

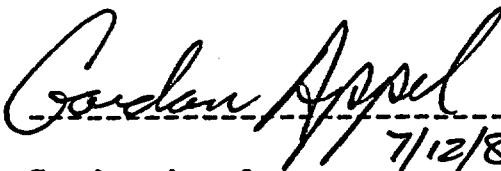
## SUMMARY OF MEETING ON NNWSI 88-9 QA PLAN

A meeting was held between representatives of the NRC and DOE on July 8, 1988 in the NRC's White Flint North building in Rockville, Md. The purpose of the meeting was to discuss the NNWSI Quality Assurance Plan, NNWSI 88-9, Revision 0 (formerly 196-17).

The participants also included representatives from the State of Nevada, General Accounting Office, Utility Nuclear Waste Management Group (EEI), and private industry. A list of attendees is attached as Enclosure 1.

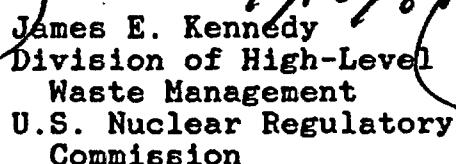
The NRC staff had 30 open QA items as a result of its review of the 88-9 document; DOE responses to the August 25, 1986 and November 21, 1986 NRC requests for additional information; NQA-3 draft standard for waste management QA; and the staff's internal draft of the revision to the June 1984 QA Review Plan.

At the meeting, the DOE provided responses to the NRC's open items (Enclosure 2) and amended responses to the DOE's previous resolutions on SOP-02-01 (Enclosure 3). Some of the major items that were resolved were QA GTP guidance on Peer Review, Qualification of Existing Data, and Q-List (NUREGs 1297, 1298, and 1318 respectively), software QA, and special processes. Based on information provided at the meeting, the staff indicated that one open item remained for the 88-9 review, the DOE rationale for including Criterion XI "Test Control" measures in their controls for Scientific Investigations. A justification was provided by DOE to the staff near the end of the meeting and will be reviewed by the staff. In addition, the staff will perform a detailed review of the other DOE responses and notify the DOE of any problems prior to the DOE formal submittal of a revised 88-9 to the NRC. Three open items were identified which do not affect the review of 88-9 but will be tracked on the master list of open items from the July 7, 1988 meeting. They are QA measures for study plans, NRC review of the OCRWM QA program, and QA measures for conceptual designs.



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ENCLOSURE 1

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JULY 8-1988 Mfg. For 88-9 w/ DOE, STATE, NRC et al.

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NNWSI/88-9 QUESTIONS

1. The DOE letter dated May 19, 1988 forwarding the NNWSI QA Plan 88-9 Revision 0, (QA Plan), indicates that the staff guidance in the Q-list, Peer Review, and Qualification of Existing Data GTP's (NUREG-1318, 1297, and 1298 respectively) will be incorporated into the OCRWM Quality Assurance Requirements document and the NNWSI plan revised as necessary to conform to the OCRWM document. These topics will remain as open items until either the positions are incorporated into the NNWSI plan or alternatives to these positions are provided by DOE and found acceptable by the NRC staff.

Notwithstanding the above, the NRC staff reviewed the QA Plan against the positions in the staff's technical positions. Peer reviews and Q-list development, as currently addressed in the QA plan, meet many of the staff positions. Several for Q-list are not addressed, but will be described in implementing procedures which the staff will review. The NNWSI requirements for qualification of existing data differ in many ways from the staff's guidance. All three of these open items need to be fully resolved for the staff to accept the QA Plan.

RESOLUTION

The subject NUREGs are considered applicable and will be specifically referenced in the NNWSI QA Plan, NNWSI/88-9, Rev. 1. The following changes to NNWSI/88-9 will be made:

- 1) Section II, page 2, Para. 1.4, 3rd sentence will be revised to read: "Requirements applicable to this activity shall be consistent with NUREG-1298 (February 1988)." Appendix G will be deleted.
- 2) Section II, page 3, para. 1.5.2, 2nd sentence will be revised to read: "This procedure shall meet the requirements of NUREG-1318 (April 1988)."
- 3) Section III, page 13, para. 40~~(D)~~. A new sentence will be added after the first sentence which reads: "Peer reviews shall meet the requirements of NUREG-1297 (February 1988)." The remainder of para. 4.0 will remain the unchanged.

It should be noted that future revisions of NUREGS 1297, 1298 and 1318 will not be imposed upon DOE without completion of the appropriate review/comment process.

2. Our letter of August 25, 1986 had a general comment that Level I, as defined by NNWSI, excluded the waste package. NNWSI appears to have addressed this concern, but some ambiguity still remains in the QA Plan. Page v states that "the definition of QA Level I was modified in Section II, ¶ 2.2.2.1 and Appendix A to avoid the presumption that items and activities associated with the waste package would not be QA Level I." Section 2.2.2.1 still does not conform with the language in NUREG-1318 and as a result, is still ambiguous regarding the inclusion of the waste package on the Q-list. In particular, this section states that engineered and natural barriers which "inhibit" the release of radionuclides are on the Q-list. The principle function of the waste package is to "contain" waste for period of 300-1000 years. It is not clear whether this different wording would have an effect on the inclusion of the waste package on the Q-list.

The staff suggests that in revising the QA Plan to conform to NUREG-1318, DOE either use the exact wording in that position or provide acceptable alternatives.

#### RESOLUTION

This item is no longer applicable based on the resolution of Item #1. NNWSI/88-9, Rev. 0 will be revised for consistency with NUREG-1318. The Introduction and Sections I, II and III of NNWSI/88-9 will be revised accordingly. This revision will be reflected in Revision 1 to the NNWSI QA Plan.

3. In a letter to DOE dated November 13, 1987, the staff identified software QA as an area where requirements are still being developed by the nuclear industry, DOE and NRC. The QA Plan will need to be revised at a later date as nuclear consensus standards are completed (e.g., NQA-2 and/or NQA-3), or as internal DOE groups, such as the Technical Code Coordinating Group, define internal DOE practices.

The NNWSI plan has failed to include the general guidance on software QA from Section 3.1 of NQA-1 Supplement 3S-1 (Enclosure 1). The staff recommends that it be included in the QA Plan.

#### RESOLUTION

The NNWSI QA Plan, NNWSI/88-9, Section III will be revised and a new Appendix will be added to address this issue. (See attachment). The attachment shall be modified as follows:

- 1) delete "with the level of commercial support available."
- 2) put a period (.) after ...of the software.
- 3) Add following sentence: 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.

## SUPPLEMENT 3S-1 SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL

### 1 GENERAL

This Supplement provides amplified requirements for design control. It supplements the requirements of Basic Requirement 3 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

### 2 DESIGN INPUT

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. 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. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.

### 3 DESIGN PROCESS

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled.

Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall:

(a) be relatable to the design input by documentation in sufficient detail to permit design verification; and

(b) identify assemblies and/or components 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 and/or testing 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.

#### 3.1 Design Analyses

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.

(a) Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

(1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

(2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.

(b) Documentation of design analyses shall include (1) through (6) below:

(1) definition of the objective of the analyses;  
 (2) definition of design inputs and their sources;

(3) results of literature searches or other applicable background data;

(4) identification of assumptions and indication of those that must be verified as the design proceeds;

(5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem;

(6) review and approval.

#### 4 DESIGN VERIFICATION

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish

the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this Standard.

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.

##### 4.1 Extent of Design Verification

The extent of the design verification required is a function of the importance to the 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 this Standard, 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 standard 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.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

##### 4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.



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. Cursory supervisory reviews shall not satisfy the intent of this requirement. 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 MANAGEMENT PROJECT OFFICE REVIEW

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.

### 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 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."

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## 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:

- o Definition of the objective of the analysis.
- o Definition of design input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data.
- o Identification of assumptions and indication of those which require verification as the design proceeds.
- o 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.
- o 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.

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## 2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES

Design information transmitted across interfaces shall be documented and controlled. 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 WMPD. 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 XVII 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 and with the level of

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commercial support available. Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the software 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:

- o 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.
- o 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.
- o Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.
- o Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
- o Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analyses.
- o 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.

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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 the 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 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.

3.1.7 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.

3.1.8 Procedures for determining the applicability of requirements and managing interfaces involving software, documentation, configuration management, change, qualification, verification, and validation, administratively at the Project level, are contained in the NNWSI Project Administrative Procedures Manual.

## 3.2 DOCUMENTATION OF COMPUTER SOFTWARE

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

- o Software requirements specification;
- o Software design and change documentation;
- o Description of mathematical models and numerical methods;
- o Software verification and validation documentation;
- o User documentation;
- o Code assessment and support;
- o Continuing documentation and code listings; and
- o 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 this software and other computer software used on the NNWSI Project.

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### 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

The WMPO retains the authority and responsibility to initiate peer reviews.

#### 4.1 APPLICABILITY

The requirements of the following paragraphs are applicable to all peer reviews that are initiated or conducted by the WMPO.

#### 4.2 GENERAL REQUIREMENTS

Peer reviews are required for activities that support a license application and involve use of data collection or analysis procedures and methods that are untried or beyond the state of the art or where detailed technical criteria and requirements do not exist or are being developed. Other instances where a peer review should be considered in lieu of a technical review include situations in which:

- o Analytical modeling techniques are (or will be) applied to a range of conditions outside of their normally accepted boundaries.
- o Data collection results are not predictable with a high degree of certainty.
- o Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- o Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- o Results of tests are not reproducible or repeatable.
- o Data or interpretations are ambiguous.
- o Data adequacy is questionable, i.e., data may not have been collected in conformance with an established QA program.

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## 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 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:

- o Reduce the likelihood of defects entering executable code during development.
- o Ensure that the end product answers the requirements of its intended application.
- o 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 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. Individuals or organizations involved in the development and maintenance of computer software shall have in place written policies and procedures that shall assure that the requirements of this part are implemented in a consistent and systematic manner.

## 3.0 TERMS AND DEFINITIONS

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

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## 4.0 SOFTWARE LIFE CYCLE

Individuals or organizations implementing software development activities shall adhere to a software life cycle model that requires that software development 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. Verification and/or validation of computer software is 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 involves activities (i.e., iterations of tests and runs) to arrive at a final product. It is not required to document all of these activities performed to satisfy the software developer. The results of this stage shall, however, form the input to a verification and/or validation plan that shall be documented, reviewed, and approved prior to independent tests. 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 before succeeding phases can begin. 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:

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- o The software products to which it applies.
- o The organizations responsible for software quality and their tasks and responsibilities.
- o Required documentation.
- o Standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.
- o The required software reviews.

4.1.2 Regardless of the life cycle model used, the following requirements shall apply as interpreted and defined by the 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:

- o A format and language that is understood by the programming organization and the user.
- o Enough detail to allow for objective verification.
- o Adequate definition to provide for the response of the software to all realizable classes of input data.
- o 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:

- o The generation of design-based test cases.
- o The review and analysis of the software design.
- o The verification of the software design.

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#### 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:

- o The possible modification of test cases necessary due to design changes made during coding.
- o 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:

- o The evaluation of the completed software to assure adherence to the requirements.
- o 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 Section 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 in the Verification and Validation Report.

### 5.1 VERIFICATION

Verification activities shall be integrated into all 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 at the end of the software development cycle 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, including an evaluation of the degree of validity of the model. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. The results of the validation shall be reported in the Verification and Validation Report.

## 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.

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### 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:

- o Uniquely identifies each configuration item or version number.
- o Identifies changes to configuration items by revision.
- o Places the configuration item in a relationship with other configuration items.
- o Provides the ability to reconstruct the configuration of the software from the requirements phase up to the present time.

### 6.2 CONFIGURATION CHANGE CONTROL

A proposal for changes to baseline software shall be formally documented. This documentation shall contain a description of the proposed change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The proposal shall 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.

### 6.3 CONFIGURATION STATUS ACCOUNTING

The information that is needed to manage configuration control of software 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

The following is the minimum acceptable documentation of computer software developed or modified for use on the NNWSI Project. It follows the phases of the software life cycle. Additional documentation may also be identified in the software quality assurance plan for each NNWSI Project participant or software project.

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## 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:

- o **Functionality** - the functions the software are to perform.
- o **Performance** - The time-related issues of software operation such as speed, recovery time, response time, etc.
- o **Design constraints imposed on implementation** - any elements that will restrict design options.
- o **Attributes** - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.
- o **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:

- o A description of the major components of the software design as they relate to the requirements of the software requirements specification.
- o A technical description of the software with respect to control flow, data flow, control logic, and data structure.
- o A description of the allowable and tolerable ranges for inputs and outputs.
- o The design described in a manner that is easily traceable to the software requirements.
- o Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.
- o Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

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### 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 shall be the basis for the software Verification and Validation Plan.

### 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 at the end of the development cycle. 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:

- o Program considerations, options, and initialization procedures.
- o Anticipated error situations and how the user can correct them.
- o Internal and external data files, their input sequence, structures, units, and ranges.
- o 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 prior to proceeding to the next development phase. 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.

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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, consistent, and formatted to provide traceability of requirements throughout the development cycle. 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 and concludes in review and approval of the verification and validation plan.

### 8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW

The software verification and validation review is an evaluation of the adequacy of completed software verification and validation activities and concludes in review and approval of the Verification and Validation Report.

### 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 shall assure that, as a minimum:

- o Defects are documented and corrected.
- o Defects are assessed for criticality and impacted as previous applications.
- o Corrections are reviewed and approved before changes to the software configuration are made.
- o 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

Requirements 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. The software shall be used only for those applications for which the documentation is complete.

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 in the user's manual 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.

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### 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 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 shall be included in documentation of technical calculations performed and shall 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.

4. The QA Plan indicates that Appendix B to 10 CFR Part 50 criteria IX (special processes), X (inspections), XI (test control) and XIV (inspection test and operating status) apply only to engineered items and not to scientific investigations. No rationale is provided for such a practice in the plan or in response to the NRC staff's RAI of August 25, 1986. This rationale should be furnished to the NRC staff for review.

RESOLUTION

- 1) Criterion IX. Special Processes. No changes to NNWSI/88-9 are required. The NRC agrees with the DOE rationale for this deviation. (See attachment for rationale) No further action required.
- 2) Criterion X. Inspection. The NRC is presently evaluating the DOE rationale for this deviation. (See attachments for DOE rationale and proposed revisions to NNWSI/88-9 to add additional requirements to Section III relative to verification activities associated with scientific investigations).
- 3) Criterion XI. Test Control. The NRC will evaluate the attached rationale for this deviation.
- 4) Criterion XIV. Inspection, Test, and Operating Status. The NRC is presently evaluating the DOE rationale for this deviation. (See attachment)

## SCIENTIFIC INVESTIGATIONS AND SPECIAL PROCESSES

### PURPOSE

The term "special" processes historically has been applied to processes used to produce items that are physical structures. The quality of the results of such processes (e.g., welding) may be uncertain and highly dependent on the mechanical or interpretive skills of the individual performing the work. For these reasons, additional controls were placed on the conduct of such work, e.g., the requirements for the procedure to be used being subjected to added tests and the individual being tested to provide additional confidence in the skills of the worker. The predictable results of such "special" process controls provides adequate confidence and reasonable assurance that the process, when applied, will provide an end product meeting the original design intent.

In contrast, processes used in scientific investigations focus on the controlled collection, preparation and analysis of data; the results of which are intended to meet the licensing requirements for a geologic repository as specified in 10CFR60. This paper discusses the nature of processes in scientific investigations, the distinction between traditional special processes and describes the controls used to assure the quality of the data gathered through the use of such processes.

### DISCUSSION

Scientific investigations involve a large number of different processes, both laboratory and field, directed to the collection and analysis of data derived principally from the natural environment in and around Yucca Mountain. This includes studies of the waste package environment. There are at least four parts to any scientific investigation; the collection of data, the preparation of data, its analysis and its interpretation. All of these activities are controlled processes which receive appropriate reviews and approvals as required by the quality program. We focus in this report on the first three activities since these are the ones most likely to be interpreted as involving special processes.

The scientific studies include a wide range of activities some of which are:

1. Cutting and retrieving core from boreholes;
2. Waxing core;
3. Identifying the minerals in a sample of tuff through x-ray diffraction analysis of a powdered specimen;

ENCLOSURE 2

4. Identifying minerals in a sample of tuff using thin section analysis;
5. Preparing and analyzing geophysical logs from a borehole;
6. Determining ground water level through monitored boreholes;
7. Determining the chemistry of pore waters extracted from a core; and
8. The shaping of a piece of core for resistivity or induced polarization measurements.

This is a typical list and is not all inclusive, however, these scientific investigations utilize various analytical instruments which measure some parameter(s). The main variable is the material and it is the variability in some parameter or subset of parameters that is the object of the analysis. Note that because most of this material is natural we do not know in advance the parameters and their variability. The instruments used in analyses provide information (output) due to a specific response between some input of energy and the material being examined. The output is the results of a set of physical and chemical laws that govern the interaction between the input energy (e.g., x-ray beam of some intensity) and the material (e.g., a mineral).

Theoretical and empirical evidence of the adequacy of these analytical instruments (with their associated procedures) to produce the desired results are established in a number of ways, principally through appropriate calibration of the instrument and through correlation with existing scientific literature. Given that the analysis is performed correctly, we are confident that the results reflect the parameter we want to measure because there is a large body of literature which supports our reading of the output. Further, this body of published support was obtained through controlled laboratory processes utilizing calibrated equipment and has broad acceptance throughout the scientific community. Fundamentally, it is the mass of technical literature describing known responses of material to known physical and chemical laws that gives us confidence in our results.

The criteria in 10 CFR 50, Appendix B, represents an adequate set of controls for the instrumental analysis used in scientific investigations without the need to categorize such processes as special. Sections of the QA Plan which are applicable to the topic of this report are:

Section II: QA Program - Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description.

**Section III: Scientific Investigation and Design Control -** Criteria for the planning, review/approval, and performance of scientific investigations are prescribed. Scientific notebooks and/or technical implementing procedures are used for describing how the work is to be done and for documenting the activity. Surveillances of scientific investigations are conducted to ensure that procedures are followed and documented.

**Section IV: Procurement Document Control -** Technical requirements for equipment and services used in data collection, preparation and analysis are adequately documented.

**Section V: Instructions, Procedures, Plans and Drawings -** Activities affecting quality shall be prescribed and performed in accordance with documented instructions, procedures, plans or drawings. A technical review of the documents used to implement the activities is required.

**Section VI: Document Control -** applicable current documents are available at the location where they are to be used.

**Section VII: Control of Purchased Items and Services -** Measures are established to ensure that purchased material, equipment and services conform to the procurement documents.

**Section VIII: Identification, Control of Items, Samples and Documents -** Procedures shall be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use.

**Section IX: Control of Processes -** Measures shall be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means.

**Section XII: Control of Measuring and Test 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 specific periods to maintain accuracy within necessary limits.

**Section XIII: Handling, Shipping, and Storage -** Measures shall be established to control packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss or deterioration.

**Section XV: Control of Nonconforming Items --** Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use.

**Section XVI: Corrective Action -** A corrective action system is defined to ensure that significant conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical.

Section XVII: QA Records - Records that furnish documenting evidence of quality shall be specified, prepared and maintained in accordance with NNWSI Administrative Procedures.

Section XVIII: Audits - All NNWSI Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA Program and to determine their effectiveness. The audit program will be supplemented by independent surveillance activities.

It is important to recognize then that there are controlled processes governing the collection, preparation and analysis of data in scientific investigations. The interest is not in the sample per se, but in physical or chemical parameters obtained from the sample. Data is gathered from a sample the precise parameters of which are not known in advance. If the processes controlling the collection, preparation and analysis of the material are adequate and documented as having been followed during the activity by qualified scientists or technicians (Sections II, III and V), reasonable assurance that the data accurately represents the correct value(s) is obtained. To further ensure the quality of the work, instruments used in the data collection and analysis processes are calibrated (Section XII) before and after measurements are made.

While it is true that standards are included in the analysis of materials (e.g., standard tables for the identification of minerals from x-ray diffraction data), there are no standards for the sample itself. That is to say there may or may not be clay in the sample and one or more clay mineral species may be present. Similarly a technician may use standard solutions (National Bureau of Standards (NBS) Standards) to calibrate the recording instrument prior to a chemical analysis. This calibration indicates that the instrument is reading values within an acceptable range and sensitivity.

The preparation of many samples must meet certain standards, but these can be evaluated with objective tests the results of which are not solely dependent on the certification and/or qualification of the operator and the procedures. For example: thin sections must be cut to a thickness of 30 microns (evaluated by recognizing the appropriate birefringence "color" of the contained minerals in polarized light); core specimens in resistivity and induced polarization measurements must be shaped on a saw (shape is measurable) and waxed core wrapped at the drill site to preserve the contained volume of fluids (preservation determined by weighing the sample at the drill site and weighing it at the laboratory) illustrate this. In all of these examples the uncertainty about the quality of the data (i.e., does the sample measure up to standards) is very low.

Although there are some parallels between control of processes and special processes there are significant differences.

1. The examples cited in 10 CFR 50, Appendix B, and in NQA-1 of the application of special processes are focused on items that are to be a permanent part of a facility rather than the collection of data. Special processes as defined in Basic Requirement #9 are as follows: "Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

2. The quality of the resulting items is solely a function of the processes having been performed and tested by qualified personnel using qualified procedures. Since one cannot directly test for the quality of the item (e.g., an item undergoing welding), its quality can only be assumed predicated on the confidence that the material will, when subjected to the same process variables as those used during process qualification, yield the same material or chemical properties. It is necessary to establish the qualifications of the operator through some established requirements (e.g., a written certification test or a performance test).

The scientists and technicians performing scientific investigation are qualified on the basis of their academic record and/or work experience (Section II) prior to their appointment. Procedures in scientific investigations receive a technical review for adequacy and completeness (Sections II, III, and V). Quality is further ensured through calibration of the instruments used in data collection, preparation, and analysis (Section XII). Audits and surveillances are conducted to be sure that procedures are being followed and the work properly documented (Section XVIII).

3. The item to be incorporated as a permanent part of a facility must meet certain pre-established criteria, codes or standards. In special processes both the materials being used and the controlling variables on the process being applied to the materials are known quantities and are included in the industry wide standards or codes required for such activities.

The parameters for materials being studied in scientific investigations are not known in advance. The purpose of the investigation is to determine the characteristics of the material. Except for situations where the size, amount or shape (e.g., a 4-inch piece of whole core) of a sample is specified (and these are all measurable features) the sample itself cannot meet some predetermined acceptance criteria.

The evaluation of processes in scientific investigations involves several steps. Initially the purpose of the process (which may

consist of one or more technical procedures) must be detailed in the Scientific Investigation Plan (SIP) and the adequacy of the process determined through technical review. Individual technical procedures also receive a technical review. If a proposed process is beyond the state of the art, a peer review is utilized. These review processes are mechanisms for qualifying processes. A review of a process must determine whether the process is adequate for the purpose of the SIP. Adequate as used in scientific investigations means that the process addresses the issues detailed in the SIP and that there is sufficient confidence that the results generated by the process can be used in licensing. As part of the review process, the reviewers must determine if the controls specified in the 18 criteria of 10 CFR 50, Appendix B are adequately built into the technical procedure(s) to produce quality results (i.e., results in which there is a high degree of confidence that they are acceptable for use in licensing). Calibration of measuring equipment, confirmatory or corroborative measurements by independent processes, and the use of the 18 criteria exclusive of special processes appear to be sufficient to ensure quality results in scientific investigations.

#### SUMMARY

Processes in scientific investigations are oriented toward the collection and the analysis of data, not toward preparing an item for use as part of a permanent structure. Pre-established acceptance criteria for samples or for the results of data collection and analysis does not normally exist in scientific investigations. The main variable is the sample or material and it is this variability in some parameter or subset of parameters that is the object of an instrumental and/or chemical analysis.

Process controls which have traditionally been utilized where the product of an activity could be sensitive to the mechanical abilities of the worker (as in welding) or to the interpretative abilities (as in nondestructive examination) will not provide added assurance that the results of a scientific investigation will be substantially more accurate. There are many scientific processes used where the results do not depend on the ability or understanding of the process by the technician or scientist at all (e.g., automated ultraviolet spectroscopy).

The results of all scientific investigation processes used in the High-Level Waste Repository program depend on the technical abilities of the scientists and technicians to apply the laws of physics, chemistry, engineering and other sciences. This is supported by a very large volume of scientific data already in existence and accepted by the scientific community and regulatory bodies. The imposition of special process controls will not provide increased assurance that the results of a scientific investigation is more correct or accurate than those controls currently used.

## APPLICATION OF CRITERION 10 "INSPECTION"

It is the policy of the NNWSI Project that scientific investigations are conducted to discover and interpret the nature and extent of natural phenomena. It is important to emphasize the words "discover" and "interpret" when describing the goals of scientific investigations. Discovery is the process of acquiring knowledge that was previously unknown. Interpretation, of course, is the "...act of explaining the meaning of". Scientific investigations are unique in the sense that such activities do not have established acceptance criteria which may be used to verify conformance.

Predetermined acceptance criteria is an essential element in the conduct of inspections. Traditionally, inspections are performed to verify conformance of an engineered item to predetermined acceptance criteria. This same approach is inappropriate for verification of scientific investigations because such activities rely on discovery and the interpretation of those natural and physical laws of science that aid in the explanation of the phenomena. It follows that the requirements of Criterion 10, "Inspection" are not appropriate for use where scientific investigations must be controlled. However, controls are necessary.

The NNWSI QAP describes a set of quality assurance requirements for scientific investigations that when properly implemented provide a high degree of confidence that the results of such activities are accurate and complete. The approach given by the NNWSI QAP assures the following:

- a thorough plan of the investigation is prepared and approved
- a technical review of the plan is completed by the participant
- activities are governed by technical procedures or in instances where a high degree of technical expertise is necessary, the use of scientific notebooks is required
- computer programs are verified and validated
- interfaces, both internal and external to the investigations are identified and controlled
- surveillances, which include technical team members, are performed to verify compliance
- a close out verification is performed by the participant to assure adequacy and completeness

From the description of the controls given by the NNWSI QAP it is clear that scientific investigations are activities, not items. It is also clear that such controls are intended to capture the essence of an activity whose purpose is to discover and interpret.

## **PROPOSED CHANGES TO NNWSI/88-9 VERIFICATION ACTIVITIES**

The following changes are proposed for the NNWSI Project QA Plan, NNWSI/88-9, Section III in order to clarify verification activities related to scientific investigations:

Add new para. 1.8 as follows:

### **1.8 VERIFICATION OF SCIENTIFIC INVESTIGATIONS**

#### **1.8.1 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 and revisions.
- o Recording identification of the verifier and the results of the verification.

#### **1.8.2 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.

### 1.8.3 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 quality assurance organization shall overview and monitor the verification activity.

Renumber existing para. 1.8 and all subsequent paragraphs accordingly.

## Position Paper

### TEST CONTROL

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

Test controls applied to scientific investigative type work are identified in Section III of the QA Plan wherein the documentation system is described. The approach for this type of work is clearly different than for hardware (engineered items) where predetermined acceptance criteria can be stipulated during the work planning stage. During scientific investigation planning, it is recognized that both technical implementing procedures and notebooks or logbooks may be used for the documentation and control of the work. The use of technical procedures provide test methodology where it is known, however, the use of scientific notebooks are necessary where it is not known where the work will proceed. In some cases, the test procedure must be developed as the research proceeds.

The methodology of the scientific experiment requires that the equipment, personnel and calibration requirements normally applied be used. The primary difference is that the tests, search or experiment does not have a predetermined acceptance of conformance criteria. The work being performed produces a quantitative or qualitative result which may be used in other activities.

The characteristics to be determined do not meet the traditional definition for test control. For example, a sample may contain a number of elements, the magnitude of which is unknown. Therefore, the result of the activity is the determination of what the content is and the proportion of each element. The application of the test methodology would most likely be through the use of a technical procedure, however, the "conformance to acceptance criteria" does not apply. The end product, the identification of the elements and their magnitudes would be accepted based on the ability of the instrumentation to identify them and quantitatively report their magnitudes. These instruments would adhere to the normal calibration methods using reference standards traceable to the National Bureau of Standards.

The requirements for the identification of test requirements, characteristics to be tested, methods and documentation are identified regardless of whether the investigation is conducted using technical procedures, notebooks, logbooks or some combination.

The methodology employed requires a specific format for documentation which includes initial entries to provide a written record of the research or experiment. During the progress of the activity, additional entries are required daily or as appropriate detailing information or data to a degree sufficient that another competent individual could repeat the experiment. The final entries include the requirements for the signature of the experimenter and the signature of a competent technical reviewer. All changes in this documentation receives the same review and approval process as any other technical document. Where more than one participating organization is involved, the interface controls appropriate to the activity are identified and controlled. Normal surveillance of these activities are conducted.

APPLICABILITY OF CRITERION 14 "INSPECTION, TEST, AND OPERATING STATUS" TO  
SCIENTIFIC INVESTIGATION

Criterion 14 Inspection, Test, and Operating Status was developed for the commercial nuclear power plant industry to preclude inadvertent omission of required acceptance tests and inspections of complex systems structures and components prior to operation. Complex systems, such as the Residual Heat Removal system, could require dozens of different types of inspections (wiring, welds, relays hangers etc.) and tests (hydrostatic pressure meggar ect). The tracking of these individual acceptance tests and inspections and the determination of the acceptability of the as built product required a carefully monitored and controlled operation to assure final acceptability. This criterion also required, for reasons of safety, the tagging of individual valves, motor control centers, ect, to prevent inadvertent operation of the system prior to its completion and final acceptance.

Scientific Investigation field and laboratory activities do not require the degree of control that the complicated power plant activities for the following reasons:

- 1) Scientific Investigation activities are relatively simple in nature when compared to those of a nuclear power plant.
- 2) As the end product of Scientific Investigation is data, not a structure system or component, Inspections (Criteria 10 and acceptance testing (Criterion 11) are not applicable. Therefore the stationing of those criterion is not applicable.

The NNWSI project however, intends to meet the intent of Criterion 14, by the implementation of other quality assurance and technical requirements contained in the NNWSI QAP as follows:

- 1) For any scientific investigation activity that is critical or complex in nature, a formal documented readiness review will be held.
- 2) Data collection test planes and procedures are required to contain mandatory hold/surveillance points at key critical areas.
- 3) Quality Assurance and technical personnel performs in-process monitoring of data collection activities through supervisory review, surveillance and technical/quality assurance audits.
- 4) Anomalies and deficiencies occurring during data collection are documented evaluated, dispositioned and tracked until verification of final resolution.
- 5) Resultant data from Scientific Investigation activities is documented, analyzed and evaluated in accordance with the applicable requirements of Criterion 3 to assure its validity.
- 6) Final reports on data collection activities are subjected to a technical or peer review in accordance with the requirements of Criterion 3.

It is the position of the NNWSI project that these controls, while not directly invoking Criterion 14, meet its intent in assuring the acceptability and adequacy of data collected as a part of Scientific Investigation.

5. Page III-1, ¶ 1.1.1 of the QA Plan states that study plans will receive a technical, management and QA review, but does not describe any of the details of this review. In order to evaluate whether these controls are appropriate, this information should be furnished to the NRC staff.

RESOLUTION

The present language in NNWSI/88-9 is acceptable. The NRC believes that preparation of study plans should be a QA Level I activity. DOE disagrees. This issue will be carried as an "open item" on the DOE Master Open Item Listing. This item is considered closed for the purpose of the NNWSI QA Plan (88-9). No further action is required.

6. On February 11, 1988, the DOE furnished the NRC with a draft copy of the revised HQ/OGR Quality Assurance Plan (OGR/P-3) which included the Quality Assurance Requirements for the HLNWR Program, Revision E, dated February 5, 1988 and the Quality Assurance Program Description for the HLNWR Program, Revision C, dated February 5, 1988. The above noted documents were submitted to the NRC for information and comments were not provided to the DOE from NRC. When the revisions to these documents are completed, it is our understanding that the above documents will be formally submitted to the NRC for review and comment. DOE should assure that the HQ and NNWSI documents are consistent with each other. This topic will remain as an open item until the NRC staff completes its review of the above documents.

RESOLUTION

This items is informational in nature. This item is closed. No further action is required.



May 14, 1985

Edward T. Baker  
USNRC  
Washington, DC 20555

Subject: Section XI, Division 1 Inquiry - Referencing of SNT-TC-1A in Section XI, IWA-2300.

Item: BC83-176

Reference: Your letter dated March 23, 1983

Dear Sir:

Our understanding of the question in your inquiry, and our reply, are as follows:

Question: Does Section XI, Division 1, 1980 Edition, with Addenda through Winter 1981, requirement that personnel performing nondestructive examination be qualified with a written procedure prepared in accordance with SNT-TC-1A 1980, except as modified by IWA-2300, make the requirements of SNT-TC-1A 1980 mandatory rather than guidance, i.e., "shall" is inserted in place of the permissive "should"?

Reply: Yes. It is the intent of Section XI that "shall" is to be inserted in place of "should" in SNT-TC-1A 1980.

Very truly yours,

*Steve Weinman*

Steve Weinman  
Assistant Secretary, Boiler and Pressure Vessel Committee

SW/ak

### 3. AUDITS

Section 2, "Scheduling," of Supplement 18S-1, "Supplementary Requirements for Audits," requires audits to be scheduled in a manner that provides coverage and coordination with ongoing quality assurance program activities. The following guidelines are considered acceptable for scheduling audits:

#### 3.1 Internal Audits

Applicable elements of an organization's quality assurance program should be audited at least once each year or at least once during the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the activity being audited may be useful. The evaluation may include results of previous quality assurance program audits and the results of audits from other sources, including the nature and frequency of identified deficiencies and any significant changes in personnel, organization, or quality assurance program.

#### 3.2 External Audits

After the award of a contract, the applicant or licensee may determine, based on the evaluation conducted in accordance with Section 5.1 of Appendix 4A-1, that external audits are not necessary for procuring items that are (1) relatively simple and standard in design, manufacturing, and testing and (2) adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.

For other procurement actions not covered by the above exceptions, audits should be conducted as described below.

1. The applicant or licensee should either audit its supplier's quality assurance program on a triennial basis or arrange for such audit. In either case, the audit should be implemented in accordance with Supplement 18S-1 of ANSI/ASME NQA-1-1983. The triennial period begins when an audit is performed. An audit may be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a quality assurance program that has the required scope for purchases placed during the triennial period. If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements should be conducted, thus starting a new triennial period. If the supplier is implementing the same quality assurance program for other customers that is proposed for use on the auditing party's contract, the pre-award survey may serve as the first triennial audit if conducted in accordance with the requirements of ANSI/ASME NQA-1-1983. Therefore, when such pre-award surveys are employed as the first triennial audits, they should satisfy the same audit elements and criteria as those used on other triennial audits.

2. The applicant or licensee should perform or arrange for annual evaluations of suppliers. This evaluation should be documented and should take into account, where applicable, (1) review of supplied 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.

3. 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 should satisfy the needs of all of the purchasers, and the audit report should 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.

7. In paragraph 1.0 of the Introduction section of the QA Plan, ANSI/ASME NQA-1-1986 is listed as one of the source documents used by DOE/NV to establish the QA Plan requirements. The NRC staff has compared the QA Plan against ANSI/ASME NQA-1-1986 and have the following comments;
- A. The term "Audit" in Appendix of the QA Plan does not totally agree with the definition for Audit in ANSI/ASME NQA-1-1986. The NRC staff recommends adding the clarification whereby audits should not be confused with surveillance or inspection activities.
  - B. In Appendix D of the QA Plan, SNT-TC-1A, June 1980 is utilized and applied as requirements to NDT personnel covered by Appendix D. This is consistent with the intent of ANSI/ASME NQA-1-1986, Supplement 2S-2 which also uses the SNT-TC-1A, June 1980 document. The NRC, through Regulatory Guide 1.28, Revision 3, August 1985 endorsed ANSI/ASME NQA-1-1983, Supplement 2S-2 which used the 1975 edition of SNT-TC-1A. The NRC compared the 1975 versus the 1980 editions SNT-TC-1A and found the 1980 edition to have less requirements. The NRC through an inquiry to the ASME Boiler and Pressure Vessel Committee (See enclosure 2), obtained an interpretation that SNT-TC-1980 would be acceptable providing the "shall's" be inserted in place of "should." The NRC agrees with this interpretation and recommends DOE incorporate this into the QA Plan or provide acceptable alternatives.
  - C. ANSI/ASME NQA-1-1983 was endorsed by the NRC for nuclear power plants by Regulatory Guide 1.28, Revision 3, August 1985, "Quality Assurance Program Requirements (Design and Construction)." One of the regulatory guide positions (Enclosure 3) deals with NQA-1, Supplement 18S-1, "Supplementary Requirements for Audits." Additional information should be provided in the QA Plan to address this position.

#### RESOLUTION

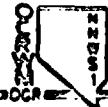
- 1) NNWSI/88-9, Rev. 0, Appendix A, Definition of Audit will be revised to read:

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, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
- 2) NNWSI/88-9, Rev. 0, Appendix D, para 1.1 is adequate as written, It states that SNT-TC-1A, June 1980 and supplements shall apply as requirements to NDE personnel.
- 3) NNWSI/88-9, Rev. 0, Section XVIII, para 1.2.1 and 1.2.2 will be revised to be consistent with the subject Regulatory Guide position.

8. On page II-10, paragraph 4.2 has been revised to state in part, "...the QA organization may participate in the actual conduct of the management assessments." By having the QA organization participate in the assessment, it appears to be contrary to the intent of what the NRC guidance in the Review Plan (Enclosure 4) requests i.e., an independent management assessment above or outside the QA organization. Additional information is needed in the QA Plan to describe how the independent management assessment can be performed with the QA organization participating in the assessment process.

RESOLUTION

On page II-10, para. 4.2 the last sentence will be deleted. (See attached)



## NNWSI PROJECT QA PLAN

N-QA-040  
1/87

### 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 DCRWM.

~~Although management above or outside the QA organization is responsible for the management assessment activity, the QA organization may participate in the actual conduct of the management assessments.~~

### 5.0 PERSONNEL SELECTION, INDOCTRINATION, & 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.

9. Paragraph 3.3. in Section XI of the QA Plan has been revised to specifically state that only those test plans and procedures used for qualification tests will be reviewed in accordance with the verification requirements defined in Section III for design verification. It is not clear as to why "qualification tests" have been added. Additional information is needed to explain why procedures for other type tests (proof, construction, operational, preoperational, prototype etc.) are not reviewed.

RESOLUTION

NNWSI/88-9, Rev. 0, Section XI, para. 3.3, first sentence will be revised as follows: "Test plans and procedures shall be reviewed in accordance with the verification requirements defined in Para. 2.4 of Section III of this document."

10. Paragraph 1.1 in Section XVII of the QA Plan states that, "All records (including superseded records) shall be retained for the NNWSI Project." At the March 18, 1988 meeting at NRC Headquarters in Rockville, Maryland, it was our understanding that this retention period would be for about 50 years. The NRC indicated that they will be working with the NQA-3 Subcommittee to develop a consensus position on what records need to be retained after closure, and for how long. Until such a position is developed, the records retention issue will remain an open item that will be resolved at a later date.

RESOLUTION

This item is informational in nature. This item is closed. No further action required.

11. At the March 13, 1988 meeting in NRC Headquarters in Rockville, Maryland, the DOE stated that certain information contained in the DOE responses to NRC's August 25, 1986 and November 21, 1986 requests for additional information, will be included in the DOE/NV Waste Management Project Office Quality Assurance Program Plan, WMPD/88-1. This will remain an open item until the NRC verifies these responses has been incorporated into the E&E-1 document. (i.e., RAI for 196-17 Question Nos. 5, 6, 10, 17, 21, 38, 43, 45, 46, and 51).

RESOLUTION

This item is closed with respect to the NNWSI QA Plan. It will be added to the DOE Master Open Items Listing.

12. Pg VI-1, ¶ 1.1, has been revised to describe certain documents not subject to document control system such as inspection reports, test reports, calibration reports, audit reports, etc. This was also discussed at the March 18, 1988 meeting. This exclusion of such documents from document control appears contrary to the definitions of QA Record and Document contained in Appendix A of the QA Plan.

"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 records); (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 (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."

"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."

#### RESOLUTION

NNWSI/88-9, Rev. 0, Section VI, para. 1.1 will be revised to delete the paragraph which begins: "Documents that are not subject to document control requirements..." (See attached) This action is appropriate since adequate document control measures exist in NNWSI/88-9.



## 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:

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

~~Documents that are not subject to document control requirements such as inspection reports, test reports, calibration reports, audit reports, etc., shall be subject to the records control requirements specified in Section XVII of this document.~~

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:

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
0	5/19/88	DOCUMENT CONTROL	VI-1

Additional Items to be Discussed at July 8, 1988 Meeting  
Which Require Clarification or Provided for Information Purposes

1. In the QAP (pg xxviii, ¶ 2.4, xxxi, ¶ 2.8.1), SAIC is identified as an integrating contractor doing safety-related work. It is not clear what QA program they are working to.

RESOLUTION

NNWSI/88-9. Introduction, page xxviii (last paragraph of 2.4) will be revised to read: "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 QAPP."

2. Pg. II-1 of the QAP identifies an "unusual occurrence." What is this and why isn't it identified in Appendix A for terms and definitions?

RESOLUTION

NNWSI/88-9, Section II, third paragraph of 1.0 which establishes requirements for unusual occurrence reporting will be removed in its entirety.

3. Pg. II-2, ¶ 1.4 deletes "primary data" in (2) places. Why has this been deleted and is the intent still to meet the definition of primary data in Appendix A?

RESOLUTION

The term "primary data" was removed since existing data is not considered to be "primary data" until qualified per NUREG-1298. This item is closed. No further action is required.

4. No action required but for future QAP revisions and submittals, NRC requests all changes be identified with vertical bars. There were many changes made in 88-9 that didn't have vertical bars to identify such changes.

RESOLUTION

This item is information in nature. This item is closed.

5. Pg. II-11, ¶ 5.1.4 of the QAP has deleted after "quality affecting activities" in the 1st sentence "that are complex in nature (i.e., assignments where it is deemed necessary to develop and demonstrate initial proficiency." Instead, after "quality affecting activities", the words, "if needed" have been added. Why this change?

RESOLUTION

It was clarified that this change was made for consistency with NQA-1, Basic Requirement 2 (next to last paragraph). Assurance that personnel are appropriately trained is accomplished via NNWSI/88-9, Section II, para. 5.1.2. This item is closed.

6. Pg V-1, ¶ 2.0 in 196-17 used to require an independent technical and QA review of all instructions, drawings, and procedures. 88-9 now states "A review of all...". Why the change?

RESOLUTION

NNWSI/88-9, Rev. 0, Section V, para. 2.0 will be revised to read: "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."

7. Pg XII-1, ¶ 2.1 has deleted, "The type, range, accuracy, and tolerance of a measuring device shall be specified in test and inspection documents. Why delete and where else is this covered?

RESOLUTION

NNWSI/88-9, Rev. 0, Section XII, para. 2.1 will be revised to add the following sentence after the 1st sentence: "The type, range, accuracy and tolerance of a measuring device shall be specified in test and inspection procedures."

8. Pg. XVIII-5, ¶s 2.1 and 2.3 have deleted portions pertaining to surveillance. Why and where else covered?

RESOLUTION

NNWSI/88-9, Rev. 0, Section XVIII, para. 2.1 and 2.3 will be revised to read:

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".

2.3 RECORDS

As a minimum, surveillance records shall identify the following:

- Item or activity.
- Date of surveillance.
- Name of individual performing the surveillance.
- Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.

- Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance.
  - Surveillance criteria.
  - Equipment used during the surveillance.
  - Results.
  - Acceptance statement.
9. In RAI #13 for 196-17, NRC requested a description to assure the design definitions between 10 CFR Part 50 Appendix B were compatible with 10 CFR Part 60 and the Atomic Energy Act of 1954. The response still is not clear as to what controls will be in place to assure the applicable QA requirements of Appendix B will be applied to each stage of design development, i.e., from conceptual design to final design.

#### RESOLUTION

NRC is presently evaluating the DOE rationale on the design phases.

10. The QA Plan states that design phases shall be assigned a Quality Assurance Level prior to execution in accordance with methods specified in the NNWSI Project Administrative Procedures Manual. The NRC staff will review those procedures to determine if they are consistent with NRC guidance and requirements.

#### RESOLUTION

NRC is presently evaluating the DOE rationale on the design phases.

11. In the process of the NRC participating in observation audits, we have had the opportunity to perform a brief overview of the DOE contractor QA Plans. We have noticed that the contractor QA plans tend to repeat the 196-17/8E-9, requirements verbatim, without providing the necessary details of how these requirements are implemented. The NRC staff realizes that certain of the details will be in the particular QA plan's implementing procedures. However, for the NRC staff to perform an acceptance review, we do look for a certain amount of detail to be in the QA Plan to assure that the regulatory framework for quality assurance is sufficiently described in order to form a licensing basis. This is particularly true in the area of organization where insufficient detail has been provided to identify the organizational elements functioning under the QA organization, their responsibilities, and authority. Also not described in sufficient detail, are all the organizational elements involved in performing quality affecting activities. Consequently, NRC encourages the DOE, prior to submitting their contractor QA plans to the NRC for review, that sufficient detail is provided in how the QA program will be implemented.

#### RESOLUTION

This item is informational in nature. This item is closed.

NEW ITEMS ASKED RESULTING FROM:

- o NQA-1
- o NQA-3
- o Draft R Plan

1. NQA-3, Draft 3, Revision 1, has what the NRC staff believes an acceptable section on corrective action (Section 16, Enclosure 5). It contains provisions which address trend analysis, reporting and resolving quality problems, and recurring quality problems. Although not required, the NRC staff recommends DOE look at this section for inclusion into their QA plan.

Similarly, NQA-3, Supplement 3SW-1 (Enclosure 6) contains provisions which address supplementary requirements for design data control. The 1984 NRC High-Level Waste Review Plan did not address this subject at the same level of detail. Consequently, the NRC also recommends DOE look at this section for possible inclusion into their QA Plan.

RESOLUTION

DOE will consider this item during future revision of NNWSI/88-9. There is no impact on NNWSI/88-9, Rev. 0. This item is closed. It should be noted that NRC is not suggesting endorsement of NQA-3 but simply suggesting that DOE consider these items.

## 16 CORRECTIVE ACTION

The provisions of NQA-1 Basic Requirement 16 shall apply, with the following additions, modifications, and amplifications.

### 16.1 TREND ANALYSIS

Trend Analysis shall be performed to the following requirements:

(a) Audit reports, surveillance reports, quality deficiency reports and related documents shall be analyzed to identify quality trends significant to quality. Trend analysis shall be performed in a manner and at a frequency that assures quality trends are identified and evaluated for root cause, effect on product or service, and for appropriate action.

(b) Trends determined to be significant to quality shall be reported to the organizations responsible for corrective action.

### 16.2 REPORTING AND RESOLUTION OF QUALITY PROBLEMS

Significant quality problems and conditions which adversely affect quality shall be identified, reported and

corrected in accordance with the following requirements:

(a) Specific criteria shall be developed for identifying significant quality problems, unusual occurrences and adverse conditions.

(b) Management information, including lessons learned from significant quality problems, unusual occurrences and adverse conditions, shall be routinely disseminated to all affected organizations.

(c) Existing, developing, or potentially out-of-control quality conditions shall be promptly reported to upper management for evaluation and action.

(d) Upon discovering or receiving notification that a significant quality problem, unusual occurrence or adverse condition exists, the following actions shall be taken:

- (1) Take timely actions to remedy the specific condition.
- (2) Determine causative factors.
- (3) Take appropriate action to prevent recurrence including review, evaluate, and revise controls if necessary.

- (4) Assess and document impact on completed work.

### 16.3 RECURRING QUALITY PROBLEMS

For recurring quality problems where corrective actions have not been effective, management, as needed, shall:

- (a) Determine the events leading to the quality problem's occurrence;
- (b) Develop an understanding of the technical and work activities associated with the quality problem;
- (c) Ascertain the quality problem's generic implications;
- (d) Determine the extent to which similar quality problems, or precursors to the problem, have been recognized by the responsible organization, the effectiveness of any corrective actions that were taken, and recognition of any generic implications and impacts on completed work;
- (e) Consider stopping work associated with the applicable activity; and
- (f) Recommend remedial actions that can be taken by the responsible organization to preclude recurrence.

### 17 QUALITY ASSURANCE RECORDS

The provisions of NQA-1 Basic Requirement 17 and Supplement 17S-1 shall

apply, with the following additions, modifications, and amplifications.

#### 17.1 SAMPLES

For a nuclear waste repository, QA records include geotechnical samples, or other materials that support data.

#### 17.2 REFERENCE RECORDS

Documents and samples referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, national codes and standards, etc., shall be retrievable from the QA records system.

#### 17.3 CLASSIFICATION OF RECORDS

In lieu of classifying QA records as defined in Supplement 17S-1 Paragraph 2.7, QA records for nuclear waste repositories shall be classified as Post-Closure, Lifetime, or Nonpermanent in accordance with the criteria specified below.

- (a) Post-Closure QA Records are those records that would likely be consulted by potential human intruders to identify the location of the geologic repository operations area, including the

**SUPPLEMENT 3SW-1  
SUPPLEMENTARY REQUIREMENTS FOR DESIGN DATA REQUIRING CONTROL.**

**1 GENERAL**

This supplement provides amplified requirements for control of data processing used in design development of engineered systems, characterization of natural systems, and performance assessment for high-level nuclear waste repositories. It supplements the requirements of NQA-1 Basic Requirement 3 and Supplementary Requirement 3S-1 when and to the extent specified by the organization invoking this Standard.

**2 APPLICABILITY**

This supplement applies to all phases of data processing which affect the quality of data. These phases involve planning, collection, recording, storage, transfer, reduction, analysis, validation, and reporting.

**3 PLANNING**

The intended use of the data shall be documented before collection as part of the planning for data processing. Any

alternate use of the data shall be evaluated for appropriateness and the justification documented. Planning shall assure compatibility of data processing with any conceptual or mathematical models used at each applicable stage. Planning shall establish provisions for data quality evaluation to assure data generated are valid, defensible, comparable, complete, representative, and of known precision and accuracy.

**4 DATA COLLECTION AND ANALYSIS**

Practices, techniques, equipment, and both manual and computerized methods used to obtain and analyze data shall be verified to assure they are technically sound, and selected properly. Controls shall be established for these processes to assure they are properly used and are free from tampering to maintain data integrity.

Data Collection and analysis shall be controlled by procedures of sufficient detail to allow the processes to be repeated. Where appropriate, quality control checks shall be performed using

## **ANSI/ASME NQA-3 Draft 3, Rev 1**

recognized methods such as replicate, spike, and split samples, control charts, blanks, reagent checks, replication of results, or alternate analysis methods.

### **4.1 Data Transfer and Reduction:**

Data transfer and reduction controls shall be established to assure data transfer is error free (or within a prescribed permissible error rate) to assure no information is lost in transfer and that the input is completely recoverable from the output. Examples of data transfer include: copying raw data from a notebook into a computerized data form or copying from computer tape to disk.

All processes which change either the form of expression or quantity of data, values, or number of data items (data reduction) shall be controlled by prescribed methods which allow for the validation of the conversion process.

### **5 DATA TRACEABILITY AND IDENTIFICATION**

All data shall be recorded so that they are clearly identifiable and traceable to the test, experiment, study, or other source from which they were generated. Identification and traceability shall be

maintained throughout the needed lifetime of the data.

### **6 DATA RECORDING, STORAGE, AND RETRIEVABILITY**

The method of data recording (e.g. laboratory and field notebooks, log books, data sheets, computerized instrumentation systems, etc.) shall be controlled to avoid data loss and permit retrievability. Controls shall be established to assure data integrity and security is maintained wherever data are stored. Controls shall prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, and access. Data shall be suitably protected from damage and unintentional destruction during their prescribed lifetime and readily retrievable from wherever stored.

### **7 CONTROL OF ERRONEOUS DATA**

Data that is determined to be erroneous, rejected, superseded, or otherwise unsuited for their intended use shall be controlled to prevent their inadvertent use. Controls shall include the identification, segregation, and disposition of inadequate data. The basis for the disposition of erroneous data shall be justified and documented.

2. NQA-1 Supplement 3S-1, Section 2.0, Design Input should be applied to existing data and qualified data prior to their use as inputs to design. (NRC Staff) (New SRP Pg III-6 #III-1.9)

REFERENCE: Page III-7, ¶ 2.2 of the QA Plan, "Design Input," does the DOE apply design input to existing data prior to their use as inputs to a design? It appears this paragraph in the QA Plan implies this.

MISSING FROM DOE RESOLUTION PACKAGE.  
HOWEVER, AT 7/8/88 MEETING, DOE INDICATED  
THEY WOULD INCORPORATE "SITE CHARACTERIZATION  
DATA INTO III-7, ¶ 2.2

3. Page III-7 ¶ III.1.11 of the new RP, NCA-1 Supplement 3S-2, Section 3.1, Design Analyses should be applied to design and data analyses. (NRC STAFF)

Page III-8 ¶ 2.3 of the QA Plan provides a description for design analysis. Does this include provisions to assure design analysis will be applied to design and data analysis?

#### RESOLUTION

NNWSI/88-9, Rev. 0, Section III will be revised to include a section on Scientific Investigation Data Interpretation and Analysis as follows:

#### 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.

#### 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.

4. Material: A substance or combination of substances, such as parts, components consumables, rock samples, and fluid samples. (Now RP definition)

Activities related to Identification and Control of Materials, Parts, and Components (17.1.8) are acceptable if:

Controls are established and described to identify and control materials (including consumables), parts, and components including partially fabricated subassemblies. The description should include organizational responsibilities. (Reactor SRP, item 8A)

Describe the QA controls that the DOE applies to consumables. (Backup information attached as Enclosure 7).

RESOLUTION

DOE will evaluate this item and provide a response to NRC. There is no present impact on NNWSI/88-9, Rev. 0.

JUN 24 1974

JUN 24 1974  
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Boyce H. Grier, AD/CSO:ED

**CONTROL AND IDENTIFICATION OF WELDING MATERIALS.**

In your letter of May 17, 1974, you noted that various opinions exist within Regulatory on the requirement for heat or lot traceability of welding filler material used in the fabrication and construction of nuclear plants and you requested that a clearly stated Regulatory position regarding this matter be established.

In this regard, Regulatory requirements for the identification of welding filler material are covered in Appendix B and Section 50.55a of 10 CFR Part 50.

Criterion VIII of Appendix B requires that measures be established for the identification and control of material, that these measures assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means throughout the fabrication, erection, installation and use of the item, and that these measures be designed to prevent the use of incorrect or defective materials.

Section 50.55a requires that components which are part of the reactor coolant pressure boundary meet the requirements of Section III of the ASME Boiler and Pressure Vessel Code or its predecessor (USAS B31.7, draft ASME Code for Pumps and Valves, etc.) dependent on the construction permit date of the reactor plant. Although several articles of Section III relate to the question, the controlling article is NB 4000, Fabrication and Installation Requirements, in which NE-4122 calls for welding materials to be identified and controlled so that they can be traced to each component and/or installation of a piping system, or else a control procedure be employed to ensure that the specified materials are used.

We believe that requirements of Appendix B and Section III of the ASME Code are consistent in that the use of "controlled procedures," and "appropriate means" other than "heat number" control are permitted to insure that the "correct," "specified," materials are used.

Enclosure 7

Boyce H. Crier

- 2 -

CEI 24 2A

It should be noted, however, that heat number control may be required for other reasons such as the need to maintain surveillance in the reactor vessel belt line region. Also, under some circumstances heat number control is the only practical method of assuring that the correct material is used. For example, in submerged arc welding the combination of flux and weld material used for production welding must be the same combination of materials that was used for the material qualifying tests.

It should be further noted that the meaning of control procedure as used by Section III of the ASME Code has not been established and is presently left to the discretion of the ASME survey team and the inspector. In this regard ASME is presently organizing a work group to prepare an appendix to Section III that would cover control procedure in detail. We propose that Mr. W. J. Collins of your staff, who is a member of the task group preparing ANSI Standard N45.2.17, "Quality Assurance Requirements for Control of Welding for Nuclear Power Plants," also serve on this ASME work group since both subjects are closely related.

In summary, Regulatory requirements for the identification and control of materials permit the use of means other than heat traceability for control of welding filler material. We propose to establish guidance on appropriate control procedures through cooperation with the ASME Boiler and Pressure Vessel Code at which time a clearly stated Regulatory position may be properly disseminated to the Licensees, A&E's, NSS suppliers and others as appropriate.

Robert R. Minogue, Deputy Director  
Directorate of Regulatory Standards

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

JAN 2 1975

*Billie*

OAB POSITION STATEMENT NO. 5

*(CPIER WELDING  
MATERIALS ATTACHED)*

**Subject:** Expendable and/or Consumable Items

**Policy:** Expendable and/or consumable items whose quality is necessary for the functional performance of safety-related structures, systems, and components shall also be classified as safety-related, and thus subject to applicable provisions of Appendix B to 10 CFR Part 50.

**Implementation:** Include in our requests for additional information on future PSAR, FSAR, or generic QA program reviews the following:

How do you assure the service quality of those expendable or consumable items necessary for the functional performance of safety-related structures, systems, or components?

Our acceptance should be based on documented provisions that considers the significance of these items to safety and establishes a requirement to check and document service quality at an appropriate time.

**Discussion:** The consideration of expendable or consumable items as safety-related arose in connection with fuel oil and lube oil for the emergency diesel generators. Appendix B states that " 'QA' comprises all those systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily inservice." Therefore, the quality of expendable or consumable items must be assured in an appropriate manner. Examples of this are as follows:

1. Weld rod whose quality or specification could affect the integrity of structures, systems, or components.
2. Tendon grouting and grease whose composition could affect long term corrosion of structural tendons.

3. Oil used in hydraulic snubbers and emergency diesel generators whose composition could affect functional performance.
  4. Fuel oil where quality could affect starting capability and functional performance of diesel generators.
  5. Boric acid where quality cannot be verified by normal operational parameters.

Richard H. Vollmer, Chief  
Quality Assurance Branch  
Division of Reactor Licensing

cc: D. J. Skovholt, RL  
QAB

5. Page II-6, ¶ 2.2.3.1 has inadvertently omitted "performance confirmation" as required by 10 CFR 60.151. This is correctly stated in the Introduction, pg xxii, ¶ 1.0.

RESOLUTION

NNWSI/88-9, Rev. 0, Section II, page 6, Para. 2.2.3.1, 4th sentence will be revised to read:

"QA Level I control and documentation must be applied to activities, including data collection, investigation, performance confirmation analysis, design, construction, fabrication, operation, decommissioning, or sealing when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard."

6. The QA Plan does not address in detail, what archival controls will be afforded for samples and the protection period during which additional information or analysis by the DOE, NRC or state may be needed, or during which natural, time-dependent deterioration processes inherent to the sample materials have not destroyed or substantially changed sample properties. The NRC staff recommends the DOE review the guidance for sample management in draft NQA-3 (Enclosure 8) and consider using such guidance for the waste management program. Note: The draft OCRWM revised QA Plan, 2/5/88 considers certain samples as QA records (Enclosure 9) and therefore, falls under the control of the QA record program controls. (New RP Pg XVII-12 ¶ XVII.5.1)

RESOLUTION

The present requirements of NNWSI/88-9 are adequate for sample control (Reference Section VIII, Part B). The NRC will review/comment on the Sample Management Plan when this document has been finalized. This item is closed.

apply with the following additions and amplifications.

## 8.1 SAMPLE MANAGEMENT

(a) Samples shall be identified and controlled in a manner consistent with their intended use. Such controls shall define the responsibilities, (including interface between organizations) for collection, identification, traceability and preservation of samples; including archival samples; for test allocation, and disposition of samples; and the generation of associated records.

(b) Samples shall be identified by placing the identification directly on the samples when possible, or on their container, or on a label or tag attached to the samples or their container. Sample identification shall be verified and documented prior to release for testing or analysis.

(c) Identification systems shall assure documented traceability of samples from the initial source, through final disposition. Measures shall be taken to preclude the use of samples that have lost their identity.

(d) Representative archival samples shall be maintained from difficult to

repeat sample collection activities such as principal bore holes.

## 9 CONTROL OF PROCESSES

The provisions of NQA-1 Basic Requirement 9 and Supplement 9S-1 shall apply for those activities affecting quality considered to be special processes, and shall be supplemented as follows.

(a) Factors to be considered in determining if a site characterization activity is a special process shall be defined and used as appropriate for each special process determination. Examples of special process evaluation factors are:

- (1) Direct inspection of the process or its results cannot be performed.
- (2) Results of the activity (i.e., product) cannot be tested to determine acceptability.
- (3) Process critical parameters exist which, if changed, require requalification of personnel, procedures, and/or equipment.
- (4) Personnel qualifications or training requirements are in excess of those normally required.

(1) Siting and Site Characterization Records

Drill hole testing procedures  
Drill hole drilling procedures  
Drill hole location surveys or maps  
Drill hole logs and samples  
Drill hole test results (including evaluations and interpretations)  
Geophysical logs and data  
Geophysical test results  
Self-potential (electrical) logs and data  
Caliper logs and data  
Radioactive logs and data (gamma, spectral-gamma, neutron-gamma)  
Lithologic logs and data  
Seismic and resistivity survey procedures  
Seismic and resistivity location surveys or location maps  
Seismic and resistivity logs and data  
Seismic and resistivity test results (including evaluations)  
Laboratory testing procedures  
Laboratory record books  
Laboratory testing data and data processing  
Geologic maps and supporting data  
Geologic library samples  
Geologic and soil sampling procedures  
Geologic test results  
In-situ test results  
Logs, maps, and geophysical data in support of subsurface correlation  
Trench logs and data (including location surveys, maps, and results)  
Aerial mapping records (photographs and interpreted overlays)  
Microseismic records (paper or magnetic tape)  
Remote imagery reports and results  
Groundwater and hydrologic regime maps and data (including results)  
Seismicity maps and supporting data  
Fault maps and supporting data  
Epicenter maps and supporting data  
Isopach maps and supporting data  
Model definition and development reports  
Model acceptance criteria reports  
Model verification reports  
Model exercise reports and results  
Hydrogeologic test procedures  
Hydrogeologic test results and data  
Atmospheric test procedures  
Atmospheric Test results and data  
Environmental study evaluations and results  
Site characteristics reference documents  
Test deviation records  
Unusual occurrence reports

7. Appendix B to 10 CFR Part 50 requires that tools, gages, instruments and other measuring and testing devices used in activities affecting quality are properly calibrated. This includes measures to assure that calibrating standards have a greater degree of accuracy than the standards being calibrated. NUREG-0800 provides guidance in this areas follows:

Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.

Calibrating standards have greater accuracy than standards 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 is identified.

In addition, the February 24, 1988 Draft 2 of IEEE 498 (Requirements for the Calibration and Control of Measuring and Test Equipment used in Nuclear Facilities) requies the following:

### 5.1 Adequacy of Reference Standards

Reference standards used for calibrating measuring and test equipment shall have calibration ranges, precisions and accuracies such that the measuring and test equipment and ultimately the plant equipment and ultimately the plant equipment can be calibrated and maintained within the required tolerances.

In general, the inaccuracy of the reference standards shall contribute no more than one fourth of the allowable measuring and test equipment tolerance. That is, reference standards utilized to calibrate measuring and test equipment must have an accuracy four (4) times greater than the measuring and test equipment being calibrated. This is depicted in Attachment A to this standard.

The rationale for deviating from these requirements shall be justified and documented.

The consideration of the above positions, we do not see any provisions in the QA Plan to assure calibrating standards used in the NNWSI Project have a greater degree of accuracy then the standards being calibrated. It would be preferable to include such a description in the 88-9 QA Plan since these requirement will be transmitted to all the DOE contractors.

RESOLUTION

NNWSI/88-9, Rev. 0, Section XII, para. 2.2 will be revised to add the following sentences:

"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 is identified.



ENCLOSURE 3

NNA.880624.0020

Department of Energy  
 Nevada Operations Office  
 P. O. Box 98518  
 Las Vegas, NV 89193-8518

*Recd 1/6/88*

JUN 23 1988

Ralph Stein, Acting Associate Director, Systems Integration & Regulations, HQ  
 (RV-30) FORS

AMENDED RESPONSE TO PREVIOUS RESOLUTIONS TO NUCLEAR REGULATORY COMMISSION  
 (NRC) COMMENTS ON NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT  
 STANDARD OPERATING PROCEDURE NNWSI SOP-02-01, REVISION 1

References: (1) Letter, Gertz to Kale, dtd. 1/5/88  
 (2) Letter, Youngblood to Stein, dtd. 3/24/88 — HQ. Memos, 3/16/88

This letter is to amend certain previous Waste Management Project Office responses to NRC comments on NNWSI Project SOP-02-01, Rev. 1, and to clarify certain aspects of the NNWSI Project Quality Assurance (QA) Program. The amendments are the result of a comment resolution meeting held with the NRC in Washington, D.C. on March 18, 1988. The amended responses are contained in Enclosure 1 to this letter and each supersedes our previous response to a particular comment in its entirety. Enclosure 2 provides the WMPO rationale for establishing the NNWSI Project position that special process requirements are not applicable to scientific investigations. Enclosure 3A contains proposed changes to Section III of the NNWSI Project QA Plan, NNWSI/88-9, Rev. 0, which are intended to clarify software QA requirements. Enclosure 3B is proposed to add Appendix H to the NNWSI QA Plan, NNWSI/88-9, Rev. 1, for software QA requirements. Enclosure 4 contains proposed changes to NNWSI/88-9, Rev. 0 to clarify verification activities related to scientific investigations. Enclosure 5 provides the NNWSI Project rationale regarding the assignment of Quality Levels to design activities.

If you have any questions or require additional information, please contact James Blaylock at PTS 544-7913.

WMPO:JB-2478

*Carl P. Gertz*  
 Carl P. Gertz, Project Manager  
 Waste Management Project Office

## Enclosures:

1. Amended Responses
2. Scientific Investigations and Special Processes
- 3A. Proposed Changes to NNWSI/88-9 Regarding Software QA
- 3B. Proposed addition of Appendix H
4. Proposed Changes to NNWSI/88-9 Regarding Verification Activities
5. The Assignment of Quality Levels to Design Activities

SAIC/T &amp; MSS

JUN 23 1988

CCF RECEIVED

## AMENDED RESPONSES

### 1) PERFORMANCE ALLOCATION

Reference WMPO: JB-813, dated 1/5/88  
Section III, Comment E

#### NRC Comment

Performance requirements should be specified for repository system components to support (1) identification of which items are important to safety and which items are important to waste isolation, (2) establishment of a graded QA approach, and (3) establishment of data gathering and analysis needs (3.2).

#### Revised WMPO Response

The preliminary requirements for each performance and design issue are found in the issue resolution strategy sections of the Site Characterization Plan. The NNWSI Project QA Plan, NNWSI/88-9, Rev. 0 Section II, Para. 1.5, establishes requirements for the formulation of a Q-List. A Q-List is a list of geologic, repository structures, systems, components, and activities that have been determined to be important to safety or waste isolation, or both, and are thereby subject to the highest quality assurance level (QA Level I) of the formal NNWSI Project QA program. Revision 0 of NNWSI/88-9 added a requirement that the Q-List procedure describe the Probabilistic Risk Assessment (PRA) techniques and performance allocation methods used for identifying Q-Listed items and activities.

### 2) PEER REVIEW

Reference WMPO: JB-813 dated 1/5/88  
Section III, Comment E

#### NRC Comment

For design or design activities that involve use of untried or state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review, should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants should be retained for needed expertise where required (3.8).

ENCLOSURE /  
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-2-

Revised VMPO Response

The NNWSI Project QA Plan NNWSI/88-9, Rev. 0, Section III, Para. 2.1.4 requires a peer review for design activities, including design output documents that involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed. Peer review is subject to the requirements of Para. 4.0, including subparagraphs of this same section of the NNWSI Project QA Plan. Revision 0 of NNWSI/88-9 added a requirement that 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 (Ref. Section III, Para. 2.4.6.4). Additionally, para. 4.0 of Section III of NNWSI/88-9 and all subparagraphs were modified to clarify peer review requirements and require all Participating Organizations and NTS Support Contractors to initiate a peer review process, when applicable. Appendix A of NNWSI/88-9, Rev. 0, defines peer review as a documented critical review performed by personnel who are independent of those who perform the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are indepth 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 the report go beyond existing state-of-the-art.

3) TECHNICAL AUDITS

Reference VMPO: JB-813, dated 1/5/88  
Section IV, Comment D

NRC Comment

TMPO AUIII

Both technical and QA programmatic audits should be performed to:

1. Provide a comprehensive independent verification and evaluation of procedures and activities affecting quality.
2. Verify and evaluate supplier's QA programs, procedures, and activities.

Revised WMPO Response

The NNWSI Project QA Plan, NNWSI/88-9, Rev. 0, Section XVIII, does not specifically differentiate between technical and QA programmatic audits. Para. 1.2 of this section requires that internal and external QA audits be scheduled in a manner that provides coverage and coordination with ongoing QA program activities. This paragraph also requires that audits be scheduled with a frequency commensurate with the status and importance of the activity. Para. 1.2.1 of this section requires that elements of an organization's QAPP be audited at least annually. In practice, the WMPO is conducting a program of technical audits as well as QA programmatic audits on a selected basis. In addition, the i.e. INTRODUCTION of NNWSI/88-9, Rev. 0, para 2.4 has been revised to clarify that the WMPO has sole responsibility for authorization of work and for management and technical direction of the activities of the Participant 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. Relative to Item 2 of this Comment, it is the WMPO position that requirements relative to evaluation of the supplier's QA programs are governed by the requirements of Section VII of NNWSI/88-9, which provides for other methods, besides audits, of verifying that the supplier's performance is adequate.

4) RECORDS RETENTION

Reference WMPO: JB-813, dated 1/5/88  
Section VI, Comment A

NRC Comment

Section 6.1.1 of the SOP identifies the scope of the document control program to include documents such as instructions, procedures, and drawings. The document control program also covers other types of documents such as procurement documents, specifications, reports (inspection, test, nonconformance, calibration, audit, design, NDE, surveillance, inventory, and corrective action), QAPPs manuals, computer software, certification, system descriptions, logs, etc. (6.1).

-4-

REVISED VMPO RESPONSE

NVO-196-17, Rev. 5, Section VI, adequately describes the scope of the document control program and establishes the following parameters for documents that need to be controlled: (1) documents containing or specifying quality requirements, and (2) documents that prescribe activities affecting quality. Although certain documents listed in this comment are subject to these requirements, such as procurement documents, specifications, design documents, etc., there are certain other documents listed that will not be subject to document control requirements (e.g., nonconformance reports, audit reports, surveillance reports, corrective action reports, logs, etc.). The current requirements for document control contained in NNWSI/88-9, Rev. 0, are consistent with NQA-1 requirements and adequately describe the bounds of the document control program. However, a revision was made to NNWSI/88-9, Rev. 0, Section VI, para. 1.1 to clarify that documents that are not subject to document control requirements such as inspection reports, test reports, calibration reports, audit reports, etc., shall be subject to the records control requirements specified in Section XVII of this document.

## SCIENTIFIC INVESTIGATIONS AND SPECIAL PROCESSES

### PURPOSE

The term "special" processes historically has been applied to processes used to produce items that are physical structures. The quality of the results of such processes (e.g., welding) may be uncertain and highly dependent on the mechanical or interpretive skills of the individual performing the work. For these reasons, additional controls were placed on the conduct of such work, e.g., the requirements for the procedure to be used being subjected to added tests and the individual being tested to provide additional confidence in the skills of the worker. The predictable results of such "special" process controls provides adequate confidence and reasonable assurance that the process, when applied, will provide an end product meeting the original design intent.

In contrast, processes used in scientific investigations focus on the controlled collection, preparation and analysis of data; the results of which are intended to meet the licensing requirements for a geologic repository as specified in 10CFR60. This paper discusses the nature of processes in scientific investigations, the distinction between traditional special processes and describes the controls used to assure the quality of the data gathered through the use of such processes.

### DISCUSSION

Scientific investigations involve a large number of different processes, both laboratory and field, directed to the collection and analysis of data derived principally from the natural environment in and around Yucca Mountain. This includes studies of the waste package environment. There are at least four parts to any scientific investigation; the collection of data, the preparation of data, its analysis and its interpretation. All of these activities are controlled processes which receive appropriate reviews and approvals as required by the quality program. We focus in this report on the first three activities since these are the ones most likely to be interpreted as involving special processes.

The scientific studies include a wide range of activities some of which are:

1. Cutting and retrieving core from boreholes;
2. Waxing core;
3. Identifying the minerals in a sample of tuff through x-ray diffraction analysis of a powdered specimen;

ENCLOSURE 2

4. Identifying minerals in a sample of tuff using thin section analysis;
5. Preparing and analyzing geophysical logs from a borehole;
6. Determining ground water level through monitored boreholes;
7. Determining the chemistry of pore waters extracted from a core; and
8. The shaping of a piece of core for resistivity or induced polarization measurements.

This is a typical list and is not all inclusive, however, these scientific investigations utilize various analytical instruments which measure some parameter(s). The main variable is the material and it is the variability in some parameter or subset of parameters that is the object of the analysis. Note that because most of this material is natural we do not know in advance the parameters and their variability. The instruments used in analyses provide information (output) due to a specific response between some input of energy and the material being examined. The output is the results of a set of physical and chemical laws that govern the interaction between the input energy (e.g., x-ray beam of some intensity) and the material (e.g., a mineral).

Theoretical and empirical evidence of the adequacy of these analytical instruments (with their associated procedures) to produce the desired results are established in a number of ways, principally through appropriate calibration of the instrument and through correlation with existing scientific literature. Given that the analysis is performed correctly, we are confident that the results reflect the parameter we want to measure because there is a large body of literature which supports our reading of the output. Further, this body of published support was obtained through controlled laboratory processes utilizing calibrated equipment and has broad acceptance throughout the scientific community. Fundamentally, it is the mass of technical literature describing known responses of material to known physical and chemical laws that gives us confidence in our results.

The criteria in 10 CFR 50, Appendix B, represents an adequate set of controls for the instrumental analysis used in scientific investigations without the need to categorize such processes as special. Sections of the QA Plan which are application to the topic of this report are:

Section II: QA Program - Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description.

Section III: Scientific Investigation and Design Control - Criteria for the planning, review/approval, and performance of scientific investigations are prescribed. Scientific notebooks and/or technical implementing procedures are used for describing how the work is to be done and for documenting the activity. Surveillances of scientific investigations are conducted to ensure that procedures are followed and documented.

Section IV: Procurement Document Control - Technical requirements for equipment and services used in data collection, preparation and analysis are adequately documented.

Section V: Instructions, Procedures, Plans and Drawings - Activities affecting quality shall be prescribed and performed in accordance with documented instructions, procedures, plans or drawings. A technical review of the documents used to implement the activities is required.

Section VI: Document Control - applicable current documents are available at the location where they are to be used.

Section VII: Control of Purchased Items and Services - Measures are established to ensure that purchased material, equipment and services conform to the procurement documents.

Section VIII: Identification, Control of Items, Samples and Documents - Procedures shall be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use.

Section IX: Control of Processes - Measures shall be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means.

Section XIII: Control of Measuring and Test 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 specific periods to maintain accuracy within necessary limits.

Section XIV: Handling, Shipping, and Storage - Measures shall be established to control packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss or deterioration.

Section XV: Control of Nonconforming Items -- Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use.

Section XVI: Corrective Action - A corrective action system is defined to ensure that significant conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical.

Section XVII: QA Records - Records that furnish documenting evidence of quality shall be specified, prepared and maintained in accordance with NNWSI Administrative Procedures.

Section XVIII: Audits - All NNWSI Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA Program and to determine their effectiveness. The audit program will be supplemented by independent surveillance activities.

It is important to recognize then that there are controlled processes governing the collection, preparation and analysis of data in scientific investigations. The interest is not in the sample per se, but in physical or chemical parameters obtained from the sample. Data is gathered from a sample the precise parameters of which are not known in advance. If the processes controlling the collection, preparation and analysis of the material are adequate and documented as having been followed during the activity by qualified scientists or technicians (Sections II, III and V), reasonable assurance that the data accurately represents the correct value(s) is obtained. To further ensure the quality of the work, instruments used in the data collection and analysis processes are calibrated (Section XII) before and after measurements are made.

While it is true that standards are included in the analysis of materials (e.g., standard tables for the identification of minerals from x-ray diffraction data), there are no standards for the sample itself. That is to say there may or may not be clay in the sample and one or more clay mineral species may be present. Similarly a technician may use standard solutions (National Bureau of Standards (NBS) Standards) to calibrate the recording instrument prior to a chemical analysis. This calibration indicates that the instrument is reading values within an acceptable range and sensitivity.

The preparation of many samples must meet certain standards, but these can be evaluated with objective tests the results of which are not solely dependent on the certification and/or qualification of the operator and the procedures. For example: thin sections must be cut to a thickness of 30 microns (evaluated by recognizing the appropriate birefringence "color" of the contained minerals in polarized light); core specimens in resistivity and induced polarization measurements must be shaped on a saw (shape is measurable) and waxed core wrapped at the drill site to preserve the contained volume of fluids (preservation determined by weighing the sample at the drill site and weighing it at the laboratory) illustrate this. In all of these examples the uncertainty about the quality of the data (i.e., does the sample measure up to standards) is very low.

Although there are some parallels between control of processes and special processes there are significant differences.

1. The examples cited in 10 CFR 50, Appendix B, and in NQA-1 of the application of special processes are focused on items that are to be a permanent part of a facility rather than the collection of data. Special processes as defined in Basic Requirement #9 are as follows: "Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

2. The quality of the resulting items is solely a function of the processes having been performed and tested by qualified personnel using qualified procedures. Since one cannot directly test for the quality of the item (e.g., an item undergoing welding), its quality can only be assumed predicated on the confidence that the material will, when subjected to the same process variables as those used during process qualification, yield the same material or chemical properties. It is necessary to establish the qualifications of the operator through some established requirements (e.g., a written certification test or a performance test).

The scientists and technicians performing scientific investigation are qualified on the basis of their academic record and/or work experience (Section II) prior to their appointment. Procedures in scientific investigations receive a technical review for adequacy and completeness (Sections III, IV, and V). Quality is further ensured through calibration of the instruments used in data collection, preparation, and analysis (Section XIII). Audits and surveillances are conducted to be sure that procedures are being followed and the work properly documented (Section XVIII).

3. The item to be incorporated as a permanent part of a facility must meet certain pre-established criteria, codes or standards. In special processes both the materials being used and the controlling variables on the process being applied to the materials are known quantities and are included in the industry wide standards or codes required for such activities.

The parameters for materials being studied in scientific investigations are not known in advance. The purpose of the investigation is to determine the characteristics of the material. Except for situations where the size, amount or shape (e.g., a 4-inch piece of whole core) of a sample is specified (and these are all measurable features) the sample itself cannot meet some predetermined acceptance criteria.

The evaluation of processes in scientific investigations involves several steps. Initially the purpose of the process (which may

consist of one or more technical procedures) must be detailed in the Scientific Investigation Plan (SIP) and the adequacy of the process determined through technical review. Individual technical procedures also receive a technical review. If a proposed process is beyond the state of the art, a peer review is utilized. These review processes are mechanisms for qualifying processes. A review of a process must determine whether the process is adequate for the purpose of the SIP. Adequate as used in scientific investigations means that the process addresses the issues detailed in the SIP and that there is sufficient confidence that the results generated by the process can be used in licensing. As part of the review process, the reviewers must determine if the controls specified in the 18 criteria of 10 CFR 50, Appendix B are adequately built into the technical procedure(s) to produce quality results (i.e., results in which there is a high degree of confidence that they are acceptable for use in licensing). Calibration of measuring equipment, confirmatory or corroborative measurements by independent processes, and the use of the 18 criteria exclusive of special processes appear to be sufficient to ensure quality results in scientific investigations.

#### SUMMARY

Processes in scientific investigations are oriented toward the collection and the analysis of data, not toward preparing an item for use as part of a permanent structure. Pre-established acceptance criteria for samples or for the results of data collection and analysis does not normally exist in scientific investigations. The main variable is the sample or material and it is this variability in some parameter or subset of parameters that is the object of an instrumental and/or chemical analysis.

Process controls which have traditionally been utilized where the product of an activity could be sensitive to the mechanical abilities of the worker (as in welding) or to the interpretative abilities (as in nondestructive examination) will not provide added assurance that the results of a scientific investigation will be substantially more accurate. There are many scientific processes used where the results do not depend on the ability or understanding of the process by the technician or scientist at all (e.g., automated ultraviolet spectroscopy).

The results of all scientific investigation processes used in the High-Level Waste Repository program depend on the technical abilities of the scientists and technicians to apply the laws of physics, chemistry, engineering and other sciences. This is supported by a very large volume of scientific data already in existence and accepted by the scientific community and regulatory bodies. The imposition of special process controls will not provide increased assurance that the results of a scientific investigation is more correct or accurate than those controls currently used.

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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. Cursory supervisory reviews shall not satisfy the intent of this requirement. 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 MANAGEMENT PROJECT OFFICE REVIEW

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.

### 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 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."

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## 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:

- o Definition of the objective of the analysis.
- o Definition of design input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data.
- o Identification of assumptions and indication of those which require verification as the design proceeds.
- o 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.
- o 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.

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### 2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES

Design information transmitted across interfaces shall be documented and controlled. 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 KAPD. 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 XVII 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 and with the level of

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## NNWSI PROJECT QA PLAN

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commercial support available. Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the software 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:

- o 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.
- o 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.
- o Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.
- o Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
- o Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analyses.
- o 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-0866, 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-0866 requirements.

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3.1.6 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 the 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 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.

3.1.7 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.

3.1.8 Procedures for determining the applicability of requirements and managing interfaces involving software, documentation, configuration management, change, qualification, verification, and validation, administratively at the Project level, are contained in the NNWSI Project Administrative Procedures Manual.

## 3.2 DOCUMENTATION OF COMPUTER SOFTWARE

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

- o Software requirements specification;
- o Software design and change documentation;
- o Description of mathematical models and numerical methods;
- o Software verification and validation documentation;
- o User documentation;
- o Code assessment and support;
- o Continuing documentation and code listings; and
- o 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 this software and other computer software used on the NNWSI Project.

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### 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

The WMPD retains the authority and responsibility to initiate peer reviews.

#### 4.1 APPLICABILITY

The requirements of the following paragraphs are applicable to all peer reviews that are initiated or conducted by the WMPD.

#### 4.2 GENERAL REQUIREMENTS

Peer reviews are required for activities that support a license application and involve use of data collection or analysis procedures and methods that are untried or beyond the state of the art or where detailed technical criteria and requirements do not exist or are being developed. Other instances where a peer review should be considered in lieu of a technical review include situations in which:

- o Analytical modeling techniques are (or will be) applied to a range of conditions outside of their normally accepted boundaries.
- o Data collection results are not predictable with a high degree of certainty.
- o Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- o Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- o Results of tests are not reproducible or repeatable.
- o Data or interpretations are ambiguous.
- o Data adequacy is questionable, i.e., data may not have been collected in conformance with an established QA program.

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## 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 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:

- o Reduce the likelihood of defects entering executable code during development.
- o Ensure that the end product answers the requirements of its intended application.
- o 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 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. Individuals or organizations involved in the development and maintenance of computer software shall have in place written policies and procedures that shall assure that the requirements of this part are implemented in a consistent and systematic manner.

## 3.0 TERMS AND DEFINITIONS

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

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ENCLOSURE 3B



#### 4.0 SOFTWARE LIFE CYCLE

Individuals or organizations implementing software development activities shall adhere to a software life cycle model that requires that software development 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. Verification and/or validation of computer software is 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 involves activities (i.e., iterations of tests and runs) to arrive at a final product. It is not required to document all of these activities performed to satisfy the software developer. The results of this stage shall, however, form the input to a verification and/or validation plan that shall be documented, reviewed, and approved prior to independent tests. 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 before succeeding phases can begin. 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:

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- o The software products to which it applies.
- o The organizations responsible for software quality and their tasks and responsibilities.
- o Required documentation.
- o Standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.
- o The required software reviews.

4.1.2 Regardless of the life cycle model used, the following requirements shall apply as interpreted and defined by the organization's 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:

- o A format and language that is understood by the programming organization and the user.
- o Enough detail to allow for objective verification.
- o Adequate definition to provide for the response of the software to all realizable classes of input data.
- o 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:

- o The generation of design-based test cases.
- o The review and analysis of the software design.
- o The verification of the software design.

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#### 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:

- o The possible modification of test cases necessary due to design changes made during coding.
- o 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:

- o The evaluation of the completed software to assure adherence to the requirements.
- o 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 Section 6.0.

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## 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 in the Verification and Validation Report.

### 5.1 VERIFICATION

Verification activities shall be integrated into all 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 at the end of the software development cycle 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, including an evaluation of the degree of validity of the model. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. The results of the validation shall be reported in the Verification and Validation Report.

## 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.

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### 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:

- o Uniquely identifies each configuration item or version number.
- o Identifies changes to configuration items by revision.
- o Places the configuration item in a relationship with other configuration items.
- o Provides the ability to reconstruct the configuration of the software from the requirements phase up to the present time.

### 6.2 CONFIGURATION CHANGE CONTROL

A proposal for changes to baseline software shall be formally documented. This documentation shall contain a description of the proposed change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The proposal shall 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.

### 6.3 CONFIGURATION STATUS ACCOUNTING

The information that is needed to manage configuration control of software 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

The following is the minimum acceptable documentation of computer software developed or modified for use on the NNWSI Project. It follows the phases of the software life cycle. Additional documentation may also be identified in the software quality assurance plan for each NNWSI Project participant or software project.

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## 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:

- o **Functionality** - the functions the software are to perform.
- o **Performance** - The time-related issues of software operation such as speed, recovery time, response time, etc.
- o **Design constraints imposed on implementation** - any elements that will restrict design options.
- o **Attributes** - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.
- o **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:

- o A description of the major components of the software design as they relate to the requirements of the software requirements specification.
- o A technical description of the software with respect to control flow, data flow, control logic, and data structure.
- o A description of the allowable and tolerable ranges for inputs and outputs.
- o The design described in a manner that is easily traceable to the software requirements.
- o Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.
- o Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

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### 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 shall be the basis for the software Verification and Validation Plan.

### 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 at the end of the development cycle. 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:

- o Program considerations, options, and initialization procedures.
- o Anticipated error situations and how the user can correct them.
- o Internal and external data files, their input sequence, structures, units, and ranges.
- o 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 prior to proceeding to the next development phase. 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.

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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, consistent, and formatted to provide traceability of requirements throughout the development cycle. 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 and concludes in review and approval of the verification and validation plan.

#### 8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW

The software verification and validation review is an evaluation of the adequacy of completed software verification and validation activities and concludes in review and approval of the Verification and Validation Report.

#### 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.

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

- o Defects are documented and corrected.
- o Defects are assessed for criticality and impacted as previous applications.
- o Corrections are reviewed and approved before changes to the software configuration are made.
- o 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

Requirements 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. The software shall be used only for those applications for which the documentation is complete.

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 in the user's manual 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.

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## 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 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 shall be included in documentation of technical calculations performed and shall 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.

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## **PROPOSED CHANGES TO NNWSI/88-9 VERIFICATION ACTIVITIES**

The following changes are proposed for the NNWSI Project QA Plan, NNWSI/88-9, Section III in order to clarify verification activities related to scientific investigations:

Add new para. 1.8 as follows:

### **1.8 VERIFICATION OF SCIENTIFIC INVESTIGATIONS**

#### **1.8.1 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 and revisions.
- o Recording identification of the verifier and the results of the verification.

#### **1.8.2 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.

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### 1.8.3 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 quality assurance organization shall overview and monitor the verification activity.

Renumber existing para. 1.8 and all subsequent paragraphs accordingly.

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## The Assignment of Quality Levels To Design Activities

### A Discussion of the NNWSI Approach

#### INTRODUCTION

The purpose of this paper is to present the principle and strategy employed by the NNWSI Project regarding the assignment of Quality Levels to design activities. The strategy described in the body of this paper was adopted for use within the NNWSI Project in May, 1986.

#### PRINCIPLE

The NNWSI Quality Assurance Plan (QAP) requires that Quality Levels be assigned to items and activities that affect quality. There is a very direct relationship between the design activity and items in the sense that the information generated by the design activity, such as the identity, function and interrelationships of items, is essential to the determination of the item's affect on quality. It follows that the design activity must be allowed to mature to a point where items are identifiable and their functions have been defined in order to arrive at a determination as to the item's affect on quality.

For this reason, the assignment of Quality Levels to the design activity must precede the assignment of Quality Levels to items.

#### STRATEGY

It is the policy of the NNWSI that the design activity be accomplished in phases. Each phase serves to narrow the scope of the activity until the effort converges to a definitive set or sets of items.

The initial phase of the design activity, the Conceptual Design Phase, is conducted to determine the range of alternatives worthy of further study. Efforts in this phase result in a broad definition of alternatives in each category of major design features. The Advanced Conceptual Design Phase follows the Conceptual Design Phase and is conducted to determine the preferred alternatives in each major design feature category. This phase involves the conduct of a comparative technical analysis of the alternatives in the Conceptual Design Phase. The License Application Design Phase follows the Advanced Conceptual Design Phase and is conducted to complete detailed analysis, drawings and specifications for use in procurement and/or construction. The last phase of design, the Final Procurement and Construction Design Phase occurs during procurement/construction and is conducted to accomodate necessary changes in the design output documents developed during the License Application Design Phase.

## **Page 2, Assignment of Quality Levels to Design Activities**

Similarly, the assignment of Quality Levels to the design activity is accomplished in phases based on a concept of increasing control. At the outset of the Conceptual Design Phase, a Quality Level of III is assigned to the design efforts conducted during this phase. As the design activity matures into the Advanced Conceptual Phase, a Quality Level of II is assigned to design efforts conducted during this phase.

As the design activity nears the end of the Advanced Conceptual Design Phase, most items will have been identified, their functions defined and therefore will have been assigned a Quality Level. Once a Quality Level is assigned to an item, all design efforts related to the item are governed by the Quality Level assigned to the item. Design efforts associated with items that have not received a Quality Level assignment continue to be governed by the Quality Level assigned to the phase of design currently underway.

At the outset of the License Application Design Phase, a Quality Level of I is assigned to the design efforts conducted during this phase. Upon completion of this phase of design, all items specified by the design output documents will have received Quality Level assignments.

Since all items will have been assigned a Quality Level at the close of the License Application Design Phase, it is not necessary to assign a Quality Level to the Final Procurement and Construction Design Phase. All activities (including design) that affect the quality of an item will be governed by the Quality Level assigned to the item.

### **ATTRIBUTES**

The approach taken by the MNWSI Project for the assignment of Quality Levels to design activities exhibits the following attributes:

- o Recognizes the need to allow the design activity to mature in order to determine an item's effect on quality.
- o Recognizes the varying degrees of influence each phase of design has on quality.
- o Encourages the assignment of Quality Levels to items after the design activity has "settled" at a point where there is reasonable assurance that the item's function and interrelationships have been clearly defined.
- o Encourages the "sifting out" of items that clearly have a slight or no effect on quality.
- o Provides reasonable assurance that the design activity associated with any item is conducted under controlled

conditions prior to determining what its effect on quality may be.

Ralph Stein

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