APR 2 9 1988

MEMORANDUM FOR: James Kennedy, Section Leader
QA Section, HLOB

FROM: John Linehan, Section Leader
Projects Sections, HLOB

SUBJECT: REVIEW OF QUALITY ASSURANCE REVIEW PLAN

In response to your memorandum dated April 1, 1988, the Projects Section has completed its review of the Quality Assurance Review Plan (QARP). Based on this review there are several comments which should be considered. The comments are of two types. One type deals with particular words or positions taken in the Plan while the second centers on the QARP itself. Enclosure 1 contains the first type of comments and Enclosure 2 has those pages of the QARP to which the individual comments apply.

With respect to the second type of comments, the Projects Section has two overall concerns with the QARP. First, the plans offers little detailed guidance on what a reviewer should do in order to ensure that a quality assurance (QA) plan is acceptable. It refers the reviewer to the different Technical Positions (TPs) that have been issued by the staff. The guidance provided in the TP on site charaterization QA discusses the applicable 10 CFR 50, Appendix B criteria, identifies the NQA-1 requirements, and elaborates on additional staff positions. This type of detailed guidance is excellent for telling someone how to develop and implement a QA program. However, it may be too detailed for use in a review plan. For example, the staff positions given in the TP on Site Characterization QA on page III-22 for Requirement 10 states that (1) measures should be established to control changes; (2) changes should be analyzed to ensure that they are necessary; and (3) associated changes to procedures and training should be provided. As noted earlier, this type of guidance is fine for developing a QA plan but should they be considered review criteria? One would expect that the review criteria for evaluating a plan would state that DOE describe its approach to controlling design changes and identify what is acceptable to the staff.

In other areas such as Requirement 1 of IV, "Procurement Document Control," there is no staff position. Does this mean that the reviewer should rely upon the guidance given in NQA-1 to do the review? If so, the NQA-1 guidance is far more detailed than need be for the evaluation of a plan. These two examples may indicate a difference of views between the Projects and QA Sections as to how the review process works.

In the view of the Projects Section, the evaluation of a QA program is a bifurcated process. First, the staff will review the QA plan to determine if the proposed approach meets the requirements of Appendix B. This review should cover the description of the proposed program. In this phase of the review, it is important to note that the staff evaluation of the program is based on a description or summary plan. It is the second phase of the review of the program where detailed criteria become important. This second phase deals with

405
WM-16
WM-1

the implementation of the plan; therefore, it becomes important that the staff ensure that, for example, the necessary design controls be in place.

If the review of a QA program is reviewed as the two step process, it becomes apparent that the present version of the QARP and its associated TP are centered on the second phase of the review. Lacking are the criteria that should be used to review the proposed plan, not its implementation. If a reviewer is to use the applicable TPs, one still must know how a program meets that guidance. For example, in the TP that was part of the Review Plan package, the staff discusses the applicable Appendix B criteria, identifies the NQA-1 requirements, and elaborates on additional staff guidance. However, this is only guidance to DOE on how to develop a QA program. The need to determine if DOE meets these positions and the criteria that should be used are still missing.

This raises the second overall concern which deals with the QARP relying on the TPs for acceptance criteria. Although both documents have the same intent, i.e. provide guidance, the QARP will be used to provide guidance to the staff in its review while the GTP will be used to provide guidance to DOE on how to develop its QA programs. Since the two documents provide guidance to different organization on how to achieve different objectives, too much of a reliance of one upon the other causes problems. The QARP should be fairly, if not completely, independent of the TPs. A reviewer should be able to use the QARP by itself to conduct the necessary reviews. At present, this is not the case. A reviewer must use the associated TPs in order to understand what should be contained in the QA program. By doing this, the staff is providing an overall guidance that, in the opinion of the Projects Section, does not fully meet the needs of either organization. If one wants to develop a review guidance document, then one should do that. Conversely if a guidance document to DOE is desired, one should be prepared. In this case we have neither but rather a hybrid of both.

As a final point in this area, the Projects Section recommends that at some place in the introduction of the documents it be stated that their intended use is to provide guidance. This is particularly true in the TP on QA for site characterization. In the staff positions, there are detailed suggestions as to how DOE can meet the particular requirements. DOE should understand that there are suggestions and that alternatives are acceptable.

Mr. Joe Holonich was the Projects Section member who reviewed the QARP. He and I are prepared to meet with you if you require our assistance.

151

John Linehan, Section Leader
Projects Section, HLOB

DISTRIBUTION: SEE NEXT PAGE

OFC	:HLOB/RHLWM:HLOB	:	:	:	:	:
NAME:	JHolonich	:JLinehan	:	:	:	:
DATE:	04/ /88	:04/ /88	:	:	:	:

OFFICIAL RECORD COPY

DISTRIBUTION

R. E. Browning
M. J. Bell
J. O. Bunting
J. J. Linehan
PDR
J. Holonich

R. L. Johnson
B. J. Youngblood
NMSS r/f
Central Files
LSS

P. T. Prestholt
R. Ballard
HLOB r/f
LPDR
CNWRA

ENCLOSURE 1

Page 1, Comment 1: No longer valid.

Page 1, Comment 2: The words "...demonstration of quality in licensing hearing" should be changed to

"... demonstration of quality to support an NRC licensing decision and to defend that decision in a licensing hearing."

Page 3, Comment 3: Change the words "... interpret and elaborate ..." to "...describe the approach DOE has taken to meet ..."

It is the staff and not DOE who interprets and elaborates the criteria in the regulations.

Page 7, Comment 4: Items a. and b. The staff should not solely rely on DOE audits to make a determination of the acceptability of DOE's QA programs. The staff must make its own independent determination or particpate as observers, to the extent necessary, on DOE audits. The staff can rely upon these DOE audits to gain assurance or continued confidence that program implementation is being done properly. However, they should not be used to develop a staff finding of acceptability.

Technical Position (TP), Page i, Comment 5

It is not the job of the staff to "help resolve" licensing issues. Rather the staff must ensure that licensing issues are acceptably resolved.

TP, Page i, Comment 6

No longer valid.

TP, Page II-16, Comment 8

How often should a review of status and adequacy be done?

TP, Page II-17, Comment 9

Same as Comment 8

TP, Page III-19, Comment 10

No longer valid.

TP, Page V-3, Comment 11

There is no additional staff guidance provided or a statement that none is needed.

TP, Page VII-11, Comment 12

Define the terms "where appropriate" and "as appropriate." Provide an example or two of the "other items". (Staff Position VTII.2.2)

TP, Page VIII-2, Comment 13

Define what "items" should have identification and control measures, i.e. samples, materials, all substances.

TP, Page VIII-5, Comment 14

Define "item."

TP, Page XI-3, Comment 15

Acceptance criteria are defined as "an acceptable range of values within which a data point should fall." What percentage of the data should fall within this range to support the validity of the tests? Should a discussion of the data outside of the range be provided.

TP, Page XIII-4, Comment 16

Add a ")" after etc.

ENCLOSURE 2

QARP PAGES

I. INTRODUCTION

The Department of Energy (DOE) is conducting a site characterization program at the Yucca Mountain site in Nevada. The purpose of this program is to collect and analyze data to determine if natural and engineered barriers can safely isolate high-level nuclear waste from the accessible environment. The information developed during the site characterization phase will be used in an application for a license submitted to the NRC to receive and possess source, special nuclear, or byproduct material.

During the site characterization phase of the repository program the NRC staff is conducting a prelicensing consultation and guidance program with the DOE. The staff will familiarize themselves with the DOE program and identify and resolve issues as early as possible and before a license application is submitted to the NRC. Through these interactions the staff will attempt to gain confidence that the DOE meets all of the applicable regulatory requirements for licensing. The staff, however, does not have the resources to independently evaluate all or even a major part of the detailed activities associated with siting, designing, constructing, and operating a waste repository prior to a licensing hearing. As a result the NRC regulations specify that the DOE implement a quality assurance (QA) program that will assure quality in the work carried out in the prelicensing phase of the program. The staff will rely on the DOE QA program and the staff's evaluation of that program to generalize the results of the staff's limited review of the work conducted in the repository program. In addition, the documentation produced under the QA program will form the record upon which the suitability of the site will be judged in the NRC licensing process.

The NRC staff has published a technical position (TP) on quality assurance for the site characterization phase of the repository program. This TP provides DOE with guidance concerning the NRC staff's positions on quality assurance and with specific QA criteria necessary to assure quality and the demonstration of quality in a licensing hearing. The NRC staff guidance is

regulations state that during site characterization the NRC is permitted to visit and inspect the locations at which activities are carried out and to observe excavations and in situ tests as they are done.

III. REVIEW PLAN

The methods by which the staff will review and assess the DOE quality assurance program for the site characterization phase of the repository program are described in this section. The DOE QA program consists of the QA plans for each organization which interpret and elaborate on the criteria in the NRC's regulations in 10 CFR Part 60 and the staff's guidance documents (TP's). The QA program also includes test plans and technical procedures which translate those requirements for specific items and activities. These documents form the basis for the application of the DOE QA Program to the site characterization phase activities.

In order to assess the adequacy and effectiveness of the DOE QA program, the NRC staff must evaluate the QA plans and procedures. In addition, the staff must evaluate the implementation of these plans and procedures. The implementation of the QA program will be accomplished by observing the implementation process and by reviewing documents resulting from implementation such as data records, audit and inspection reports, calibration records, and administrative procedures.

A. Plan and Procedure Reviews

The principal QA program documents to be reviewed by the NRC staff are the Site Characterization Plan, the QA plans and selected implementing procedures for each of the major DOE offices (i.e., HQ and the NNWSI project office), the major participants in the program (Sandia National Laboratories, Fennix and Scisson, etc.), and the other organizations supporting the DOE Headquarters, such as the Defense Waste Processing Facility.

1. Site Characterization Plan

The staff will review and comment on Section 8.6 of the Site Characterization Plan and any other sections containing pertinent information on the QA

acceptance criteria in the technical positions listed below. If the DOE deviates from the criteria listed below, the NRC staff will determine if the deviation and the rational for the deviation are acceptable on a case-by-case basis.

- Technical Position on Quality Assurance for the Site Characterization Phase of the High-Level Nuclear Waste Repository.

- Generic Technical Position on Qualification of Existing Data for the High-Level Nuclear Waste Repositories (NUREG-1298).

- Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories (NUREG-1297).

- Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements.

2. The implementation of the QA plan and procedures will be acceptable to the NRC staff if:

a. DOE staff and the staff of participating organizations determine as a result of audits, inspections, and/or other reviews that the QA plans and procedures are implemented (i.e., the audits, inspections, and other reviews identify no inadequacies or only minimal inadequacies in implementation); or

b. DOE staff and the staff of participating organizations identify, through audits, inspections, or other reviews, inadequacies in plans, procedures, and implementation; and they correct these inadequacies in a timely and acceptable manner. The program will be acceptable if these inadequacies are other than major deficiencies in the

PREFACE

Under the Nuclear Waste Policy Act of 1982, as amended, the Department of Energy (DOE) is to characterize the Yucca Mountain site for a geologic repository to determine if it is suitable for safely isolating high-level nuclear waste. The Nuclear Regulatory Commission's (NRC) role as a regulatory agency during the site characterization phase is to review and comment on the DOE program in order to identify and help resolve potential licensing issues.

The NRC regulations in 10 CFR Part 60 Subpart G require the repository program, including site characterization, to be performed under a quality assurance (QA) program. As required by the regulation, this quality assurance program shall be based on the quality assurance criteria established in 10 CFR Part 50 Appendix B for nuclear power reactors as it applies to the repository program. In addition the regulation requires that the 10 CFR Part 50 Appendix B criteria for quality assurance be supplemented as necessary. In June of 1984 the NRC published the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories." This document outlined the methods by which the NRC staff would oversee the DOE QA program. In addition the document provided in Appendix A the specific QA criteria which the NRC staff would use to review the DOE QA program. Appendix A was based on the Section 17, Quality Assurance, of the NRC Standard Review Plan (SRP) for nuclear power reactors. Some criteria in the SRP were modified and supplemented to address the items and activities in the repository program.

The revision to the NRC Review Plan was undertaken in 1987 to accomplish the following:

* incorporate recommendations (lessons learned) from the power reactor program. The staff issued the 1984 NRC Review Plan shortly after the Ford Amendment Study (NUREG-1055) was published and before many of its recommendations were implemented by the NRC. The Ford Amendment Study was performed at the request of Congress and investigated the

II.7.8 Indoctrination and training programs should be established to instruct personnel who perform quality-related activities as to the purpose, scope, and implementation of the quality-related manuals, instructions, procedures, and other documents. (Ref. 23)

II.7.9 Documentation of formal indoctrination and training programs should include the:

(a) objective;
(b) program content;
(c) instructor's name;
(d) attendee's names;
(e) dates of attendance; and
(f) results of examination, if applicable. (Ref. 23)

(9)

APPENDIX B

REQUIREMENT 8:

The applicant shall regularly review the status and adequacy of the quality assurance program.

NQA-1

No additional guidance provided by NQA-1.

SUPPLEMENTARY NRC STAFF POSITION

8

II.8.1 The applicant should review and assess the scope, status, adequacy and compliance of the QA and technical programs to the requirements in this document. This goal should be accomplished by means such as review and approval of plans and procedures, surveillance, inspection, and audit. (Ref. 19, Ref. 21 and Ref. 23)

APPENDIX B

REQUIREMENT 9:

Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

NQA-1

BASIC REQUIREMENT

...Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.

SUPPLEMENTARY NRC STAFF POSITION

(9) No additional guidance.

V.2.4 Each instruction, procedure, drawing, or plan should specify the organizations and/or positions responsible for and the organizations and/or positions that will perform the activity controlled by the instruction, procedure, drawing, or plan. (Ref. 23)

V.2.5 Instructions, procedures, drawings, and plans should specify how changes should be controlled and should indicate other work that could be affected by the changes. (DOE comment) Changes to these documents should be controlled in accordance with Criterion VI. (NRC STAFF)

V.2.6 Instruction, procedures, drawings and plans should specify the documentation that should be developed and retained as a result of implementing the procedure. (Ref. 23)

(4) documentation, as applicable to the item, was received and is acceptable.

DEFINITIONS

Nuclear Power Plant, Fuel Reprocessing Plant and other like terms: (1) high-level waste repository site; (2) an appropriate location. (NRC STAFF)

SUPPLEMENTARY NRC STAFF POSITION

VII.2.1 Both QA and technical staff, where appropriate, should participate in procurement of items and services. (Ref. 21)

VII.2.2 (NQA-1, Supplement 7S-1, 8.21) Criteria for certificate of conformance should be applied to items other than material and equipment as appropriate. (NRC STAFF)

SUPPLEMENTARY NRC STAFF POSITION

DEFINITION

Material: A substance or combination of substances, such as parts, components consumables, rock samples, and fluid samples. (Ref. 3 and Ref. 23)

VIII.1.1 Measures should be established for the identification and control of items. (NRC STAFF)

VIII.1.2 Correct identification of items should be verified and documented prior to release for use, installation, or analysis. (Ref. 23 and Ref. 21, NRC STAFF)

VIII.1.3 (NQA-1, Supplement 8S-1, 2.1 Item Identification) Items should be identified from the initial receipt or collection. These items should be identifiable throughout the lifetime of the items. The identification should relate the item to its source, such as well bore and depth, and applicable documents, including design documents, plans, test records, and technical reports. (NRC STAFF, Ref. 21 and Ref. 23)

VIII.1.4 Procedures should be developed and implemented to assure that a representative archival sample is maintained from difficult to repeat sample collection activities, such as principle bore hole coring. (NRC STAFF)

VIII.1.5 Provisions should be made for documenting the installation, consumption, or other use of items. (Ref. 18)

APPENDIX B

REQUIREMENT 3:
These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.

NQA-1

BASIC REQUIREMENT
Controls shall be established to assure that only correct and accepted items are used or installed.

SUPPLEMENT 8S-1
3.0 SPECIFIC REQUIREMENTS
3.2 Limited Life Items
Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose life or operating life has expired.

SUPPLEMENTARY NRC STAFF POSITION

(14) VIII.3.1 These identification and control measures should be designed to prevent the use of incorrect or defective items. (Ref. 23 and Ref. 19)

STAFF POSITION

XI.1.1 When a scientific investigation includes a test, the test should be controlled in accordance with Criterion XI. Other activities of the scientific investigation, such as data analysis, should be controlled in accordance with Criterion III. (NRC STAFF)

XI.1.2 The test program should include scientific investigations. (NRC STAFF)

XI.1.3 The test plans and procedures should ensure that the precision, accuracy and inherent uncertainty of data will be suitable for the intended use of that data, such as in computer models and performance assessments. (Ref. 18)

XI.1.4 Potential sources of uncertainty and error in test plans, procedures and parameters that affect data quality should be identified. (Ref. 23)

DISCUSSION

For data collection activities, acceptance limits refer to acceptance criteria for data. The acceptance criteria may be an acceptable range of values within which a data point should fall or an acceptable uncertainty in a measurement. Applicable design documents refer to plans, procedures, or other documents for the conduct of the activity.

XIII.1.9 Controls should 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 data from a notebook onto a data form for data entry or copying from computer tape to disk. (NRC STAFF)

XIII.1.10 All processes which change either the form of expression or quantity of data, values, or number of data items (data reduction) should be controlled by prescribed methods which allow for the validation of the conversion process. (NRC STAFF)

XIII.1.11 The method of data recording (e.g., laboratory and field notebooks, log books, data sheets, computerized instrumentation systems, etc.) should be controlled to avoid loss and permit retrievability. (NRC STAFF)

XIII.1.12 At each stage of data processing where data is stored, controls should be established to assure data integrity and security is maintained. (NRC STAFF)

XIII.1.13 Controls should prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, and access. (NRC STAFF)

XIII.1.14 Data should be suitably protected from damage and unintentional destruction during their prescribed lifetime and readily retrievable from wherever stored. (NRC STAFF)

XIII.1.15 Samples should be physically separated from like samples to preclude mixing. (NRC STAFF)