Department of Energy
Washington, DC 20585

AUG 15 1988

Mr. B.J. Youngblood, Chief
Operations Branch
Division of High-Level
Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Reference: 1) NRC Letter; J. Linehan to W. Purcell, dated August 25, 1986.
2) DOE Letter; R. Stein to B.J. Youngblood, dated January 20, 1988.
3) DOE Letter, R. Stein to B.J. Youngblood, dated May 19, 1988.

Dear Mr. Youngblood:

Enclosed for NRC staff review and approval is the NNWSI Quality Assurance Plan, NNWSI/88-9, Revision 1 (formerly NVO-196-17).

This document addresses the NRC comments discussed in the DOE/NRC Comment Resolution Meeting held July 8, 1988.

This Plan has been reviewed and approved at OCRWM-HQ by L. Barrett, Acting Director, Office of Quality Assurance. We would like to note that little revision of the Plan, if any, is likely to result from the completion and issuance of the OCRWM-HQ Quality Assurance Requirements document. This is consistent with OCRWM's July 7, 1988, commitment to maintain consistency between the NNWSI and OCRWM documents to the extent practicable, during the development of OCRWM's Plan. The development of the OCRWM Requirements document will ensure that the NRC GTP/NUREG guidance, and those controls from the draft ANSI/ASME Standard NQA-3, as deemed appropriate by OCRWM, are incorporated into the program.

We look forward to obtaining your approval of NNWSI/88-9, in order to provide a baseline for the WMPO QA Program in support of subsequent OCRWM Program activities.

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As requested at the July 7, 1988, QA meeting we have enclosed a paper which documents the basis for the NNWSI QA Plan's indicating that test control (criteria XI of 10 CFR 50 Appendix B) does not apply to scientific investigations and describes the approach to satisfying the intent of criteria XI in the performance of scientific investigations.

Should you have any questions, please contact Edward Regnier, of my staff at (202) 586-4590.

Sincerely,

Ralph Stein

Ralph Stein
Acting Associate Director for Systems
Integration and Regulations
Office of Civilian Radioactive
Waste Management

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Enclosure

APPLICABILITY OF THE REQUIREMENTS OF CRITERION 11.0
"TEST CONTROL," TO SCIENTIFIC INVESTIGATIONS

The NNWSI QA Plan (NNWSI/88-9) indicates that test control (Criteria XI) of 10 CFR 50, Appendix B, applies to engineered items but does not apply to scientific investigations. This paper is intended to document the Project's rational and approach to satisfy the intent of Criteria XI.

For engineered items the requirements of 10 CFR 50, Appendix B, will be met by implementation of ANSI/ASME NQA-1-1986. These requirements are supplemented in the NNWSI QA Plan (NNWSI/88/9), Section 11.0, "Test Control," buy the incorporation of guidance provided in the NRC Review Plan for QA Programs for Site Characterization of High Level Nuclear Waste Repositories.

The controls applied to scientific investigations are identified in Section III, Para. 1.0, of the NNWSI/88-9 document. The following comparison with the NRC Review Plan, Chapter 11.0, depicts how the requirements for the controls that are applicable to scientific investigations have been incorporated. Where appropriate, the requirements of ANSI/ASME NQA-1-1986 for control of tests have also been incorporated.

It is important to note that there are two basic kinds of documentation which can be used for 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 judgement or trial and error methods, or both, in their work. Alternatively, the technical implementing procedure system will generally be used when qualified technicians are performing repetitive work which does not include the use of professional judgement 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 strict sequence of actions, without endangering the validity of the results that will be obtained from the work. 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. The following indicates where the NRC Review Plan requirements are implemented for procedures and scientific notebooks.

NRC REVIEW PLAN REQUIREMENT 11.1

The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for (a) determining when a test is required or how

and when testing activities are performed , and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.

RESPONSE

The NNWSI Site Characterization Plan describes the program for scientific investigation. The work is further controlled in Section III, Para 1.1, by requiring the preparation of scientific investigation plans for individual activities.

It is not appropriate in most cases for individual procedures to address when a test or testing activities are performed. Scientific investigation activities cannot necessarily be scheduled as construction activities (e.g., take one concrete cylinder for every 50 C.Y. concrete poured). Procedures do, however, clearly define the sequence of steps to be performed for proper implementation.

Training requirements for site personnel are covered in Section II of the QAP. For both scientific notebooks (Para 1.6.4.1, 7th bullet) and technical implementing procedures (Para 1.6.2, 9th bullet) it is required that any special training or qualification requirements be clearly defined.

Section III, Para 1.9, and Section XVIII of the QAP define QA organization overview of scientific investigation activities.

NRC REVIEW PLAN REQUIREMENT 11.2

"Test plans and procedures are reviewed in accordance with the verification requirements in Section 3."

RESPONSE

This requirement is stated in Section III, Para 1.3 (for plans) and Para. 1.6.2 (for procedures).

NRC REVIEW PLAN REQUIREMENT 11.3

"The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified."

RESPONSE

This requirement is stated sin Section III, Para 1.6.4.1, 9th bullet (for scientific notebooks) and Section III, Para 1.6.2.2 (for technical implementing procedures).

NRC REVIEW PLAN REQUIREMENT 11.4

"Test procedures or instructions provide the following:

a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy."

RESPONSE

This requirement is stated in Section III, Para 1.6.2, 1st and 2nd bullets (for technical implementing procedures, with the notation that acceptance limits are to be supplied only if applicable). These requirements are not applicable to scientific notebooks since the end product of research or experiment is data which is used to establish acceptance limits.

b. "Instruction for performing the test."

RESPONSE

This requirement is stated in Section III, Para 1.6.2, 1st bullet (for technical implementing procedures). This requirement is not applicable to scientific notebooks since the purpose of experiment or research is to establish methodology.

c. "Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage."

RESPONSE

For scientific notebooks the applicable portions of this requirement are stated in Section III, Para 1.6.4.1 and for technical implementing procedures in Section III, Para. 1.6.2, 3rd bullet.

d. "Mandatory inspection hold points (as required).

RESPONSE

This requirement is stated in Section III, Para. 1.6.2, 4th bullet (for procedures), with the clarification of "mandatory verification points," as inspections are not applicable to scientific investigation. This requirement is not applicable to scientific notebooks since at that phase of research, the methodology of process is not established.

e. "Acceptance and rejection criteria, including required levels of precision and accuracy."

RESPONSE

This requirement is stated in Section III, Para 1.6.2, 5th bullet (for procedures). This requirement is clarified by also adding that accept/reject criteria means that 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 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. This requirement is not applicable to scientific notebooks as during this phase of research acceptance/rejection criteria are being developed.

f. "Methods of data analysis."

RESPONSE

For technical implementing procedure this requirement is stated in Section III, Para 1.6.2, 7th bullet. This requirement is not applicable to scientific notebooks as data is the end product.

g. "Methods of documenting or recording test data and results".

RESPONSE

This requirement is stated in Section III, Para. 1.6.2, 6th bullet (for technical implementing procedures). It is not applicable to scientific notebooks as the activity methodology has not been established at this point. Therefore, the data or its format cannot be readily determined.

h. "Provisions for assuring test prerequisites have been met."

RESPONSE

This requirement is stated in Section III, Para 1.6.2, 8th bullet (for technical implementing procedures) and Section 1.6.4.2, 2nd bullet (for scientific notebooks).

NRC REVIEW PLAN REQUIREMENT 11.5

"Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3."

RESPONSE

This requirement is stated in Section III, Para 1.9 and 1.11.