

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

OCT 03 1988

Dear Mr. Stein:

The purpose of this letter is to transmit the meeting minutes for the September 28, 1988 meeting in the NRC White Flint Building in Rockville Maryland between representatives of the NRC and DOE. Representatives for the State of Nevada and Utility Nuclear Waste Management Group also attended. The purpose of the meeting was to discuss the DOE/OCRWM Quality Assurance Requirements for the Civilian Radioactive Waste Management Program, Revision 0 and associated DOE response to NRC comments.

Should you have any questions on the enclosure, please contact Jim Kennedy (492-3402) or Bill Belke (492-0445) of my staff.

Sincerely,

151

John J. Linehan, Chief  
 Project Management and Quality  
 Assurance Branch  
 Division of High-Level Waste Management

Enclosure: As stated

cc: R. Loux, State of Nevada  
 C. Gertz, DOE/Nevada  
 K. Turner, GAO  
 L. Barrett, DOE/HQ  
 N. Montgomery, EEI/UNWGM

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PDR	NMSS R/F	On-Site Rep	CNWRA
LSS	ACNW		

\* SEE PREVIOUS CONCURRENCES

OFC :HLPM	:HLPM	:HLPM	:	:	:	:
NAME:*BBelke	:*JKennedy	:JLinehan	:	:	:	:
DATE:09/29/88	:09/30/88	:10/5/88	:	:	:	:

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 J. Blaylock, DOE/Nevada  
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OFC :HLPM	:HLPM	:HLPM	:	:	:	:
NAME:BBelke	:JKennedy	:JLinehan	:	:	:	:
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SUMMARY OF MEETING ON DOE/OCRWM QUALITY ASSURANCE REQUIREMENTS DOCUMENT

A meeting was held between representatives of the NRC and DOE on September 28, 1988 in the NRC's White Flint North building in Rockville, Maryland. The purpose of the meeting was to discuss the DOE/OCRWM Quality Assurance Requirements for the Civilian Radioactive Waste Management Program, Revision 0.

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

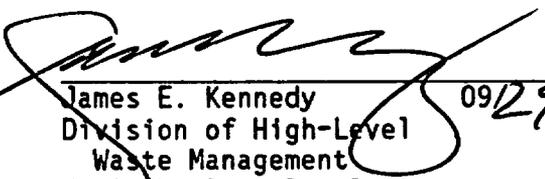
The NRC staff had 40 QA comments as a result of its review of the document. At the meeting, the DOE provided responses to the NRC's comments (Enclosure 2). Some of the major items that were resolved were QA GTP guidance on Peer Review, Qualification of Existing Data, and Q-List (NUREGs 1297, 1298, and 1318 respectively) and software QA. Based on information provided at the meeting, the NRC staff indicated that 5 open items remained. These open items include the NRC's evaluation of the exception taken by DOE to the Review Plan criteria that requires QA organization to have an active in-line support function.

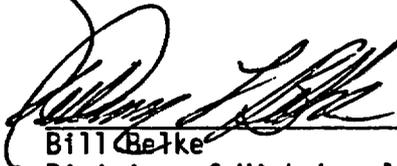
A separate topic opened by the NRC during the meeting was a new item on NNWSI 88-9 about the use of scientific notebooks and detailed technical procedures. DOE will promptly respond to this NRC item.

The NRC staff will perform a detailed review of the DOE responses and notify the DOE of any problems prior to the DOE formal submittal of a revised document to the NRC.

  
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and Regulation  
Office of Civilian Radioactive  
Waste Management  
U. S. Department of Energy

  
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MEETING 9/29/89 TO DISCUSS DOE QA REQUIREMENTS DOCUMENT

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TELEPHONE</u>
Bill Becke	NRC/NMSS	301-492-0445
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Norman Frank	CER Corp/DOE	703 875-8630
James Donnelly	NRC	301-492-0453
Craig Walenga	CER / DOE	703 875-8630
Dwight Skelton	DOE/OCRWM/OQA	202-586-1238
JAY JONES	DOE/OCRWM/OQA	202-586-1224
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GENERAL

1. NRC COMMENT

In the "Glossary" section of the QARD, numerous of the terms and definitions listed are inconsistent with those definitions contained in NNWSI/88-9, Revision 1, NRC GTP's/NUREGS, and NQA-1. For example, Activities Affecting Quality, Baseline, Corroborative Data, Design, Document etc. The glossary should be reviewed and all terms and definitions should be consistent with the definitions listed in the above documents. Rationale should be provided where differences exist or the QARD takes exception.

DOE RESPONSE

The DOE will provide resolution to NRC questions raised on the definitions of the following words or phrases:

activities affecting quality

design

document

important to safety

important to waste isolation

quality activities list

readiness review

technical review

*ENCLOSURE 2*

## 2. NRC COMMENT

### a. 3.5 Control of Scientific Investigations

- o Clarify the following sentences which appear to conflict with 10 CFR 50, App. B - Criterion VI "...Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization."

3.5.1 states: "Technical procedures shall be reviewed for technical adequacy and approved by qualified persons other than those who prepared the procedures. Changes to technical procedures for conducting scientific investigations shall be reviewed and approved by qualified persons familiar with the procedures and the purposes of the investigations to ensure that the objectives of the investigations are fulfilled."

The DOE document neither maintains the independence of the reviewers in its discussion of changes to procedures for conducting scientific investigations, nor does it maintain that reviews and approvals of changes are to be performed by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

### b. 3.5.5 Control of Erroneous Data

Clarify whether "erroneous data is controlled via the nonconformance control system established in Section XV.

- o If not, why not? What about: identification; segregation; disposition; documentation; notification of affected organizations - These must be addressed if section XV controls are not invoked.

## DOE RESPONSE

- a. Page 15, 3rd Paragraph, 4th sentence, add: "by the same organizations that performed the original review and approval unless the applicant designates another responsible organization."
- b. No. Erroneous, etc. data is not required to be controlled by Section 15.0 of QAR "Control of Nonconforming Items." "Item" is not defined as data by either the QAR or 88-9. Wording was taken from NQA-3 draft and it requires controls to be in place. These controls may be similar to an NCR system or deficiency system.

Add new paragraph 2.1j:

- o Description of the method of control of erroneous, rejected, superseded, or otherwise unsuitable data.

### 3. NRC COMMENT

In RP criterion 11, NRC asked for a commitment to NUREG 1297 for Peer Review. Section 3.4 of the QARD addresses Peer Reviews and should the DOE elect to use this in lieu of committing to NUREG 1297, the following comments need to be addressed:

1. The definitions of "Peer, Group, Peer Review, and Peer Review Report."
2. Position IV. 2. of NUREG-1297 is not addressed in the OCRWM document.
3. Section 3.4.4 of the OCRWM document does not adequately address the staff positions in IV, 3. a and b. Due to the sensitive nature of this topic, any deviation from the language found in the NUREG must be justified.
4. The following concepts in NRC staff position IV. 4 are not addressed.
  - a. The use of a chairperson for the peer review group.
  - b. The development of procedures to implement the peer review process.
  - c. The use of written minutes for meetings, deliberations, and activities of the peer review process.
5. The following concepts in NRC staff position IV. 5 are not addressed.
  - a. The peer review report should be signed by each member individually.
  - b. The peer review report should clearly state the work or issue that was peer reviewed.
  - c. The peer review report should contain any potential technical and/or organizational partiality of the reviewer.
6. Section 3.4.5 of the OCRWM document, the second half of the first sentence is not consistent with the staff positions found in the NUREG. Peer reviews should not be performed to verify conformance to specified requirements.

### DOE RESPONSE

Page 13, add new Paragraph 3.4.1 and renumber all subparagraphs.

"3.4.1 A peer review shall be performed in accordance with the guidance provided in NUREG-1297, Peer Review for High-Level Waste Repositories Generic Technical Position and the following amplifications."

4. NRC COMMENT

Paragraph 2.4 in Section 2 of the QARD describes the classification of the three tier classification system to be used in applying appropriate QA requirements. This system is inconsistent with the system NRC accepted in the NNWSI/88-9 QA Plan. Also, the system is inconsistent with the NRC GTP for the Q-List, NUREG-1318.

DOE RESPONSE

Add new lead into paragraph 2.4.1 and renumber subsequent paragraphs.

"2.4.1 The classification of quality levels shall be performed in accordance with the guidance provided in NUREG-1318, Technical Position Item and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Requirements and the following amplifications."

The QAR is consistent with 88-9 though 88-9 provides more specificity for each level. By requiring the use of NUREG-1318 the QAR has provided more definitive guidance to PROGRAM participants on the development of the classifications. Upon issuance of QAAPs 2.3, "Quality Level Classifications" and 2.4, "Quality Assurance Grading" and the development of the methodology for determining the quality levels, the details of the classification and grading will be clarified. These will be consistent with 88-9.

5. NRC COMMENT

Sections 9, 10, 11 and 14 of the QARD state that the requirements of these sections apply to engineered items only and do not apply to scientific investigation activities. The rationale for this application should be described in the QARD.

DOE RESPONSE

Having sections 9, 10, 11, and 14 apply to engineered items only is consistent with 88-9. OCRWM will provide a document that provides the basis for this application. This position paper will be consistent with the rationale provided by Nevada for the NRC acceptance of 88-9.

6. \* NRC COMMENT

The Introduction Section of the QARD references Regulatory Guide 1.28 as opposed to a commitment to it. Although originally intended for application to nuclear power plants, the NRC staff considers Regulatory Guide positions C.1 and C.3 applicable to the high-level waste repository program. This position should be considered for application in the QARD.

DOE RESPONSE

We agree to accept those positions for C.1:

- a. Section 2.0 GENERAL, insert "Appendix 2A-1" into the statement.
- b. Section 2.5.1 insert "Appendix 2A-1"

For C.3:

OCRWM will commit to C.3 position of Reg. Guide 1.28 which defines provisions for conducting Internal and External audits.

- a. Develop a new section 18.3, "Internal Audits"
- b. Develop a new section 18.4, "External Audits"

1. > REVIEW PLAN (RP) CRITERION

1.1 The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.

NRC COMMENTS

In the "Introduction" of the Office of Civilian Radioactive Waste Management Quality Assurance Requirements Document (QARD), it is stated that the Program Director retains responsibility for the total quality assurance program. The reporting relationship of this position should contain provisions to assure this position has sufficient authority to carry out this function and is independent from cost and schedule considerations. The QARD should also contain provisions to assure the respective QA organization verifies the proper performance of work through implementation of appropriate QA controls.

DOE RESPONSE

The PROGRAM Director is the Director, OCRWM. This is specified in the QAPD, Paragraph 1.1.1 and shown in Figure 1.1.A of the QAPD. The general statement of responsibilities is given on page 2 of the QAR.

Add first sentence to QAR Section 1.1. to read "The quality assurance organization is responsible to verify the proper performance of work through the implementation of appropriate QA controls that include, as a minimum, audits and surveillances."

*ENCLOSURE 2*

2. - RP CRITERION

1.2 DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.

NRC COMMENTS

The QARD should contain provisions which require program participants to provide a description of any major work delegated to other organizations in establishing and implementing the QA program.

DOE RESPONSE

QAR Paragraph 1.2 add sentence:

"PROGRAM participants shall describe the major delegations of work involved in establishing and implementing the quality assurance program or any part thereof to other organizations."

3. . RP CRITERION

1.3 DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.

NRC COMMENTS

The QARD should contain provisions to address the extent of management responsibility and authority from DOE headquarters and field office.

DOE RESPONSE

The responsibility of QA management is provided in QAR 1.1.c. The description of the OCRWM responsibilities for the overall QA program is provided in the QAPD. PROGRAM participants are required to include such a description by NQA-1 Basic Requirement 1, first sentence, which reads "The organizational structure, functional responsibilities, level of authority, and lines of communication for activities affecting quality shall be documented." This meets the intent of RP requirements 1.3.

4. RP CRITERION

1.4 DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.

NRC COMMENTS

The QARD should contain provisions which address Position C3 of Regulatory Guide 1.28, Revision 3 (attached) concerning the frequency and method for scheduling audits. Presently, the Introduction of the QARD only contains a reference to Regulatory Guide 1.28.

DOE RESPONSE

Adopted position C.3 as indicated above (See General Comment 6).

## 5. > RP CRITERIA

- 1.6 Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.
- 1.7 Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility.
- 1.9 DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.

### NRC COMMENTS

For the above criteria, the QARP refers to NQA-1 Supplement 1S-1. Supplement 1S-1, Sections 3.1, 3.2.1 and 3.2.2 require internal and external interface controls be defined and documented. NQA-1 does not specifically address the above RP criteria, e.g., require organizational charts, define lines of communication, "onsite" and "offsite" organizational elements etc. Consequently, the QARD should contain provisions which require Program participants to address the above NRC RP criteria.

### DOE RESPONSE

Will provide the following words in second paragraph of 2.1.

"PROGRAM participants shall include in quality assurance program documents:

- a. Descriptions of the management controls and lines of communication that exist with their contractors to assure direction of the quality assurance program.
- b. Descriptions of all onsite and offsite organizational elements that function under the cognizance of the quality assurance program and the lines of responsibility.
- c. Descriptions of the QA responsibilities of each of the organizational elements noted on the organization charts."

6. • RP CRITERION

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

NRC COMMENTS

Section 2, paragraph 2.2 requires the Program participants to identify certain QA activities, but does not require a description whereby the QA organization is involved in accordance with the above RP criterion.

DOE RESPONSE

Will add the words "including the QA organization" to line 3 of Paragraph 2.2 after the word "organizations". This meets the intent of RP 1.8.

## 7. RP CRITERION

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

- a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
- b. Has effective communication channels with other senior management positions.
- c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.
- d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

### NRC COMMENTS

Section 1, paragraph 1.1(g) of the QARD states that the quality assurance management position shall have review and approval recommendation. The QARD should contain provisions to identify the position having responsibility for the actual approval of the QA manuals, changes and interpretations. This position should also have effective communication channels with other senior management positions.

### DOE RESPONSE

Change 1.1.f to read...

"Access to senior management and management at the next higher..."

Change 1.1.g by adding the following "revisions to and interpretations thereof."

The responsibility for final approval of QA manuals is defined in QAR Paragraph 2.1.

## 8. RP CRITERION

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

### NRC COMMENTS

The QARD does not require verification of conformance to established requirements to be accomplished by personnel within the QA organization. Section 10 of the QARD requires NQA-1 Supplement 10S-1 to be met. Supplement 10S-1 contains provisions for inspection personnel only. Verification by definition of NQA-1 includes the act of reviewing, inspecting, testing, checking, auditing etc., i.e., "verification" is not limited to "inspecting". Consequently, the QARD should contain provisions to address the above RP criterion or provide alternatives found acceptable by the NRC staff.

### DOE RESPONSE

Add new Paragraph 2.2 and renumber subsequent paragraphs:

#### 2.2 REPORTING INDEPENDENCE OF PERSONNEL

Verifications shall be performed by personnel who do not report directly to the immediate supervisor responsible for performing the activity being inspected. If verification 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 verification personnel are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the inspection activity.

9. RP CRITERION

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

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

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

NRC COMMENTS

The QARD references NQA-1 Basic Requirement for the above criterion. This is acceptable providing the QARD contains a provision whereby the personnel with the authority to execute these actions should be required to be identified.

DOE RESPONSE

Add new Paragraph 2.1.d.

2.1.d Descriptions of persons and organizations that have authority to identify and resolve quality problems and of the programs that will implement these actions." (See Comment No. 5)

## 10. RP CRITERION

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

### NRC COMMENTS

Section 2, paragraph 2.4 of the QARD addresses only the quality levels and graded QA approach. It does not address the rationale for determining how items or activities are important to safety or waste isolation as defined in 10 CFR 60.2 (below) which is defined as numerical performance objectives and standards.

"Important to safety," with reference to structures, systems, and components means those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure.

"Isolation" means inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

### DOE RESPONSE

See General Comment 4. By committing to NUREG-1318, we meet the intent of RP 2.1 QAAP 2.3 will provide the methodology.

## 11. RP CRITERIA

- 2.2. The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."
- 3.8 For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.

### NRC COMMENTS

The QARD does not contain provisions for Program participants to commit to the guidance contained in NUREG-0856. Similarly, the QARD does not contain provisions for Program participants to meet the other NRC QA Generic Technical Positions of NUREGs-1297, (Peer Review), 1298 (Qualification of Existing Data), and 1318 (Q-List).

### DOE RESPONSE

General Comment 3 committed to NUREG-1297.

Will add to QAR Paragraph 3.5.7 so that the first sentence reads, "shall be qualified in accordance with NUREG-1298, Qualification of Existing Data for High-Level Nuclear Waste Repositories Generic Technical Position."

Will add to QAR Paragraph 3.2.4 so that first sentence reads, "As applicable computer software documentation shall meet NUREG-0856, Final Technical Position Documentation of Computer Codes for High-Level Waste Management."

12. RP CRITERION

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

NRC COMMENTS

Clarify whether paragraph 2.1 in Section 2 of the QARD requires Program participants to provide a listing of existing or proposed procedures to provide confidence that each of the 18 criteria of Appendix B to 10 CFR Part 50 will be met as appropriate.

DOE RESPONSE

a. Will add new paragraph to 2.1.e

"2.1.e Identification of existing or proposed quality assurance administrative procedures." (See Comment No. 5)

b. Add new Paragraph 5.2 Procedures List

"5.2 PROGRAM Procedures List participants shall maintain a list of detailed Technical procedures that are applicable to the quality assurance program."

### 13. RP CRITERION

3.1 The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refers to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954.

#### NRC COMMENTS

The definition for design in the QARD Glossary differs from the above RP criterion definition. It should be emphasized that design control should be included at each stage of design development from conceptual to final. The terminology for design in the QARD should be consistent with the RP criterion and the QARD should contain provisions to emphasize the application of design control at all phases of design.

#### DOE RESPONSE

Add to first sentence of Paragraph 3.0, "...shall apply to design from conceptual design through final design."

Our definition of design is a generic definition acceptable to broad interpretation to cover all aspects of the PROGRAM.

#### 14. RP CRITERION

3.2 The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities as described in 3.1. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.

#### NRC COMMENTS

Section 3 of the QARD references NQA-1 Supplement 3S-1 for the above RP criterion. Supplement 3S-1 does not describe measures that provide for translation of (at the time of submittal of the Site Characterization) applicable regulatory requirements and design bases into design, procurement, and procedural documents.

#### DOE RESPONSE

We maintain that RP 3.2 is described adequately by NQA-1 Basic Requirement 3 for design.

We maintain that NQA-1 Basic Requirement 4 adequately describes the procurement issue of RP 3.2.

Add words to Paragraph 5.1 "..., including the correct translation of design requirements," after "technical adequacy."

Additional clarification: The DOE must take exception to the RP with respect to having a fully qualified QA program in place at the time the SCP is issued.

Justification: This is a timing issue and not directly related to the QARD. However, it should be noted that the ESF design and study plans will be qualified through review and application of design controls prior to start of new site characterization activities. The qualification process will be described to the NRC staff as part of its acceptance of the QA program for new site work.

15. RP CRITERION

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

NRC COMMENTS

The QARD provides the description whereby design and design documents are to be prepared, reviewed, approved and verified. However, the QARD does not require the Program participants to identify who is responsible for accomplishing this verification. Also, the QARD should describe provisions to assure design and design information documents will be validated in accordance with the above RP criterion.

DOE RESPONSE

Add new Paragraph 2.1.f (See Comment No. 5)

"2.1.f Description of the organizational responsibilities for reviewing, approving, verifying, and validating design criteria and design documents."

16. RP CRITERION

3.6 Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.

NRC COMMENTS

This RP criterion does not appear to be addressed in the QARD especially, with the review being conducted with QA involvement.

DOE RESPONSE

This item remains an open issue subject to NRC acceptance of the exception taken by OCRWM to the direct involvement of the QA organization in line functions. Justification for the DOE position was provided to the NRC at the September 28, 1988 meeting. This position paper was titled, Quality Assurance Requirements Document, Revision 0, Exception to NRC Review Plan Criteria dated September 16, 1988.

Additional clarification of DOE's approach will be provided in the "INTRODUCTION" to the QAR.

17. RP CRITERION

3.7 Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification, provided:

- (a) The supervisor is the only technically qualified individual.
- (b) The need is individually documented and approved in advance with concurrence of the quality assurance manager.

NRC COMMENTS

The use of the designer's supervisor to perform design verification requiring approval by the QA manager should be addressed in the QARD.

DOE RESPONSE

This item remains an open issue subject to NRC acceptance of the exception taken by OCRWM to the direct involvement of the QA organization in line functions. Justification for the DOE position was provided to the NRC at the September 28, 1988 meeting. This position paper was titled, Quality Assurance Requirements Document, Revision 0, Exception to NRC Review Plan Criteria dated September 16, 1988.

Additional clarification of DOE's approach will be provided in the "INTRODUCTION" to the QAR.

18. RP CRITERION

3.10 Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.

NRC COMMENTS

The QARD should contain provisions to assure that for design changes, the change is analyzed and considered for possible changes to procedures, whether training of involved personnel is necessary, and that the changes should be communicated to affected groups or individuals.

DOE RESPONSE

Add new Paragraph 3.2, renumber subsequent paragraphs

"3.2 Design Changes - The impact of design changes on procedures and training shall be evaluated. The changes shall be communicated to all affected groups or individuals.

19. RP CRITERION

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

NRC COMMENTS

Section 4, paragraph 4.1 of the QARD references NQA-1 Supplement 4S-1 for the above RP criterion. Supplement 4S-1 does not describe provisions that QA personnel review procurement documents to determine whether design basis, and other requirements are referenced or stated in the procurements; there are adequate acceptance and rejection criteria; and whether the procurement documents have been prepared, reviewed and approved in accordance with QA program requirements.

DOE RESPONSE

OCRWM takes exception to the criterion as it applies to QA organization's total involvement. QAR Paragraph 4.1 defines the role of the QA organization's involvement. The basis for the exception is the same as provided in the position paper on QA organization's direct involvement in line activities.

20. RP CRITERION

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

NRC COMMENTS

Section 4 of the QARD or NQA-1 Supplements do not describe provisions to assure review and concurrence of supplier QA programs will be accomplished prior to the initiation of activities affected by that program. Also, there are no provisions to assure the involvement of the QA organization in the procurement process will be described.

DOE RESPONSE

Add new Paragraph 7.1

"7.1 Supplier's Quality Assurance Programs. When required by procurement documents, supplier's QA PROGRAMS shall be reviewed and accepted prior to initiation of activities affected by the quality assurance program."

QA involvement is described in QAR Paragraph 2.1

21. RP CRITERION

6.2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality-related aspects.

NRC COMMENTS

Section 6 of the QARD references NQA-1 Basic Requirement 6 and Supplement 6S-1 for the above RP criterion. NQA-1 does not contain provisions to address whether procedures are reviewed for technical adequacy if the QA organization reviews and concurs in the procedures for quality-related aspects.

DOE RESPONSE

This item remains an open issue subject to NRC acceptance of the exception taken by OCRWM to the direct involvement of the QA organization in line functions. Justification for the DOE position was provided to the NRC at the September 28, 1988 meeting. This position paper was titled, Quality Assurance Requirements Document, Revision 0, Exception to NRC Review Plan Criteria dated September 16, 1988.

Additional clarification of DOE's approach will be provided in the "INTRODUCTION" to the QAR.

22. RP CRITERION

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

NRC COMMENTS

The above RP criterion does not appear to be addressed other than for design by virtue of the commitment to Section 4 of NQA-1 Supplement 3S-1.

DOE RESPONSE

Add new Paragraph 6.2.d

"d) Identification and control of documents released prior to completing the approval process."

23. RP CRITERION

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

NRC COMMENTS

The criteria for determining those processes controlled as special processes are not described in the QARD. NQA-1 Supplement S-1 contains a definition for special processes which would be acceptable to the NRC staff for the above RP criterion if it became a requirement of the QARD.

DOE RESPONSE

We have committed to the definitions in NQA-1, Supplement S-1 as stated in the Glossary to the QAR.

24. RP CRITERION

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

NRC COMMENTS

Section 17 of the QARD requires that NQA-1 Basic Requirement 17 and Supplement 17S-1 shall apply. Basic Requirement 17 requires that records that furnish documentary evidence of quality to be specified, prepared, and maintained. This does not specifically address the above RP criterion whereby procedures are to be established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

DOE RESPONSE

Add new Paragraph 9.4

"9.4 Evidence of Accomplishment

Each PROGRAM participant shall establish procedures for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel."

## 25. RP CRITERIA

10.1 The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.

10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.

### NRC COMMENTS

Section 10 of the QARD references NQA-1 Basic Requirement 10 and Supplement 10S-1. The NQA-1 references do not contain provisions to assure the scope of the inspection program will be described to indicate an effective inspection program has been established. It also does not contain provisions that describe the involvement or participation of the QA organization. In addition, the QARD should also contain provisions to assure other organizational responsibilities for inspection are required to be described.

### DOE RESPONSE

- a. This item remains an open issue subject to NRC acceptance of the exception taken by OCRWM to the direct involvement of the QA organization in line functions. Justification for the DOE position was provided to the NRC at the September 28, 1988 meeting. This position paper was titled, Quality Assurance Requirements Document, Revision 0, Exception to NRC Review Plan Criteria dated September 16, 1988.
- b. Add new Paragraph 2.1.g (See Comment No. 5)
- "g) Description of the inspection program and organizational responsibilities."

26. RP CRITERION

11.1 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed; and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.

NRC COMMENTS

Section 11 of the QARD references NQA-1 Basic Requirement 11 and Supplement 11S-1. The NQA-1 references do not contain provisions to assure the Program participants QA program will include a description of the scope of test control program to indicate an effective test program has been established. NQA-1 does not appear to contain specific provisions to assure the above RP criterion will be addressed.

DOE RESPONSE

Add paragraph 2.1.h (See Comment No. 5)

"2.1.h Description of the scope of the test control program."

27. RP CRITERION

11.2 Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.

NRC COMMENTS

The NRC staff can not find how the QARD addresses the above RP criterion.

DOE RESPONSE

RP sections 3.7, 3.8, and 3.9 are not applicable to testing of engineered items. The requirements of RP 3.7, 3.8, and 3.9 are covered in QAR Section 3.

28. RP CRITERION

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

NRC COMMENTS

Section 3, paragraph 3.5.2 addresses the above RP criterion for scientific investigation only. The QARD should also address this criterion for tests conducted outside the scope or in addition to site investigation.

DOE RESPONSE

Add new Paragraph 11.2

"11.2 Uncertainty and Error

Potential sources of uncertainty and error shall be identified in test plans and procedures. In addition, parameters that must be controlled and measured to assure that tests are well controlled shall be identified."

29. RP CRITERION

11.4 Test procedures or instructions provide for the following:

- a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.
- b. Instructions for performing the test.
- c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.
- d. Mandatory inspection hold points (as required).
- e. Acceptance and rejection criteria, including required levels of precision and accuracy.
- f. Methods of data analysis.
- g. Methods of documenting or recording test data and results.
- h. Provisions for assuring test prerequisites have been met.

NRC COMMENTS

Section 11 of the QARD does not contain provisions to address the precision and accuracy aspects in the above RP criterion 11.4 a and e.

DOE RESPONSE

Add new Paragraph 11.3

"11.3 Precision and Accuracy

Precision and accuracy considerations shall be identified in test procedures."

30. RP CRITERION

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.

NRC COMMENTS

Section 12 of the QARD references NQA-1 Basic Requirement 12 and Supplement 12S-1. The NQA-1 references do not contain provisions to assure Program participants will include a description of the scope of the program for measuring and test equipment and the types of equipment to be controlled.

DOE RESPONSE

Add new Paragraph 2.1.i (See Comment No. 5)

"2.1.i. Description of the scope and types of measuring and test equipment to be controlled by the quality assurance program."

31. RP CRITERION

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.

NRC COMMENTS

The QARD and references to NQA-1 do not appear to require the review and documented concurrence of the functions in the above RP criterion to be identified.

DOE RESPONSE

This is covered by QAAP for calibration controls, etc. Procedures are covered by QAR Section 5 and 6.

32. RP CRITERION

13.1 Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

NRC COMMENTS

The QARD does not appear to address whether the above requirements will be accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

DOE RESPONSE

All activities affecting quality are required to be performed in accordance with procedures by QAR Section 5. NQA-1 Basic Requirement 2 and Supplement 2S-4 require suitable training.

33. RP CRITERION

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

NRC COMMENTS

Section 17 of the QARD references DOE/RW-0194, "Records Management Policies and Requirements" for the scope of the quality assurance records program. In order for the NRC staff to determine acceptability of the above RP criterion, we will need a copy of the DOE document.

DOE RESPONSE

A copy of RW-0194 was provided. NRC to review the RP criterion again.

34.7 RP CRITERION

18.4 Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.

NRC COMMENTS

For the above RP criterion, the QARD references NQA-1 Supplement 18S-1, paragraph 5. Supplement 18S-1 does not describe provisions to assure that audit data are analyzed for the QA organization and reported to management for review and assessment.

DOE RESPONSE

- a. QAR Sections 16.1 and 2.8 address this criterion.
- b. Add new Paragraph 18.3

18.3 ANALYSIS OF AUDIT DATA

Data from the performance of an audit shall be analyzed by the QA organization and the results reported to responsible management for review, assessment, and appropriate action. A method for meeting this requirement is to include the data analysis results in the audit report.