regulatory criteria against which the 88-9 QAP was reviewed, summarizes the content of the 88-9 QA Plan, and provides a basis for NRC staff acceptance of it.

There are several limitations on the scope of this review. The 88-9 QA Plan is a higher tier requirements document. Therefore, this review does not include the QA program plans and procedures that each of the organizations in the NNWSI Project will prepare and the implementation of these into the site and laboratory investigations. The QA program plans and procedures will be designed to meet the requirements of the 88-9 QAP Revision 1. NRC staff will review and accept these plans (after DOE incorporates necessary changes) at a later date. The staff will also review the incorporation into the technical programs of the administrative controls of the QA program described in the above plans and procedures during its planned technical reviews of, for example, the Site Characterization Plan (SCP), study plans, and technical procedures, and its onsite inspections, audits, and observations of DOE audits.

2. BACKGROUND

On August 25, 1986, the NRC provided comments to DOE on the 88-9 QA Plan (formerly 196-17, Revision 4, dated January 14, 1986). Similarly, on November 21, 1986, the NRC provided comments to DOE on NNWSI-SOP-02-01, dated January 31, 1986, "Quality Assurance Program Plan Requirements for NNWSI Project Participating Organizations and NTS Support Contractors."

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The purpose of this latter document was to delineate the QA requirements to be addressed in the QA program plans of the participating organizations and NTS support contractors. DOE provided responses to the above NRC comments on January 20, 1988 and discussed these at a March 18, 1988 meeting at the NRC Headquarters in Rockville, Maryland. The 196-17 QA Plan and NNWSI-SOP-02-01 documents were subsequently incorporated into what is currently the 88-9 QA Plan. On May 19, 1988, DOE submitted the 88-9 QA Plan (Rev. 0) for NRC staff review. The NRC staff had 30 open QA items as a result of its review of the 88-9 QA Plan and DOE responses to the August 25, 1986 and November 21, 1986 NRC requests for additional information. NRC and DOE discussed these open QA items at a July 8, 1988 meeting at the NRC Headquarters in Rockville, Maryland. Other participants included representatives from the State of Nevada, the General Accounting Office, the Utility Nuclear Waste Management Group, and private industry.

At this meeting, DOE provided responses to NRC's open items and amended responses to DOE's previous resolutions on NNWSI-SOP-02-01. The major items that were resolved at the meeting concerned how DOE was addressing the NRC staff's Technical Positions on "Peer Review", "Qualification of Existing Data", "Q-List", and "Documentation of Computer Codes", (NUREGs 1297, 1298, 1318, and 0856 respectively); software QA; inspections; and special processes. NRC identified three open items (QA measures for study plans, NRC review of the Office of Civilian Radioactive Waste Management (OCRWM) QA program, and QA measures for conceptual designs) that do not affect the review of the 88-9 QA Plan but will be tracked on the master list of open items which had been discussed at a July 7, 1988 meeting between DOE and NRC. Based on the above, the NRC staff concluded it had sufficient information on which to base an SE for the 88-9 QA Plan.

The NRC staff used the following review criteria to determine whether the 88-9 QA Plan appropriately addressed Appendix B to 10 CFR Part 50:

- "NRC Review Plan - Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Facilities";[1]
- American National Standards Institute (ANSI)/American Sociaty of Mechanical Engineering (ASME) NQA-1 - 1986;[2]
- Regulatory Guide 1.28[3] (endorses ANSI/ASME NQA-1-1983);
- Criteria from ANSI/ASME NQA-3[4] (Revision 1, 2/88) on design data control;
- NRC staff Technical Position on Peer Review,[5]
- NRC staff Technical Position on Qualification of Existing Data,[6]
- NRC staff Technical Position on Q-List,[7] and
- NRC staff Technical Position on Documentation of Computer Codes for High-Level Waste Management.[8]

3. STAFF EVALUATION

The following sections describe in detail the staff's evaluation of the 88-9 QA Plan for each of the 18 criteria of Appendix B, 10 CFR Part 50. Each section identifies the areas of the 88-9 QA Plan reviewed by the staff, summarizes the QA measures that apply (from the criteria listed above), and the content of the 88-9 QA plan and, where necessary, provides NRC staff analysis of DOE's justifications for various approaches taken to fulfill the requirements of Subpart G of 10 CFR Part 60. The staff's finding on the approach outlined in the 88-9 QA Plan is also presented.

3.1 "Organization" (Criterion I)

The staff reviewed the description of "Organization" provided in the Introduction and Section I of the 88-9 QA Plan. The criteria identified in Section 2 of this SE were used to assess the description. These criteria, in summary, are:

a. The responsibilities for establishing and implementing the QA program shall be established.

b. Persons performing QA functions shall have sufficient independence, authority, and organizational freedom to identify, initiate, recommend, and provide solutions to quality problems.

c. The responsibilities for achieving and assuring quality shall be clearly established.

Figure 1 shows the organization of the NNWSI Project for QA. The Secretary, DOE Headquarters (DOE/HQ), is responsible for executing the Nuclear Waste Policy Act of 1982. The Secretary has delegated this responsibility to OCRWM to integrate QA and management policies and requirements for the overview of the activities that the DOE/NV field operations office performs. The OCRWM provides programmatic and policy guidance to DOE/NV to assure that adequate QA and technical objectives of the project are achieved. The OCRWM Office of Quality Assurance is responsible for: (1) reviewing and approving the 88-9 QA Plan, the quality-related administrative procedures, and the WMPO Quality Assurance Program Plan; (2) specifying the appropriate requirements contained in the OCRWM Quality Assurance Program Plan; and (3) performing QA audits of the WMPO.

For the Nevada Operations Office, the DOE/NV Manager has ultimate accountability and responsibility for the NNWSI Project. Within the DOE/NV organization is the WMPO, which has been established to manage the NNWSI Project, under the programmatic direction of the OCRWM. The DOE/NV field operations office is responsible for the implementation of the QA and technical activities of the NNWSI Project.

The WMPO is responsible for authorizing work and the management and technical direction of the activities that the respective Participating Organizations and NTS Support Contractors conduct. This is accomplished through the issuance of technical and programmatic guidance; technical integration, planning, and QA programmatic guidance.

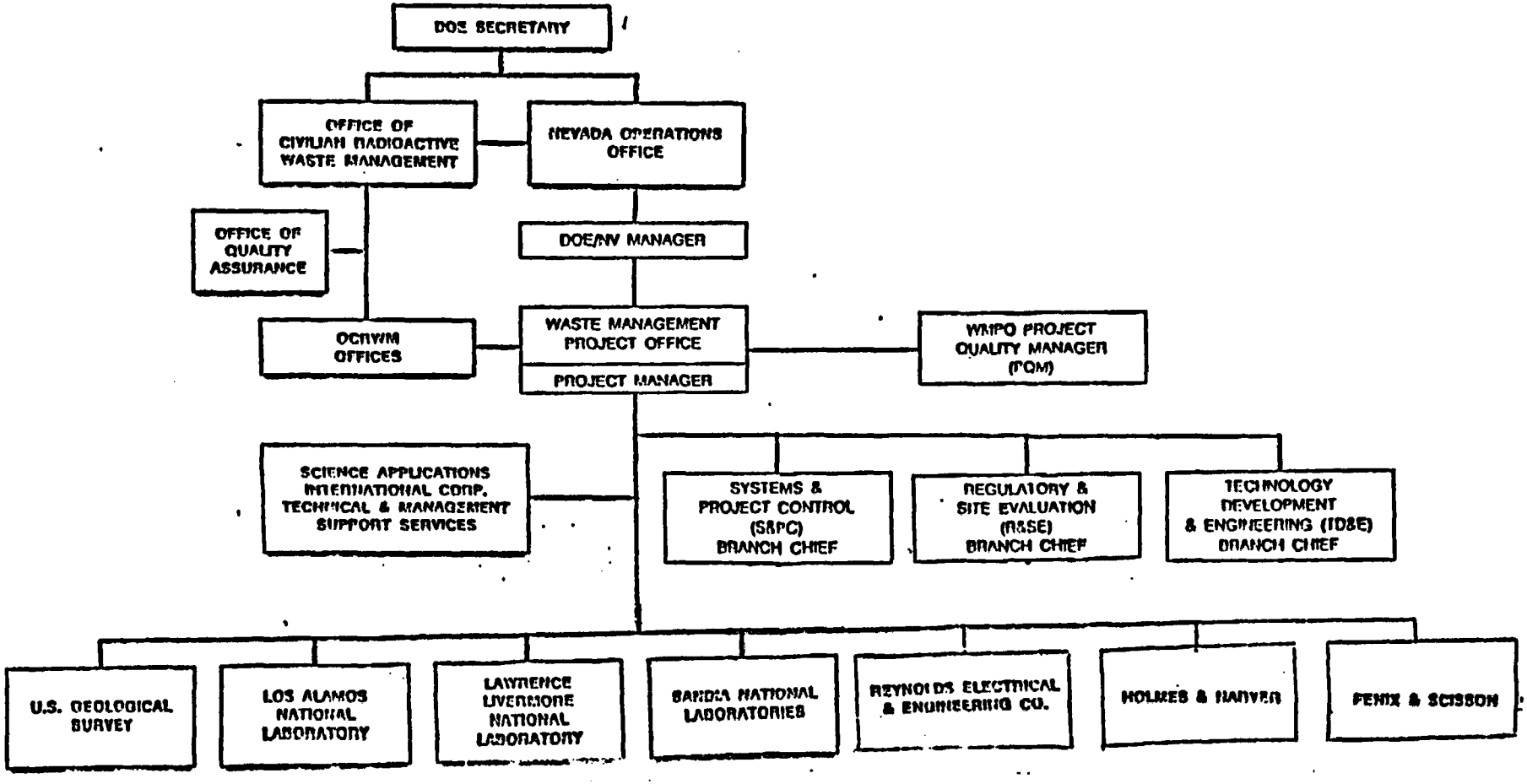

FIGURE 1 NNWSI PROJECT ORGANIZATION

The WMPO Project Manager, reporting to the DOE/NV Manager, is responsible for the NNWSI Project actions, which include: (1) planning and directing; (2) establishing goals and objectives and assessing progress toward achieving these goals; (3) administering procurement of materials and services; (4) issuing technical and programmatic guidance; (5) organizing and conducting peer reviews; (6) complying with applicable regulations, laws, and DOE policies; and (7) implementing the WMPO QA program.

Reporting to the WMPO Project Manager are three technical branches, each under the direction of a branch chief. The Regulatory and Site Evaluation Branch is responsible for: (1) site characterization in field and laboratory activities; (2) performance assessment; (3) interactions with the NRC; (4) preparation of project documents; (5) site investigation documents; and (6) review and approval of NNWSI Project quality-related documents.

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.

The Systems and Project Control Branch is responsible for: (1) administration and management support; (2) records management/information management system; (3) QA 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.

Also reporting to the WMPO Project Manager is the WMPO Project Quality Manager (PQM), who is responsible for directing and managing the NNWSI QA Program. The PQM has sufficient organizational position and authority to exercise control over the WMPO QA Program. The reporting relationship of the PQM is such that this position is the same or higher than the highest line manager responsible for activities affecting quality. The PQM is also sufficiently independent from cost and schedule considerations, when opposed to safety considerations, to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Responsibilities of the PQM include: (1) approval of the NNWSI QA Plan; (2) approval of the quality-related implementing procedures and changes thereto; (3) coordinating WMPO QA activities; and (4) verifying the adequacy and effectiveness of the QA plans, requirements, and QA program implementation by the WMPO and NNWSI project participants through audits and surveillances. Reporting to and supporting the PQM is the Science Applications International Corporation's Technical and Management Support Services (SAIC/T&MSS). Resolution of disputes involving quality, between QA personnel and others, will be directed to the PQM and, if necessary, referred to the DOE/NV Manager. If a dispute cannot be resolved within the DOE/NV organization, it will be referred to the OCRWM, for ultimate resolution.

SAIC/T&MSS provides the PQM support which includes: (1) audit and surveillance of QA and technical activities; (2) provision of policy guidance; (3) review of support contractors' and participating organizations' QA program plans; and (4) review of NNWSI implementing procedures for compliance with the NNWSI Project requirements.

Quality throughout the NNWSI program is to be verified through checking, review, surveillance, inspection, testing, and audit to determine whether an item or activity conforms to specified requirements. Consistent with ANSI/ASME NQA-1-1986, the 88-9 QA Plan requires that individuals who perform the quality verification who are not directly responsible for performing the actual work activity. The QA organization is required to overview and monitor the inspection activity. All responsibilities relating to QA program development and achieving and assuring quality are to be documented in the QA program plan of each participating organization.

The NRC staff has assessed the above and the additional information on the organization described in the 88-9 QA Plan. The staff finds that it meets the regulatory review criteria described in Section 2 (Background) of this SE, pertaining to Criterion I of Appendix B to 10 CFR Part 50.

3.2 "Quality Assurance Program" (Criterion II)

The staff reviewed the description of the QA program provided in the 88-9 QA Plan in Section II, "Quality Assurance Program"; Appendix C, "Requirements for the Qualification of Inspection and Test Personnel"; Appendix D, "Requirements for Qualification of Non-Destructive Examination Personnel"; Appendix F, "Requirements for the Qualification of Quality Assurance Program Audit Personnel"; and Appendix I, "Requirements for the Identification of Items and Activities to be Included on the Q-List" against the criteria identified in Section 2 of this evaluation. These criteria, in summary, are:

a. Activities that affect quality shall be planned and documented.

b. The QA program shall be documented in policies, procedures and instructions.

c. Management shall regularly assess the QA program for adequacy and implementation.

d. Personnel performing work affecting quality shall be indoctrinated and trained.

e. Items and activities important to safety or waste isolation shall be identified and controlled under Appendix B, Part 50, as applicable.

f. Activities affecting quality shall be accomplished under controlled conditions.

g. The QA program shall provide control over items and activities to an extent consistent with their importance to safety.

As previously noted, the 88-9 QA Plan is a requirements document which must be met by DOE/NV and all participating organizations and support contractors. The 88-9 QA Plan and all quality-related project procedures and changes thereto, shall be submitted to OCRWM for approval. QA program plans of each participating organization and participating contractor shall be submitted to and approved by YMPO. A graded application of quality is applied to items and activities, commensurate with the importance of their roles or functions in the NNWSI Project. The NNWSI Project has committed to portions of NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements." This guidance document defines methods by which items and activities important to safety or waste isolation, a subset of the overall items and activities within the repository program, are to be identified. However, the staff positions in Section 4 of the NUREG are not exactly repeated in the 88-9 QA Plan and no justification was provided for the deviations from the staff positions. DOE should either endorse the staff positions, or where exceptions are desired, identify the exceptions and justify their adequacy. This item is identified in Section 5, "Open Items," for future action by DOE.

NNWSI has developed a three level system for grading QA measures. Its Level I contains items and activities important to safety or waste isolation. NRC regulates all of these. Level II contains items and activities defined by reliability, maintainability, public and repository worker non-radiological health and safety, repository worker radiological health and safety, and other operational factors that could have an impact on DOE and WMPO concerns and the environment. NRC regulates some of the activities within Level II. Level II QA requirements are similar to those in Level I (i.e., Appendix B to 10 CFR Part 50), except that deviations are permissible within Level II provided that adequate justification has been documented and WMPO has approved it. Level III items and activities are those which have no major function in the characterization of the site and design of the repository. The controls applied are those managerial, administrative, scientific, engineering, commercial and laboratory practices that are commonly used by the participating organizations in the project. NRC will not regulate any of the activities within Level III, if DOE classifies them properly.

Other basic provisions from the criteria have been adopted and elaborated on in the 88-9 QA Plan. Management assessments are required to be conducted annually to independently determine the adequacy and effectiveness of the QA program implementation. All NNWSI participants are required to establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities affecting quality. Position descriptions shall indicate minimum qualifications and provide for indoctrination or training before incumbents perform a quality-affecting activity. The indoctrination and training program ensures that personnel performing activities affecting quality are knowledgeable in QA/quality control requirements, implementing procedures and instructions, and that

they have competence and skill in the performance of their quality-related activities. It also provides for the retraining of personnel performing activities affecting quality.

The NRC staff finds the 88-9 QA Plan description for the QA program meets the regulatory review criteria described in Section 2, ("Background"), of this SE, pertaining to Criterion II of Appendix B to 10 CFR Part 50, with the exception of Open Item No. 4, identified in Section 5 of this evaluation.

3.3 "Design Control" (Criterion III)

The staff reviewed the description of "Scientific Investigation Control and Design Control" provided in Section III of the 88-9 QA Plan against the criteria defined in Section II of this SE. The staff also reviewed several appendices in the 88-9 QA Plan in its evaluation. These were Appendix B, "Design Inputs"; Appendix G, "Requirements for Qualification of Existing Data Not Generated Under a QA Program Meeting the Requirements of 10 CFR Part 60 Subpart G"; Appendix H, "Requirements for Computer Software Used to Support a High-Level Nuclear Waste Repository License Application"; and Appendix J, "Requirements for Peer Review." The staff review criteria in Section 2, in summary, are:

a. Measures shall be established to assure that the regulatory requirements and design bases are correctly translated into specifications, drawings, procedures, and instructions for items important to safety or waste isolation.

b. The design control program includes general plans and detailed procedures for site characterization data collection and analysis.

c. Appropriate quality standards shall be specified.

d. Interfaces between design organizations shall be controlled.

e. Designs shall be verified for adequacy by individuals or groups other than those who performed the original design.

f. Design changes shall be subject to control measures commensurate with those applied to the original design.

g. For design or design activities which involve use of untried or beyond the state of the art techniques, or where detailed technical criteria and requirements do not exist, a peer review should be conducted.

h. Verification and validation should be performed on computer software.

For design control, DOE has adopted the positions in NQA-1-1986. The description for design control in the 88-9 QA Plan includes the use of specifications, drawings, design criteria and component performance requirements for the natural and engineered components of the repository system. The data resulting from scientific investigations will be used to produce design input. Design controls include measures for peer review;

design analysis; design input, output, and verification; design analysis; change control; internal and external interface control; and control of computer software used to perform design analysis. DOE has committed to the staff Technical Position NUREG-0856 "Final Technical Position on Docmentation of Computer Codes for High-Level Waste Management" and extensive additional controls for controlling computer software.

The 88-9 QA Plan, as an upper-tier requirements document, appropriately addresses in a general manner the QA controls to be applied to conceptual designs, including basic assumptions about the site contained in the SCP and study plans. The NRC staff has identified concerns with the implementation of these general requirements and will be tracking these items formally and separately to assure that they are satisfactorily resolved.

The 88-9 QA Plan has included both scientific investigations (i.e., collection and analysis of data providing design input) and conventional design activities within Section III, which addresses Criterion III of Appendix B to 10 CFR Part 50, "Design Control". This approach is consistent with the staff's definition of design control in the QA Review Plan. In addition, DOE has also included within its "Scientific Investigation Control" section measures from Criteria IX ("Control of Special Processes"), X ("Inspections"), and XI ("Test Control"). At the request of the staff, DOE provided a justification for this approach and either demonstrated that the controls identified in Section 3 for scientific investigations were equivalent to those in the above three criteria, or in some cases, were not appropriate due to the nature of the work. A number of additional controls were added in response to the staff's questions. An explanation of DOE's approach to these criteria of Appendix B follows.

Criterion IX of Appendix B, "Control of Special Processes," requires that measures be established to assure that special processes be controlled and accomplished by qualified personnel using qualified procedures in accordance with codes, standards, specifications, etc. A special process is a process, the results of which are highly dependent upon 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. Site characterization data collection activities cannot be inspected or tested after completion to measure their quality.

NNWSI has incorporated controls into Section III of the 88-9 QA Plan which address those required by Criterion IX of Appendix B, Part 50. The 88-9 QA Plan includes requirements for qualification of all personnel performing activities affecting quality, including those performing scientific investigations. NNWSI has also included provisions for qualification or verification of procedures. The 88-9 QA Plan allows for technical reviews or peer reviews of procedures and processes to assure that they are suitable for their intended use. This general approach is acceptable to the staff and will be verified for appropriate implementation in staff technical audits and reviews of procedures.

NNWSI has also incorporated controls from Criterion X of Appendix B, "Inspections," into the section on scientific investigations. NNWSI will use surveillances of scientific investigations to help assure that such

investigations are being performed in accordance with procedures. NNWSI will apply its independence and qualification requirements to those persons performing surveillances. Technical personnel are required for all surveillance teams, along with QA personnel. NNWSI will monitor deficiencies, non-conformances, and potential quality problems until it verifies that personnel have taken corrective action.

Criterion X of Appendix B requires that personnel perform inspections for each work operation where necessary to assure quality. In lieu of inspections of each work operation, the 88-9 QA Plan contains requirements for periodic surveillances, use of qualified individuals (scientists and technicians) to perform work, and verifications of completed work. The staff finds the approach that the 88-9 QA Plan adopts is appropriate for scientific work.

NQA-1 Supplement 10S-1 contains provisions for final inspections of items to assure that they conform to requirements. For scientific investigations, NNWSI will conduct technical reviews of results of completed work and will use a close-out verification by technical personnel to assure that the records are adequate and complete. The staff finds this approach for verification in lieu of a final inspection to be acceptable and appropriate for the work to be performed.

The 88-9 QA Plan also incorporates controls from Section XI of Appendix B, "Test Control", into the section on scientific investigations. This section of Appendix B was written for confirmatory tests of items such as safety-related components in a nuclear power plant to determine if they meet specified requirements. Many site characterization activities will produce data whose values are not known before testing and which will not fall within predetermined numerical acceptance criteria. Nevertheless, many of the controls of Section XI apply to data collection, and the staff requested DOE to furnish a detailed comparison of the staff positions in the NRC QA Review Plan vs. the requirements in Section III. This comparison was furnished in the August 19, 1988 letter forwarding the 88-9 QA Plan Rev. 1 to the staff. The controls incorporated include the use of technical procedures and/or lab notebooks for the documentation and control of the work, calibration of equipment, development of an overall test program (which includes the SCP program of testing), identification of test requirements, and others. The staff finds the measures applied to Criterion XI of Appendix B to scientific investigations to be acceptable.

The 88-9 QA Plan has outlined two different approaches for documenting scientific investigations described in study plans or scientific investigation plans. For investigations involving a high-degree of professional judgment by qualified individuals or trial and error methods, or both, scientific notebooks will be used. The documentation in the notebook is to 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 principal investigator.

For repetitive work performed by qualified technicians which does not include the use of professional judgment or trial and error methods, a detailed technical implementing procedure will be utilized. Detailed technical procedures are required when it is not possible to deviate from a strict sequence of actions without endangering the validity of the results that will be obtained from the work. These procedures are subject to formal and rigorous change control.

The staff has several concerns with the approach outlined. First, when scientific notebooks are utilized, there appear to be inadequate provisions to assure that tests which could affect the waste isolation capabilities of the site, interfere with other site characterization tests, or which are not repeatable (and therefore if performed incorrectly would preclude obtaining needed site data) will be appropriately controlled. Although study plans are to identify tests which could affect these three areas, there appears to be no controls to assure that investigations conducted with scientific notebooks are controlled to assure that these three areas are not affected. The individual responsible for an experiment is solely responsible for the details of its implementation.

The staff believes that additional controls need to be added to the 88-9 QA Plan to address this concern. For example, a change in a test that is conducted using scientific notebooks that is outside of the scope of the study plan or investigation plan, or could potentially impact any of the three areas addressed above should be subjected to additional review.

Second, the current criteria for tests using detailed implementing procedures are, the staff believes, unnecessarily restrictive and discourage their use in situations where detailed procedures are beneficial. They are to be used "when it is not possible to deviate from a strict sequence of actions without endangering the validity of results that will be obtained from the work." Changes to them are to be rigorously controlled. The staff believes that allowance should be made for tests where a procedure can be prepared with an appropriate level of detail (which is not necessarily a strict sequence of actions) and changed more easily in the field than is currently allowed. Such a practice would encourage the use of more procedures (as opposed to scientific notebooks), with their additional controls and assurance that work will be performed adequately.

Third, the 88-9 QA Plan currently requires that certain initial entries be included in scientific notebooks prior to beginning an experiment. These include the objective, identification of equipment and materials, calibration requirements, and others. The staff believes that a general procedure as to how the initial work is to be conducted should also be included as an initial entry, rather than rely only on in-process entries. Alternatively, the 88-9 QA Plan could reference detailed information on approaches for conducting experiments in the study plans.

Finally, the approach outlined in the 88-9 QA Plan for scientific investigations using scientific notebooks appears to conflict with the NRC/DOE agreement from the May 7-8, 1986 meeting on SCP level of detail. The staff believes the approach in the 88-9 QA Plan is acceptable when the above items are satisfactorily addressed, and these should be incorporated into any other documents which have been developed to implement the NRC/DOE meeting agreements for technical procedures. Furthermore, the NRC/DOE agreement regarding DOE providing NRC with non-standard procedures for review should be changed to DOE making all procedures and scientific notebooks available for NRC review and audit at DOE or DOE contractors' offices.

The 88-9 QA Plan includes a commitment to follow the guidance contained in the NRC Generic Technical Positions, "Peer Review for High-Level Nuclear Waste Repositories," (NUREG-1297) and "Qualification of Existing Data for High-Level Nuclear Waste Repositories," (NUREG-1298). Certain of the specific positions from NUREGs 1297 and 1298 were not entirely consistent with the 88-9 QA Plan and are carried as Open Items 1 and 2 in Section 5 of this SE. Open item 3, concerning provisions for precision and accuracy for initial entries in the records for experiments or research (from Criterion XI in the NRC 1984 Review Plan) was inadvertently omitted from the 88-9 QA Plan and will be included in the next revision to the 88-9 QA Plan.

The NRC staff has assessed the above and the additional information provided for "Design Control" and "Scientific Investigation Control" in the 88-9 QA Plan, and finds that it satisfactorily addresses the regulatory review criteria described in Section 2 (Background) of this SE with respect to Criteria III, and IX, X, and XI as they pertain to scientific investigations, except as noted previously and in Section 5 of this report.

3.4 "Procurement Document Control" (Criterion IV)

The staff reviewed Section IV of the 88-9 QA Plan against the criteria identified in Section 2 of this SE. The criteria which pertain to Procurement Document Control, in summary, are:

a. Procurement documents shall include all applicable requirements.

b. Procurement documents shall require contractors or subcontractors to develop a QA program implementing portions or all of the requirements of Appendix B.

The 88-9 QA Plan has incorporated the guidance in NQA-1-1986 and the NRC QA Review Plan. It includes a requirement to assure that applicable regulatory and technical requirements, design bases, and other necessary requirements are included in procurement documents. Suppliers are required to have a program implementing portions or all of NQA-1-1986. The staff finds the requirements adopted in the 88-9 QA Plan to be acceptable.

3.5 "Instructions, Drawings, and Procedures" (Criterion V)

The staff reviewed Section V of the 88-9 QA Plan, "Instructions, Drawings, Plans, and Procedures," against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

a. Activities affecting quality shall be accomplished in accordance with instructions, procedures, and drawings.

b. Instructions, procedures, and drawings shall include or reference acceptance criteria.

The 88-9 QA Plan has incorporated the basic requirements of Appendix B, the QA Review Plan, and NQA-1. It has added plans to the basic requirements of Appendix B. The staff finds the requirements adopted in the 88-9 QA Plan for control of instructions, procedures, plans and drawings to be acceptable.

3.6 "Document Control" (Criterion VI)

The staff reviewed Section VI of the 88-9 QA Plan against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established for the preparation, review, approval and issuance of documents that prescribe activities affecting quality.

b. Document changes shall be properly controlled.

The 88-9 QA Plan requires that the preparation, reviews, approval, and issuance of documents be controlled to assure that only correct documents are used. Documents are to state appropriate quality requirements and provide for the identification of responsibility for preparing, reviewing, approving and controlling changes thereto. Obsolete documents are required to be controlled and a master list established to identify the current list of documents.

The 88-9 QA Plan has incorporated the provisions of NQA-1-1986 and the NRC QA Review Plan. The staff finds requirements adopted for Section VI, "Document Control", to be acceptable.

3.7 "Control of Purchased Items and Services" (Criterion VII)

The staff reviewed Section VII of the 88-9 QA Plan, Control of Purchased Items and Services, against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to assure that purchased material, equipment, and services conform to procurement documents.

b. Measures shall be established for source evaluation and selection.

c. Objective evidence of quality shall be furnished by the contractor or subcontractor.

d. The effectiveness of the control of quality by contractors and subcontractors shall be periodically assessed.

The 88-9 QA Plan has incorporated the guidance from the NRC QA Review Plan and NQA-1-1986 addressing each of the requirements listed above. Requirements are included in the 88-9 QA Plan which address procurement planning, source evaluation and selection, bid evaluation, supplier performance evaluation, control of supplier-generated documents, control of changes in items or service, acceptance of items or services, control of non-conformances, and requirements for commercial grade items.

The staff finds the requirements listed in Section VII of the 88-9 QA Plan acceptable.

3.8 "Identification and Control of Items" (Criterion VIII)

The staff reviewed Section VIII of the 88-9 QA Plan, "Identification and Control of Items, Samples, and Data" against the criteria in Section 2 of this SE. The 88-9 QA Plan has expanded the scope of this section from the requirements in Appendix B of 10 CFR Part 50, which only addresses the identification and control of items. The NRC QA Review Plan added samples within this criterion. DOE has also included under this section certain measures for control of data, in addition to those it has prescribed in Section III of the 88-9 QA Plan, "Scientific Investigation Control."

The requirements from the criteria listed in Section 2 of this SE, in summary, are:

a. Items and samples shall be identified and controlled according to procedures.

b. Correct identification of samples is verified and documented before release for use or analysis.

c. Items shall be identified throughout fabrication, erection, installation and use of the item.

d. Identification should be on the sample or its container when possible, or on records traceable thereto.

Section VIII of the 88-9 QA Plan contains the provisions from NQA-1-1986 for controlling items, which is an acceptable method to the staff for meeting the requirements of Appendix B of 10 CFR Part 50. The 88-9 QA Plan also contains provisions for control of samples which meet the guidance in the NRC QA Review Plan, Section 8.

The 88-9 QA Plan also contains several additional requirements for control of data under this section. All data are to be identified to assist in the determination of their correct use. This identification is to be verified as correct before releasing the data for use.

The staff finds the requirements listed in the 88-9 QA Plan for identification and control of items and samples acceptable.

It should be noted that the staff will be reviewing the detailed procedures for control of samples in the new sample management facility of the NNWSI project to assure that the general requirements identified in the 88-9 QA Plan are acceptably translated into detailed procedures.

3.9 "Control of Special Processes" (Criterion IX)

The staff evaluated Section IX of the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. Processes affecting the quality of items or services shall be controlled.

b. Special processes that control or verify quality, such as welding, heat treating, and non-destructive examination, shall be performed using qualified personnel using qualified procedures in accordance with specified requirements.

The 88-9 QA Plan has incorporated the guidance in NQA-1-1986 for fulfilling the requirements for process control in Appendix B and the NRC QA Review Plan, as they relate to engineered items. The QA Review Plan does not address whether Criterion IX controls apply to scientific investigations. In this review, the staff evaluated the controls for scientific investigations using the requirements in Criterion IX of Appendix B. DOE identifies these controls within Section III of the 88-9 QA Plan, and the staff evaluation of the adequacy of those controls is discussed in Section 3.3 of this SE.

Based on the incorporation of NQA-1-1986 requirements for control of processes related to engineered items and the inclusion of appropriate controls for scientific investigations (see Section 3.3), the staff finds the approach in the 88-9 QA Plan for process control acceptable.

3.10 "Inspection" (Criterion X)

The staff evaluated Section X of the 88-9 QA Plan against the criteria identified in Section 2 of this SE. The criteria, in summary, are:

a. Inspections to verify conformance of an item or activity to specified requirements shall be planned and executed.

b. Inspections shall be performed by individuals other than those who performed or directly supervised the activity being inspected.

c. Hold points should be used, as appropriate.

d. Examinations, measurements, or tests shall be performed for each work operation, where necessary.

e. Process monitoring shall be used where necessary to assure quality.

The 88-9 QA Plan has included provisions addressing the guidance in the NRC QA Review Plan and NQA-1-1986, with the exceptions that inspections are to be applied only to engineered items, and that inspectors need not be part of the QA organization (unless special expertise is needed). With respect to the first deviation, Section 3.3 of this SE describes the DOE controls to be applied to scientific investigations and evaluates their acceptability. With respect to the staff position in the NRC QA Review Plan that all inspectors be within the QA organization, the staff has changed its position to be consistent with and has been superseded by the guidance in NQA-1, which has been endorsed by the NRC since the issuance of the NRC QA Review Plan. In addition, the position in the NRC QA Review Plan is contrary to findings in the Ford Study (NUREG-1055, pg. 3-23 and 3-24).

The approach described in the 88-9 QA Plan is acceptable to the staff.

3.11 Test Control (Criterion XI)

The staff reviewed the 88-9 QA Plan Section XI against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. A test program shall be established to assure that all structures, systems, and components will perform satisfactorily in service.

b. The program shall be performed in accordance with written test procedures which incorporate test requirements and acceptance limits.

c. Test procedures shall include provisions for assuring that all prerequisites for a test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

d. Test results shall be documented and evaluated.

"Testing" is defined in NQA-1-1986 as "an element of verification for determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions."

Consistent with the above, the 88-9 QA Plan applies these controls to engineered items only. Although most scientific investigations do not fall under this definition of testing, the staff requested DOE to either incorporate the controls from Section XI of Appendix B and the NRC QA Review Plan into the 88-9 QA Plan, or provide justifications for why they did not apply. DOE's responses and the staff evaluation of them are discussed in Section 3.3. The 88-9 QA Plan includes most of the above provisions within that section, rather than Section XI of the plan.

For engineered items, the 88-9 QA Plan incorporates guidance in NQA-1-1986 and the NRC QA Review Plan. The staff finds the DOE approach for test control to be acceptable.

3.12 "Control of Measuring and Test Equipment" (Criterion XII)

The staff reviewed the description in Section XII of the 88-9 QA Plan against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted to maintain accuracy within the necessary limits.

The 88-9 QA plan has incorporated the provisions from NQA-1-1986 and the NRC QA Review Plan. The scope of the program includes all measuring and test equipment or systems used to calibrate, measure, gauge, 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. The staff finds the requirements described in the 88-9 QA Plan to be acceptable.

3.13 "Handling, Shipping, and Storage" (Criterion XIII)

The staff reviewed the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment.

b. When necessary, special protective environments, such as an inert gas atmosphere, shall be specified and provided.

The 88-9 QA Plan has adopted the provisions of NQA-1-1986 for material and equipment. However, the NRC QA Review Plan expanded the scope of this criterion to cover samples collected during site characterization. In lieu of addressing samples in this section, the 88-9 QA Plan has incorporated the controls from the NRC QA Review Plan and other controls into Section VIII, Part B, "Identification and Control of Samples." The staff reviewed these controls in Section VIII of the 88-9 QA Plan and finds them acceptable for meeting the requirements of Appendix B, Part 50.

3.14 "Inspection, Test, and Operating Status" (Criterion XIV)

The staff reviewed the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. The status of inspections and tests performed on items shall be established by markings, such as stamps, tags, labels, routing cards or other suitable means.

b. These status markings shall provide for identification of items which have passed required inspections and tests.

c. Measures shall be established for indicating the operating status of structures, systems, and components, such as by tagging of valves and switches, to prevent inadvertent operation.

Consistent with the language above (taken from Appendix B, the NRC QA Review Plan, and NQA-1-1986), the 88-9 QA Plan applies a requirement of Criterion XIV to engineered items only. DOE provided a detailed rationale for this approach in the meeting of July 8, 1988, which is documented in the minutes dated July 15, 1988.

The objective of Criterion XIV is to preclude inadvertent omission of required acceptance inspections and tests of nuclear plant components. This criterion also requires, for reasons of safety, the tagging of individual valves, switches, etc. to prevent their inadvertent operation. In as much as scientific investigations are not directly related to safety as are nuclear plant components the controls of Criterion XIV do not apply. Alternatively, NNWSI has established the following controls to assure that data collected from scientific investigations are valid:

a. For any scientific investigation activity that is critical or complex, a formal documented readiness review is held.

b. Data collection test plans and procedures are required to contain mandatory hold/surveillance points at critical areas.

c. QA and technical personnel perform in-process monitoring of data collection activities through supervisory review, surveillance, and technical/QA audits.

d. Anomalies and deficiencies occurring during data collection are documented, evaluated, dispositioned, and tracked until verification of final resolution.

e. Resultant data from scientific investigation activities are documented, analyzed, and evaluated in accordance with the applicable requirements of Criterion III of the 88-9 QA Plan to assure their validity.

f. Final reports on data collection activities are subjected to a technical or peer review in accordance with the requirements specified in Criterion III of the 88-9 QA Plan.

The objective of all of these controls is to assure that data are adequate when used in analyses of the repository.

In addition, to reduce the risk of losing data in the lab or the field due to inadvertent interruption, the 88-9 QA Plan requires in Section III that ongoing field and lab investigations be clearly identified at the location at which they are being conducted.

For engineered items, the 88-9 QA Plan has adopted the guidance in NQA-1-1986 and the NRC QA Review Plan.

The staff finds the approach described in the 88-9 QA Plan for criterion XIV of Appendix B acceptable.

3.15 "Control of Nonconforming Items" (Criterion XV)

The staff reviewed the 88-9 QA Plan against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to control items and activities which do not conform to requirements.

b. Nonconforming items and activities shall be reviewed and accepted, rejected, repaired, or reworked in accordance with procedures.

The 88-9 QA Plan has adopted the guidance in NQA-1-1986 and the NRC QA Review Plan for control of nonconforming items. This approach is acceptable to the staff for meeting the requirements of Appendix B. However, the 88-9 QA Plan is unclear as to whether the requirements in Section XV will be applied to nonconformances generated during surveillances of scientific investigations, a staff position in the NRC QA Review Plan. Although nonconformances are referenced in Section III, "Control of Scientific Investigations," and in Section XVIII, "Audits" (where surveillance requirements are described), there is no direct connection to Criterion XV. DOE should clarify whether the requirements in Section XV apply to nonconformances generated during surveillances. Until this is resolved, this item will remain open. It is identified in Section 5 of this report.

3.16 "Corrective Action" (Criterion XVI)

The staff reviewed the 88-9 QA Plan against the criteria in Section 2 of this SE. The criteria, in summary, are:

a. Measures shall be established to assure that conditions adverse to quality are promptly identified and corrected.

b. For significant conditions adverse to quality, (i.e., which if uncorrected would have a serious effect on safety or operability), the cause of the condition and the corrective action taken shall be documented and reported to management.

The 88-9 QA Plan has included the guidance in NQA-1-1986 and the NRC QA Review Plan for meeting the above criteria. The staff finds this approach acceptable.

3.17 "Quality Assurance Records" (Criterion XVII)

The staff reviewed Section XVII, "Quality Assurance Records," and Appendix E of the 88-9 QA Plan against the criteria in Section 2 of this SE. The criteria, in summary, are:

a. Records furnishing evidence of quality shall be maintained.

b. Records include results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, qualifications of personnel, procedures, and equipment.

c. Records shall be identifiable and retrievable.

d. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

The 88-9 QA Plan incorporates the provisions of the NRC QA Review Plan and NQA-1-1986 as requirements for project participants. Appendix E contains a list of "typical" QA records for site characterization which is, however, not as complete as the current draft of NQA-3. The 88-9 QA Plan defines generally the criteria for defining QA records, so that the smaller scope in this list of typical records is not a deviation from the requirements. Also, NQA-3 is only a draft standard and its final list of typical records could be different from that currently in place. The staff will assure that complete records are being maintained in its audits and observations of DOE audits.

All records have been defined by the 88-9 QA Plan as lifetime records and are required to be retained for the life of the project. The 88-9 QA Plan does not address at this time the post-closure records required to be retained to fulfill the requirements of 10 CFR Part 60, Section 60.51. However, since all records are being retained for the life of the project, this item does not need to be resolved during the site characterization phase of the repository. The staff will review and evaluate DOE's scope of post-closure records before issuing an amendment to the license application for permanent closure.

The 88-9 QA Plan has included within the scope of QA records only those which provide evidence of the quality of data taken from samples and not the sample itself since there is no current regulatory requirement to classify samples as QA records. However, there may be requirements under the proposed rule for the Licensing Support System (LSS) for their retention. DOE should be aware of these possible future requirements for the LSS. This item is not being considered as an open item because there is no existing regulatory requirement.

The staff finds the 88-9 QA Plan approaches for meeting the requirements of Appendix B, Criterion XVII to be acceptable.

3.18 "Audits" (Criterion XVIII)

The staff reviewed the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. QA audits shall be planned and documented to verify compliance with all aspects of the program and to determine the effectiveness of the program.

b. The preparation, performance, reporting, response, and follow-up of audit activities shall be controlled.

c. Follow-up action shall be taken where indicated.

The 88-9 QA Plan has incorporated the provisions of NQA-1-1986 and the NRC QA Review Plan for audits. Staff position 18.1 of the NRC QA Review Plan states that DOE should audit prime contractors and representative subcontractors, consultants and vendors to assess the effectiveness of the prime contractor's program (i.e., the program participants). The staff believes that the guidance in NQA-1-1986, NQA-3, and Regulatory Guide 1.28, is an appropriate interpretation of this position. These require that all DOE program participants audit contractors, subcontractors and consultants, as applicable. The staff will audit and monitor the effectiveness of subcontractors', consultants', and vendors' programs during its own audits and observations of audits within the DOE program.

Although not an explicit staff position in the NRC QA Review Plan, nor a requirement in NQA-1-1986, DOE has committed to using technical specialists on some audits. In practice, DOE has been using technical specialists in most cases. The staff believes this is an essential practice highlighted in the Ford Study (NUREG-1055). The staff will continue to monitor DOE's use of technical specialists to help assure that a technical input is used by the audit teams to assess the effectiveness of the program.

The 88-9 QA Plan has also included requirements for surveillances in Section XVIII, "Audits." These requirements are in excess of those required by 10 CFR Part 50, Appendix B or the various guidance documents.

The staff finds the approaches outlined in the 88-9 QA Plan acceptable.

4. CONCLUSION

The NRC staff reviewed the 88-9 QA Plan for the NNWSI Project and has verified that it meets the criteria of 10 CFR Part 60, Subpart G and Appendix B to 10 CFR Part 50, as applicable. The NRC guidance to address Subpart G is contained in the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories," and staff Technical Positions on "Peer Review", "Existing Data", "Q-List", and "Documentation of Computer Codes" (NUREGs 1297, 1298, 1318 and 0856 respectively). In addition, ANSI/ASME NQA-1-1986, Regulatory Guide 1.28 (endorses ANSI/ASME NQA-1-1983), and selected portions of NQA-3 (Draft 3 Revision 1, 2/88) were used as review criteria. The NRC staff review of the 88-9 QA Plan concludes that it meets the guidance listed above or DOE has provided acceptable alternatives with the exception of the open items identified in Section 5. The 88-9 QA Plan describes alternatives in the areas of special processes; inspection; testing; and inspection, test, and operating status, whereby the controls do not fully apply to scientific investigations. The NRC staff has evaluated these exceptions and finds they are acceptable alternatives.

On the basis of its detailed review and evaluation of the 88-9 QA Plan, the NRC staff concludes that the 88-9 QA Plan contains adequate requirements and planned and systematic controls that address each of the appropriate criteria of Appendix B to 10 CFR Part 50 in an acceptable manner, with the exception of the open items listed below. With the resolution of these items, this QA requirements document can serve as an adequate framework for DOE/NV and its project participants to develope specific policies, plans, and procedures to implement the QA Program for the NNWSI Project.

The DOE and NRC staffs have discussed the open items and they are expected to be resolved in Revision 2 to the 88-9 QA Plan. With the implementation of the modifications to address these open items, the staff will find the 88-9 QA Plan fully acceptable.

5. OPEN ITEMS

1. 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.

2. 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.

3. 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.

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

5. The control of non-conformances generated by surveillances 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.

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

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3. U. S. Nuclear Regulatory Commission, "Quality Assurance Program Requirements (Design and Construction)," Regulatory Guide 1.28, Rev.3 1985.

4. ANSI/ASME, NQA-3 (Draft), "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories," 1988.

5. U. S. Nuclear Regulatory Commission, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, 1987.

6. U. S. Nuclear Regulatory Commission, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298, 1987.

7. U. S. Nuclear Regulatory Commission, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements," NUREG-1318, 1988.

8. U. S. Nuclear Regulatory Commission, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," NUREG-0856, 1983.