

ENCLOSURE

MINUTES FOR JOINT BI-MONTHLY QUALITY ASSURANCE MEETING
JULY 11, 1989

On July 11, 1989, staff of the U. S. Nuclear Regulatory Commission (NRC), representatives of the U. S. Department of Energy (DOE) and the State of Nevada held the bi-monthly quality assurance (QA) meeting to discuss QA activities and the NRC staff's review comments on several QA program plans (QAPP). Representatives of the affected-units-of-local governments were not present. The meeting was conducted in two separate sessions. A list of attendees for each session of the meeting is shown in Attachments 1 and 2 respectively.

FIRST SESSION

DOE stated that because of the ongoing efforts to evaluate the feasibility of the schedule for starting the Exploratory Shaft Facility (ESF) construction and because the staff requested a DOE schedule of audits during a recent NRC/DOE meeting held on July 6, and 7, 1989, it had prepared schedule updates for conducting the remaining qualification audits of its support contractors for the Yucca Mountain Project Office (YMPO). DOE stated that the remaining audits, to be conducted between July 1989 and October 1989, will cover procedural as well as technical implementation aspects of the quality assurance program (QAP), where possible. Scheduled dates for the audits are provided in Attachment 3, "Status of DOE QA Program Implementation."

DOE reported that, during a recent YMPO review of the Sandia National Laboratory (SNL) QA program plan (QAPP), the YMPO identified deficiencies including unauthorized changes in the language to the QAPP procedures. The review revealed that in Appendix H, Section 7.2, "Software Life-Cycle Requirements," of the SNL QAPP, there were changes to requirements related to software lifecycle that effectively diluted the requirement and made it less stringent. Consequently, YMPO issued a stop-work order to SNL, effective July 10, 1989. DOE projected that the deficiencies will be reviewed and corrected by July 14, 1989. This would affect a postponement of the July 17, 1989 SNL audit to a later date (July 19, 1989).

DOE stated that lifting the stop-work order is dependent upon fulfillment of two requirements: 1) SNL's satisfactory correction of the YMPO deficiency reports; and 2) corrections to SNL's QAPP to bring it into compliance with the requirements in the "Nevada Nuclear Waste Storage Investigations Quality Assurance Plan" (NNWSI QAP 88-9), Revision 2. DOE committed to provide additional information to the NRC by July 14, 1989 on the progress towards lifting the stop work order and subsequent plans to conduct the SNL audit.

Next, DOE presented a summary of the results of its surveillances for accepting the project participants' QA programs that were performed by the YMPO and the Office of Civilian Radioactive Waste Management. A summary status report, "QAP Acceptance Surveillances Status" is provided in Attachment 4. DOE reported that 90 of the planned total of 104 surveillances of the project participants and the YMPO were conducted since January 1989 and that the 14 remaining surveillances were planned to be completed by the end of July 1989. The NRC staff inquired whether there were any remaining surveillances of Fenix and Scisson (F&S) and Holmes and Narver (H&N) regarding their readiness to start ESF, Title II design activities. DOE indicated that surveillances planned for completion by the end of July 1989 included F&S, H&N and the U. S. Geological Survey (USGS), although the USGS schedule appeared to be optimistic at this time. No acceptance surveillances will be conducted until mid-August 1989. DOE further stated that an integrated YMPO surveillance approach will be used to examine a sample of every aspect of ESF, Title II design activities (i.e. a cross-cut of all technical disciplines).

In response to NRC staff concerns raised in the May 9, 1989 QA meeting regarding a need for clarification in the usage of the terms "observation" and "deficiency" to report audit findings, DOE made a short presentation further clarifying the YMPO requirements pertaining to documentation of observations and deficiencies. As noted in the May 9, 1989 meeting minutes, DOE stated that deficiencies are used to describe or identify noncompliances resulting from inadequate implementation of procedural or regulatory requirements while observations identify a condition that could lead to a deficiency if left uncorrected. During the meeting (July 1989), DOE stated that, in the future, observations on approved procedures that are cited as a result of an audit will be considered a deficiency. In addition, observations cited during previous audits will be revisited and appropriately corrected in accordance with this procedure.

DOE made a short presentation summarizing the results of its Lawrence Livermore National Laboratory (LLNL) audit held during the week of June 5, 1989. No concerns were raised by the staff or the meeting participants.

NRC staff then presented a summary of the preliminary findings resulting from its observations of the DOE audit of the LLNL held during the week of June 5, 1989. The staff indicated that there is a need for improved coordination between the DOE technical specialists and auditors working in the related areas. The staff also stated that the DOE audit procedure(s) should explicitly require previous NRC and State of Nevada observations to be reviewed in determining the scope of the audit. With respect to particular concerns the staff identified with the LLNL program, it was noted that the LLNL procedures should require that all internal review comments on technical procedures be permanently documented. In addition, the staff found that the LLNL interchange of information between technical groups should be formally documented. Finally, the staff suggested that DOE should make provisions to keep NRC informed of the details of its ongoing peer review process.

The next discussion at the meeting was to assess the status of the open items identified in the July 7, 1988 NRC/DOE QA meeting. DOE indicated that of the 20 items identified at the July 7, 1988 meeting, it had responded to 16 items and therefore considered those items closed. DOE's record and status of open items are provided in Attachment 5, "Results of July 7-8 NRC/DOE Meeting." The meeting participants agreed that since the July 7, 1988 meeting, new open items had evolved and some of the existing items have been reclassified. The meeting participants agreed to provide input regarding areas where there was a major misunderstanding or objection to the status of an open item. The meeting participants identified two additional open items that should be included on DOE's list. The two open items are: 1) issues related to the G-Tunnel testing activities; and 2) Open Item QA-E-1 (DOE Number), qualification of existing data. The staff indicated that DOE committed to qualify data in accordance with the staff's technical position in the NNWSI QAP 88-9; however, DOE has not forwarded the procedure on qualifications of existing data to NRC.

DOE inquired whether the open items can be addressed as part of the qualification audits. The staff stated that the items should be included as part of the qualification audit and will remain open until the NRC staff has accepted the DOE response or action in attempts to close that item. The participants agreed that the subject of open item status should be discussed at a future meeting focused specifically on determining the status, nature and scope of the open items.

Finally, the NRC staff expressed concern about the extended time of the DOE responses to the NRC June 8-12, 1987 audit of LANL. Five DOE reports have been submitted to the NRC noting the corrective action for the 17 NRC audit findings. After the NRC review of these 5 corrective action reports by DOE, 12 of the 17 audit findings remain open. The NRC staff indicated that there is concern on whether an effective corrective action program has been established to implement corrective action in a timely manner when after two years, 12 findings are still not closed.

There was a final discussion on the form and structure of the meeting which resulted in agreement by all parties to work cooperatively to focus the meetings on specific QA issues and to bring issues needing resolution to the forefront of the meeting. The schedule of the next meeting, in which this approach will be implemented, is tentatively September 6, or 7, 1989.

Potential agenda items for future meetings discussed were:

- Shaft "Q-List" Open Item
- Core drilling procedures
- OGR/B-14
- Procedures for qualifying existing data
- Plans and problems related to prototype borehole testing
- Participants briefing on problem areas

Other item(s) discussed that will necessitate a separate meeting:

- Open items from July 7, 1988 NRC/DOE QA meeting

Statement by the State of Nevada

The following is the State of Nevada's written statement regarding this meeting that was provided to the NRC Project Manager subsequent to the conclusion of the meeting.

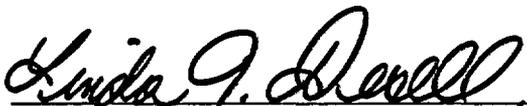
"The State of Nevada echoes the NRC comments at the close of this meeting, to have the meeting focused on more specific QA issues in an effort to make these meetings more productive and beneficial."

SECOND SESSION

Subsequent to the first session of the July 11, 1989 meeting a separate meeting was held in which the participants engaged in a working session to review DOE's written responses to NRC review comments on the USGS, LLNL and SNL QAPPs.

DOE provided responses to NRC's review comments on the USGS QAPP (QAPP-01), Rev. 5, (Attachment 6); the LLNL QAPP (033-YMP-R), Rev. 0 (Attachment 7); and the SNL QAPP (SLTR 88 - 0001) Rev.C, (Attachment 8) respectively.

NRC staff indicated which responses, provided during the meeting, were acceptable; however, as agreed to at the beginning of the meeting, final acceptance would be granted by NRC only after DOE's submittal of the appropriate revised pages in the QAPPs. DOE projected that the revised pages to the QAPPs could be completed as early as August 25, 1989. It was agreed, that a teleconference call between the participants would be held to review the revised pages to the QAPPs prior to final submittal of the revised QAPP. The revised pages and any pertinent material will be provided to the participants at least two working days in advance of the teleconference call to facilitate the participants preparation for the discussion.


Linda J. Desell *8/28/89*
Licensing Branch
Office of Radioactive Waste
Management
U. S. Department of Energy


Brian E. Thomas, Project Manager
Repository Licensing and Quality
Assurance Project Directorate
U. S. Nuclear Regulatory Commission

QA BI-MONTHLY MEETING
JULY 11, 1989
LIST OF ATTENDEES

| <u>NAME</u> | <u>ORGANIZATION</u> |
|-----------------------|---------------------|
| Brian Thomas | NRC |
| Linda Desell | DOE |
| Dwight Shelor | DOE |
| Joe Holonich | NRC |
| Susan Zimmerman | State of Nevada |
| Ed Wilmot | DOE/YMP |
| Nancy Voltura | DOE/YMP |
| Jim Kennedy | NRC |
| Tilak Verma | NRC |
| Tatiana Austin | DOE |
| Tom Colandrea | EEl |
| Christopher J. Henkel | EEl/UWASTE |
| Jim Conway | NRC |
| Ken Hooks | NRC |
| Bill Belke | NRC |
| Ram Murphy | DOE/YMP |
| Terry Dunn | CER/RTTD |
| Henry Paul Nunes | LANL |
| Michael J. Regenda | FSN |
| Harry R. Tutnill | Holmes & Narver |
| Carl Gertz | DOE/YMP |
| Stan Echols | DOE |
| Sue Gagner | NRC |
| Steven Rossi | DOE |
| Gina Roseboom | USGS |
| Ray Wallace | USGS-HQ/DOE-HQ |
| J. R. Caldwell | MACTGE |
| Mono Fox | REECe |
| Gary Faust | Weston |
| Rick Bahorich | Westinghouse |
| Don Miller | CER Corp. |
| Tim Johnson | OCRWM |
| Catherine Hampton | DOE/YMPO |

Attachment 2

QA BI-MONTHLY MEETING
JULY 11, 1989
(QAPP REVIEW)

LIST OF ATTENDEES

| <u>NAMES</u> | <u>ORGANIZATION</u> |
|--------------------|---------------------|
| Brian Thomas | NRC |
| Linda Desell | DOE |
| Jim Conway | NRC |
| Ken Hooks | NRC |
| Susan Zimmerman | State of Nevada |
| Bill Belke | NRC |
| Nancy Voltura | DOE/YMP |
| Jim Kennedy | NRC |
| Steven Rossi | DOE |
| Ray Wallace | USGS-HQ/DOE-HQ |
| Catherine Hampton | DOE/YMP |
| Timothy W. Johnson | DOE |
| Don Miller | CER. CORP. |
| J. W. Estella | SAIC |
| R. J. Bahorich | Westinghouse |
| Ed Wilmot | DOE/YMP |
| Harry Tuthill | Holmes & Narver |
| Terry Dunn | CER/RTTD |
| Karl Sommer | DOE |

STATUS OF DOE QA PROGRAM IMPLEMENTATION

| QA PROGRAM PLAN | | | | | QUALIFIED QA PROGRAM | | |
|---------------------------------|--------------------------------|-------------------------------|--------------------------------|----------------------------|----------------------|--------------------------|-------------|
| ORGANIZATION | DOE SUBMITS | NRC COMMENTS | DOE REVISES | NRC ACCEPTS | QUALIFICATION AUDITS | DOE ACCEPTS ⁴ | NRC ACCEPTS |
| OCRWM ¹ ₂ | AUG. 26, 1988 SEP. 16, 1988 | SEP. 28, 1988 NOV. 3, 1988 | NOV. 29, 1988 DEC. 21, 1988 | MAY 8, 1989 MAY 2, 1989 | OCT. 16, 1989 | NOV. 27, 1989 | NO |
| YMP | AUG. 15, 1988 | OCT. 14, 1988 | DEC. 13, 1988 | DEC. 30, 1988 | NA | NA | NA |
| YMPO | AUG. 1, 1989 | NO | NO ³ | NO | SEP. 25, 1989 | NOV. 6, 1989 | NO |
| F&S | FEB. 21, 1989 | MAR. 22, 1989 | JUL. 28, 1989 | NO | APR 10-14, '89 | AUG. 7, 1989 | NO |
| H&N | MAR. 3, 1989 | APR. 26, 1989 | JUL. 28, 1989 | NO | APR 24-26, '89 | AUG. 7, 1989 | NO |
| SNL | APR. 14, 1989 | JUN. 26, 1989 | AUG. 25, 1989 | NO | JUL. 17, 1989 | AUG. 28, 1989 | NO |
| USGS | APR. 14, 1989 | JUN. 20, 1989 | AUG. 25, 1989 | NO | AUG. 14, 1989 | SEP. 25, 1989 | NO |
| REEC _o | FEB. 21, 1989 | MAY 5, 1989 | JUL. 28, 1989 | NO | SEP. 11, 1989 | OCT. 23, 1989 | NO |
| LLNL | MAR 3, 1989 | JUN. 19, 1989 | AUG. 25, 1989 | NO | JUN 5-9, 1989 | AUG. 25, 1989 | NO |
| LANL | MAR. 15, 1989 | NO | NO ³ | NO | AUG. 28, 1989 | OCT. 9, 1989 | NO |

- 1) QARD 2) QAPD 3) 4 WEEKS AFTER RECEIPT OF NRC COMMENTS
4) BASED ON RECEIPT OF NRC OBSERVATIONS WITHIN 30 DAYS AFTER AUDIT

QAP ACCEPTANCE SURVEILLANCE STATUS

| | <u>SCHEDULED</u> | <u>PERFORMED</u> | <u>IN PROCESS</u> | <u>REMAINING</u> |
|-------------------|------------------|------------------|-------------------|------------------|
| F&S | 21 | 21 | COMPLETE | 0 |
| USGS | 10 | 9 | 0 | 1 |
| H&N | 9 | 9 | COMPLETE | 0 |
| LANL | 11 | 6 | 0 | 5 |
| LLNL | 14 | 14 | COMPLETE | 0 |
| YMP | 16 | 10 | 0 | 6 |
| REEC _o | 10 | 9 | 0 | 1 |
| SNL | 13 | 12 | 0 | 1 |
| <hr/> | | | | |
| TOTAL | 104 | 90 | 0 | 14 |

NOTE: IMPLEMENTATION SURVEILLANCES ARE NOT REFLECTED ABOVE
PERCENT COMPLETE = 87%

RESULTS OF PROJECT OFFICE PROGRAMMATIC SURVEILLANCE

F&S

- 21 SURVEILLANCES HAVE BEEN PERFORMED
- 13 PROCEDURAL DEFICIENCIES WERE REPORTED ASSOCIATED WITH 10 OF 64 PROCEDURES REVIEWED;
- NO IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED

USGS

- 9 SURVEILLANCES HAVE BEEN PERFORMED
- 7 IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED
- 19 OF 35 PROCEDURES WERE FOUND DEFICIENT AND REVISED IMMEDIATELY

RESULTS OF PROJECT OFFICE PROGRAMMATIC SURVEILLANCE

(CONTINUED)

H&N

- 9 SURVEILLANCES HAVE BEEN PERFORMED
- 10 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 27 OF 35 PROCEDURES REVIEWED
- 3 PROCEDURES WERE REVISED IMMEDIATELY (NOTE: 3 OF THE 10 DEFICIENCIES WERE GENERIC AND APPLIED TO MANY OF THE H&N PROCEDURES REVIEWED)

LANL

- 6 SURVEILLANCES HAVE BEEN PERFORMED
- 15 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 13 OF 19 PROCEDURES REVIEWED

RESULTS OF PROJECT OFFICE PROGRAMMATIC SURVEILLANCE

(CONTINUED)

LLNL

- 14 SURVEILLANCES HAVE BEEN PERFORMED
- 24 OF 34 PROCEDURES REVIEWED CONTAINED MINOR DEFICIENCIES
- PROCEDURES WERE REVISED IMMEDIATELY
- NO DEFICIENCY REPORTS WERE ISSUED

YMP

- 10 SURVEILLANCES HAVE BEEN PERFORMED
- 26 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 22 OF 39 PROCEDURES REVIEWED

RESULTS OF PROJECT OFFICE PROGRAMMATIC SURVEILLANCE

(CONTINUED)

REECo

- 9 SURVEILLANCES HAVE BEEN PERFORMED
- PROCEDURAL DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 24 OF 32 PROCEDURES REVIEWED

SNL

- 12 SURVEILLANCES HAVE BEEN PERFORMED
- 18 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 50 OF 53 PROCEDURES REVIEWED

(NOTE: 1 OF THE 18 DEFICIENCIES WAS GENERIC - LACK OF QA RECORDS SECTION - AND APPLIED TO 50 SNL PROCEDURES REVIEWED)

RESULTS OF JULY 7-8 NRC/DOE MEETING

The July 7-8, 1988 DOE/NRC meeting resulted in the identification of three types of DOE action items:

1. Previously identified items which were still open and required closure. These items constitute the 11 NRC QA Open Items identified in the minutes of the meeting.
2. Previously identified items which were closed at the meeting based on DOE commitments to perform specific actions. These items are identified by the designation QA-X-Y, where X is a letter designation and Y is a numerical identifier.
3. New items identified at the meeting. These items are identified by the NRC item number given in the Attachment to the meeting minutes.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING

ACTION ITEM 1

NRC OPEN ITEM 3: CDSCP COMMENTS ON QA. (QA-C-2)

STATUS: LETTER FROM S. ROUSSO OCRM, TO HL THOMPSON JR. NRC, TRANSMITTED SCP TO NRC. THE COVER LETTER IDENTIFIES THAT THE NRC COMMENTS ON THE CDSCP HAVE BEEN ADDRESSED BY INCORPORATION OF INFORMATION INTO THE SCP.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 2

NRC OPEN ITEM 4, 5, AND 6: NRC REVIEW OF DEFENSE WASTE QA PLAN (QA-F-1). NRC OVERVIEW (AUDITS) OF THE DEFENSE WASTE PROGRAM (QA-F-3). OCRWM OVERVIEW (AUDITS) OF THE DEFENSE WASTE PROGRAM (QA-F-2).

STATUS: OGR B/14 TRANSMITTED TO NRC ON 8/9/89.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 3.

NRC OPEN ITEM 7: (QA-G-1, 1A, AND 1D) RESPONSES TO NRC AUDIT OBSERVATIONS.

STATUS: RESPONSES TO NRC AUDIT OBSERVATIONS ON AUDITS 88-01, 88-02, AND 88-03, SENT TO NRC ON 12/29/88. PREVIOUS AUDITS OF PARTICIPANTS ALSO INCLUDED IN TRANSMITTAL. TRANSMITTAL OF AUDITS IS AN ONGOING ACTION.

ACTION ITEM 4

NRC OPEN ITEM 8: NRC REVIEW OF THE OCRWM QA PROGRAM.
(7/7 MEETING AND QA-B-2)

STATUS: QAR AND QAPD TRANSMITTED TO NRC ON 11/29 AND 12/21 RESPECTIVELY.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 5:

NRC OPEN ITEM 9: Q-LIST FOR THE EXPLORATORY SHAFT. (PRE-MEETING ENCLOSURE 2 ITEM 13)

NRC OPEN ITEM 11: QUALITY ASSURANCE MEASURES APPLIED TO CONCEPTUAL DESIGN. (7/8 MEETING)

STATUS: A MEETING WAS HELD WITH THE NRC ON 7/18-19/88, TO DISCUSS THESE ITEMS. PERFORMED ESF DESIGN ACCEPTABILITY ANALYSIS (DAA). SURVEILLANCE OF READINESS FOR TITLE II DESIGN PERFORMED IN MARCH OF 89. Q-LIST FOR EXPLORATORY SHAFT WAS INCLUDED IN SCP.

RESPONSE TO NRC REVIEW COMMENTS
USGS QAPP (QAPP-01), REV. 5

NRC COMMENT NO. 1

Criterion 1.11 of the Review Plan (RP) states, in part, "...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."

This criterion is not addressed in the USGS QAPP.

RESPONSE TO COMMENT NO. 1

This requirement is satisfied by Section II of NNWSI/88-9, Rev. 2 which provides for establishment of QA levels and a "graded approach" in the selection of the quality assurance requirements to be applied to an item or activity commensurate with the relative importance of the role or function assigned to the item or activity. The methodology for implementation of these requirements to satisfy NUREG-1318 are contained in YMP Administrative Procedures which provide for the establishment of QA controls by the QA staff in combination with the line staff based upon the specific activity, its complexity, and its importance to safety or waste isolation. Section 2 of the USGS QAPP contains the equivalent of the NNWSI/88-9 requirements relative to the application of graded QA.

During the next general revision of NNWSI/88-9, Rev. 2, Criterion 1.11 of the NRC Review Plan will be incorporated explicitly and the USGS QAPP will be subsequently revised to address this provision.

7/11/89
Accepted pending submittal
of documented
page change to NRC.
7/11/89

NRC COMMENT NO. 2

Criterion 1.18 (1.17 of Rev.2 of NRC SRP) of the RP states, "Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or from outside the responsible organization(s)."

This criterion is not addressed in the USGS QAPP.

RESPONSE TO NRC COMMENT NO. 2

Since Criterion 1.17 was not included in NNWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) USGS did not address this subject.

During the next general revision of NNWSI/88-9, provisions will be added for requiring that internal and external allegations of inadequate quality be resolved at all organizational levels. The USGS QAPP will be revised to contain the provision.

Additionally, at the Yucca Mountain Project level, a procedure has been developed to deal with internal and external quality concerns. The procedure, AP-5.8Q, Reporting and Resolution of Quality Concerns, describes the system that will provide all Project personnel the means to express quality concerns with assurance that those concerns will be investigated and resolved.

7/11/89
Accepted
pending documented
page change

NRC COMMENT NO. 3

Criterion 5.4 of the RP states, in part, "Provisions are described for controlling changes to field and laboratory procedures associated with exploratory investigation within the site characterization program..."

This criterion is not addressed in the USGS QAPP.

RESPONSE TO NRC COMMENT NO. 3

Since Criterion 5.4 was not included in NNWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) USGS did not address this issue. However, NNWSI/88-9, Section III, Paragraph 1.6.2 and Sections V and VI contain requirements for controlling changes to all procedures which would include field and laboratory procedures associated with site characterization activities. Equivalent requirements are contained in the USGS QAPP Section 3, Paragraph 3.1.7.2 and Sections 5 and 6. Criterion 5.4 of the NRC Review Plan will be incorporated into the next general revision of NNWSI/88-9 and the USGS QAPP will be subsequently revised accordingly.

7/11/89
Accepted pending
submission of revised pages

NRC COMMENT NO. 4

Criterion 6.2 of the RP states in part "...procedures assure that the technical ... requirements are correctly included ... through reviews by qualified authorized personnel who did not provide input to the document.

In the USGS QAPP, there is no provision for a technical review of documents by qualified authorized personnel who did not provide input to the document.

RESPONSE TO NRC COMMENT NO. 4

Criterion 6.2 of the NRC Review Plan represents a modification to a previous requirement and as such is not addressed in NNWSI/88-9, Rev. 2 or the USGS QAPP. However, Section VI of NNWSI/88-9, Rev. 2 and Section 6.0 of the USGS QAPP require a review of documents for technical adequacy, completeness and correctness. Technical review is defined by both documents as:

"A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluation of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness."

This modified NRC Review Plan requirement will be incorporated during the next general revision to NNWSI/88-9 and the USGS QAPP will be subsequently revised.

7/11/89
accepted
pending revised
changes

NRC COMMENT NO. 5

Criterion 12.2 of the RP states, "QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program."

This criterion is not addressed in the USGS QAPP.

RESPONSE TO NRC COMMENT NO. 5

The USGS QAPP will be revised to describe the QA and other organization's responsibilities for establishing, implementing, and assuring effectiveness of the calibration program.

7/11/89
Accepted
pending submittal
of revised pages
to NRC

RESPONSE TO NRC REVIEW COMMENTS
LLNL QAPP (033-YMP-R), REV. 0

NRC COMMENT NO. 1

Criterion 1.17 of the RP states, "Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or from outside the responsible organization(s)."

This criterion is not addressed in the LLNL QAPP.

RESPONSE TO COMMENT NO. 1

Since criterion 1.17 was not included in NNWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) LLNL did not address this subject.

During the next general revision of NNWSI/88-9, provisions will be added for requiring that internal and external allegations of inadequate quality be resolved at all organizational levels. The LLNL QAPP will be revised to contain the provision.

Additionally, at the Yucca Mountain Project level, a procedure has been developed to deal with internal and external quality concerns. The procedure, AP-5.8Q, Reporting and Resolution of Quality Concerns, describes the system that will provide all Project personnel the means to express quality concerns with assurance that those concerns will be investigated and resolved.

OK 7/11
pending submitted &
revised per 905
EF

NRC COMMENT NO. 2

Criterion 2.13 of the RP states, "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."

This criterion is not addressed in the LLNL QAPP.

RESPONSE TO COMMENT NO. 2

Criterion 2.13 is a new NRC Review Plan requirement which is not presently contained in the YMP QA Plan (NNWSI/88-9), Rev. 2 and therefore was not addressed in the LLNL QAPP. During the next general revision of NNWSI/88-9, provisions will be added to incorporate this NRC Review Plan requirement. Subsequently, the LLNL QAPP will be revised to incorporate the requirement.

OK 7/11/89
pending submittal of
revised pages

NRC COMMENT NO. 3

Criterion 11.8 of the RP states, "Items tested should be identified, controlled, and ultimately dispositioned, and samples should be archived, as required by procedures."

This criterion is not addressed in the LLNL QAPP.

RESPONSE TO COMMENT NO. 3

Criterion 11.8 is a new NRC Review Plan requirement which is not presently contained in the YMP QA Plan (NNWSI/88-9), Rev. 2 and therefore was not addressed in the LLNL QAPP. However, it should be noted that Section VIII of NNWSI/88-9, Rev. 2 presently requires identification and control of items and samples. These provisions are also contained in the LLNL QAPP. During the next general revision of NNWSI/88-9, provisions will be added to directly incorporate this NRC Review Plan requirement. Subsequently, the LLNL QAPP will be revised to incorporate the requirement.

2/11/88
OK pending
revised pages

NRC COMMENT NO. 4

Criterion 14.5 of the RP states, "Procedures are established and described to control altering the sequence of required tests, inspection, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval."

This criterion is not addressed in the LLNL QAPP.

RESPONSE TO COMMENT NO. 4

Criterion 14.5 is a new NRC Review Plan requirement which is not presently contained in the YMP QA Plan (NNWSI/88-9), Rev. 2 and therefore was not addressed in the LLNL QAPP. However, it should be noted that Section X of NNWSI/88-9 and the LLNL QAPP presently provide requirements for the establishment of hold points which provides a mechanism to control the sequence of required tests, inspection, and other operations important to safety. During the next general revision of NNWSI/88-9, provisions will be added to directly incorporate this NRC Review Plan requirement. Subsequently, the LLNL QAPP will be revised to incorporate the requirement.

7/11/89
ok pending submittal
of revised pages to
NRC

NRC COMMENT NO. 5

Criterion 14.6 of the RP states, "The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified."

The LLNL QAPP does not identify the organization(s) responsible for this function.

RESPONSE TO COMMENT NO. 5

Criterion 14.6 is a new NRC Review Plan requirement which is not presently contained in the YMP QA Plan (NNWSI/88-9), Rev. 2 and therefore was not addressed in the LLNL QAPP. However, it should be noted that Section XV of NNWSI/88-9, Rev. 2 and the LLNL QAPP presently contain requirements for the control of nonconforming items to prevent inadvertent installation or use. During the next general revision of NNWSI/88-9, provisions will be added to directly incorporate this NRC Review Plan requirement. Subsequently, the LLNL QAPP will be revised to incorporate the requirement.

7/11/89
OK pending
revised pages

RESPONSE TO NRC REVIEW COMMENTS
SNL QAPP (SLTR 88-0001) REV. C

NRC COMMENT NO. 1

Criterion 1.10 of the Review Plan (RP) states, "Organization charts clearly identify all the "on-site" and "off-site" organizational elements which function under the cognizance of the QA program."

This criterion is not addressed in the QAPP.

RESPONSE TO COMMENT NO. 1

The Sandia Nuclear Waste Repository Technology Department (Dept. 6310) is shown in Figure 1 of Section 1.0 of the SNL QAPP. This organizational chart also depicts the Technical Divisions who have designated responsibility for YMP activities. Although SNL will be performing work at the Yucca Mountain location as well as in Albuquerque, New Mexico, there is no separate "on-site" organizational structure established for the performance of this work. Therefore, the organizational chart presently contained in the SNL QAPP is complete and accurate.

closed item

7/11/89

BT

NRC COMMENT NO. 2

Criterion 1.17 of the RP states, "Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or from outside the responsible organization(s)."

This criterion is not addressed in the QAPP.

RESPONSE TO COMMENT NO. 2

Since Section 1.17 was not included in NNWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) SNL did not address this subject.

During the next general revision of NNWSI/88-9, provisions will be added for requiring that internal and external allegations of inadequate quality be resolved at all organizational levels. The SNL QAPP will be revised to contain the provision.

Additionally, at the Yucca Mountain Project level, a procedure has been developed to deal with internal and external quality concerns. The procedure, AP-5.8Q, Reporting and Resolution of Quality Concerns, describes the system that will provide all Project personnel the means to express quality concerns with assurance that those concerns will be investigated and resolved.

7/11/89
Accepted
pending submittal
of documented
change

Procedure 5-APQ

NRC COMMENT NO. 3

Criterion 2.8 of the RP states, "A policy statement signed by a senior management official renders the implementation of the QA program mandatory."

The policy statement in the QAPP is not signed by a senior manager.

RESPONSE TO COMMENT NO. 3

The policy statement presently contained in the SNL QAPP will be endorsed by a senior management official and redistributed to SNL QAPP manual holders.

7/11/89
OK pending
submission to NRC

NRC COMMENT NO. 4

Criterion 5.4 of the RP states, "Provisions are described for controlling changes to field and laboratory procedures associated with exploratory investigations within the site characterization program to assure that such changes are subsequently documented and verified in a timely manner by authorized personnel."

This criterion is not addressed in the QAPP.

RESPONSE TO COMMENT NO. 4

Since Criterion 5.4 was not included in NNWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) SNL did not address this issue. However, NNWSI/88-9, Section III, Paragraph 1.6.2 and Sections V and VI contain requirements for controlling changes to all procedures which would include field and laboratory procedures associated with site characterization activities. Equivalent requirements are contained in the SNL QAPP Section 3.0, Paragraph 3.7.3 and Sections 5 and 6. Criterion 5.4 of the NRC Review Plan will be incorporated into the next general revision of NNWSI/88-9 and the SNL QAPP will be subsequently revised.

2/11
OK - pending
submission to NRC

NRC COMMENT NO. 5

Criterion 14.5 of the RP states, "Procedures are established and described to control altering the sequence of required tests, inspection, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval."

This criterion is not addressed in the QAPP.

RESPONSE TO COMMENT NO. 5

Criterion 14.5 is a new NRC Review Plan requirement which is not presently contained in the YMP QA Plan (NNWSI/88-9), Rev. 2 and therefore was not addressed in the SNL QAPP. However, it should be noted that Section X of NNWSI/88-9 and the SNL QAPP presently provide requirements for the establishment of hold points which provides a mechanism to control the sequence of required tests, inspection, and other operations important to safety. During the next general revision of NNWSI/88-9, Rev. 2 the subject requirement will be incorporated and the SNL QAPP will be revised accordingly.

7/11/89
OK - pending & revised pages
submitted by [signature]

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 6

NRC OPEN ITEM 10: CONTROL OF CORE AT NNWSI. (PRE-MEETING ENCLOSURE 2 ITEM 39, AND NRC LIST ITEM 7)

STATUS: LIST OF CORE HANDLING PROCEDURES SENT TO NRC FOR THEIR SELECTION OF PROCEDURES TO REVIEW. THE NRC APPARENTLY WANTS TO RECEIVE ALL CORE HANDLING PROCEDURES. SINCE THE PROCEDURES HAVE NOT ALL BEEN APPROVED, THIS ITEM IS OPEN PENDING THEIR APPROVAL AND SUBMITTAL TO THE NRC.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 7

QA-A-1: LETTER FROM DOE TO NRC IDENTIFYING FINAL SCHEDULE FOR APPROACH TO ACCEPTANCE OF QA PROGRAM FOR NEW SITE CHARACTERIZATION ACTIVITIES. LETTER TO INDICATE THE LINKAGE OF PROGRAM ACCEPTANCE AND NRC REVIEW AND APPROVAL OF STUDY PLANS.

QA-B-1d (1): LETTER FROM DOE TO NRC EXPLAINING DOES'S COMMITMENT TO A QUALIFIED QA PROGRAM PRIOR TO STARTING NEW SITE CHARACTERIZATION. TO INCLUDE NECESSITY OF BALANCING THIS COMMITMENT AND THE AVAILABILITY OF RESOURCES AGAINST OTHER PROGRAMMATIC ISSUES.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 7 (CONTINUED)

QA-G-3, 4, AND 5: LETTER FROM DOE TO NRC REGARDING THE PENDING ACTIONS SCHEDULED TO ACCOMPLISH ACCEPTANCE OF OCRWM'S QA PROGRAM AND IMPLEMENTATION. (

QA-G-6: LETTER FROM DOE TO NRC STATING THAT CORRECTIVE ACTION RESPONSES FROM THE AUDITED ORGANIZATION SHOULD BE DISTRIBUTED TO THE NRC.

ITEM 1 (ATTACHMENT): LETTER FROM DOE TO NRC DEFINING TITLE I, II, AND III DESIGN PHASES. (

STATUS: NO ACTION

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 8

QA-B-1C: DOE TO OBTAIN DOCUMENTS RELATED TO NRC INSPECTION PROGRAMS AND READINESS REVIEW PROGRAMS (QA-B-1C).

STATUS: LETTER REQUESTING DOCUMENTS SENT ON 1/23/89.

ACTION ITEM 9

ITEM 10 (ATTACHMENT): RIGHTS OF ACCESS BETWEEN PNL AND LLNL.

STATUS: LETTER FROM STEIN TO YOUNGBLOOD TRANSMITTED DOE-RL RESPONSE ON RIGHTS OF ACCESS.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 10

QA-B-1D (14): TRANSMIT LETTER EXPLAINING YMP'S AUTHORITY OVER PROJECT PARTICIPANTS.

STATUS: INTERAGENCY AND MANAGEMENT AGREEMENTS ARE BEING FINALIZED. STOP WORK ORDER PROCEDURE APPROVED.

ACTION ITEM 11

QA-B-10: RESPONSE TO COMMENTS ON LANL QA PLAN REV. 1.

STATUS: COMMENTS INCORPORATED INTO LANL QA PROGRAM PLAN AND TRANSMITTED TO NRC ON 3/10/89.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 12

NRC OPEN ITEM 1: QUALITY LEVEL FOR THE PREPARATION OF
THE SCP (QA-C-1).

NRC OPEN ITEM 2: QUALITY LEVEL FOR THE PREPARATION OF
STUDY PLANS. (7/7 MEETING AND QA-C-1)

STATUS: SCP MANAGEMENT PLAN AND AP 1.10Q, "PREPARATION,
REVIEW AND APPROVAL OF SCP STUDY PLANS"
TRANSMITTED TO NRC ON 1/23/89.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 13

QA-E-2 AND 3: TRANSMIT EXPLANATION OF APPROACH TO
EXPERIMENTS CONCERNING ROCK MECHANICS.

STATUS: LETTER FROM DOE DATED 12/29/88 - TRANSMITTED
"APPROACH TO EXPERIMENT PLANNING AND DATA
MANAGEMENT".

ACTION ITEM 14

QA-G-2: CORRECTIVE ACTION FOR LANL AUDIT.

STATUS: LETTER FROM APPEL TO LINEHAN TRANSMITTED FIRST
MONTHLY REPORT OF STATUS OF CORRECTIVE
ACTIONS FOR LANL. STATUS REPORTS SENT ON 3/3/89,
4/13/89, AND 4/28/89.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 15

QA-G-8 (YMP): PROVIDE NRC WITH A LIST OF CONTRACTORS FOR YMP, THEIR CONTRACTUAL RELATIONSHIP, AND IDENTIFY IF THEY PERFORM WORK WHICH IS IMPORTANT TO SAFETY OR WASTE ISOLATION (QA-G-8).

STATUS: LETTER FROM DOE TO NRC DATED 6/23/89 TRANSMITTED THE LIST OF YMP CONTRACTORS AND THEIR SCOPES OF WORK.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 16

QA-G-8 (OCRWM): PROVIDE NRC WITH A LIST OF CONTRACTORS FOR OCRWM, THEIR CONTRACTUAL RELATIONSHIP, AND IDENTIFY IF THEY PERFORM WORK WHICH IS IMPORTANT TO SAFETY OR WASTE ISOLATION.

STATUS: LETTER FROM DOE DATED 1/23/89 FROM APPEL TO LINEHAN POINTED OUT THE SECTION OF THE QAPD THAT CONTAINED INFORMATION ON OCRWM CONTRACTORS.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 17

ITEM 2 (ATTACHMENT): IDENTIFY HOW NRC CONCERNS ON TRAINING WILL BE ADDRESSED

STATUS: LETTER FROM DOE DATED 12/29/89 TRANSMITTED YMP'S TRAINING MANAGEMENT PLAN.

ACTION ITEM 18

VARIOUS ITEMS: DEVELOP OCRWM QA PROGRAM WHICH IS CONSISTENT WITH 88-9 (QA-A-2, AND 3, QA-B-1A, 1B, 1D(5), 1D(12), AND QA-G-12).

STATUS: QAR AND QAPD SENT TO NRC 11/29/88 AND 12/21/88 RESPECTIVELY.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 19

ITEM 11 (ATTACHMENT): NRC CONCERNS ON ADEQUACY OF DOE-RL PRE-AUDIT TRAINING (NRC ITEM 11 FROM ATTACHMENT TO JULY 7-8 MEETING MINUTES).

STATUS: LETTER FROM DOE TO NRC DATED 12/28/89 TRANSMITTED DOE-RL RESPONSE REGARDING ADEQUATE PRE-AUDIT TRAINING.

RESULTS OF JULY 7-8, 1989 DOE/NRC MEETING (CONTINUED)

ACTION ITEM 20

ITEM 13 (ATTACHMENT): PERSONNEL QUALIFICATIONS ARE NOT ACCESSIBLE DUE TO PRIVACY ACT CONCERNS.

STATUS: RW-3 IS WORKING WITH GENERAL COUNSEL AND PERSONNEL MANAGERS TO INITIATE A MUTUALLY ACCEPTABLE SYSTEM TO BE IN COMPLIANCE WITH THE PRIVACY ACT. STATUS PROVIDED AT 5/9/89 QA REVIEW MEETING.