

MAY 9/10 QA MTG MINUTES

- 1 -

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

AUG 04 1989

Dear Mr. Stein:

SUBJECT: MINUTES FROM THE MAY 9-10, 1989 BIMONTHLY QUALITY ASSURANCE MEETING

The purpose of this letter is to transmit to you the minutes from the May 9 and 10, 1989 bimonthly quality assurance (QA) meeting. The minutes were prepared by the staff of the U.S. Nuclear Regulatory Commission (NRC) and representatives for the U.S. Department of Energy (DOE). A written statement regarding the State of Nevada's interest in this meeting has also been included.

One of the major areas of discussion during the meeting was what "selected technical products" would be necessary for the qualification audits to be able to demonstrate acceptable implementation of the QA program. In the January 25, 1989 bimonthly QA status meeting, examination of "selected technical products" was one of the five criteria that the staff identified as necessary for an acceptable qualification audit. At that time, the staff's expectation was that the QA program's implementation could be evaluated by reviewing completed exploratory shaft facility, Title II design activities and site characterization planning activities, such as completed study plans and technical procedures. Based on this expectation, the staff position at the May 9 and 10, 1989 meeting was that the recently conducted audits of the Lawrence Livermore National Laboratory (LLNL), Fennix and Scisson (F&S), and Holmes and Narver (H&N) were insufficient to verify program implementation. This was because program milestones had slipped and the amount of program implementation was less than anticipated. This is the staff position taken in the enclosed minutes.

Following the May 9 and 10, 1989 bimonthly QA meeting, the staff reexamined its position regarding what is needed to demonstrate acceptable implementation of the QA program. This reexamination evaluated what is needed in the DOE audits to verify acceptable QA program implementation as opposed to whether the DOE audit covered all of the completed activities identified as part of the original expectation. As a result of this reexamination, the staff believes that the degree of implementation for the LLNL, F&S, and H&N QA audits is sufficient to make a finding on the programs' acceptability. This conclusion is based on the staff's belief that the implementation examined to date can be used to evaluate whether the staffs of LLNL, F&S, and H&N are capable of continued acceptable implementation. Overall, the audits conducted to date have examined some implementation of the QA program by the line staff of the audited organizations.

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It should be noted that the staff will not be able to make its finding on the acceptability of the LLNL, F&S, and H&N QA programs for continued implementation until DOE is able to make a finding on the acceptability of the programs. In addition, to ensure that the programs continue to be acceptably implemented and to ensure that new program activities will be started under the QA programs, the staff has requested DOE to furnish its schedules for future audits and surveillances planned over the next year. The staff will observe some of these and may conduct its own independent audits to ensure that DOE and its contractors are finding and correcting problems and ensuring continued acceptable implementation.

A second area of major discussion at the meeting dealt with the definition and usage of observation and deficiency reports. The discussion resulted in DOE's clarification of the staff's and the State of Nevada's concerns. DOE undertook an action to reexamine its procedures to ensure proper documentation of its system for resolving and tracking observations and deficiencies. Details of these discussions are provided in the enclosed minutes.

If you have any questions, please feel free to contact Brian E. Thomas of my staff on (301) 492-0435.

Sincerely,

ORIGINAL SIGNED BY

John J. Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

Enclosure: As stated

- cc: C. Gertz, DOE/NV
- R. Loux, State of Nevada
- K. Turner, GAO
- M. Baughman, Lincoln County, NV
- D. Bechtel, Clark County, NV
- S. Bradhurst, Nye County, NV

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J. Kennedy			

OFC :HLPD^{MPL} :HLPD^{MPL} :HLPD :HLPD : : :

NAME: BThomas/wd: JHolonich: JKennedy : JLinehan : : :

DATE: 08/2/89 : 08/2/89 : 08/3/89 : 08/2/89 : : :

rec'd w/ Ltr. dtd
8/4/89

MINUTES FOR DOE/NRC
JOINT BIMONTHLY QUALITY ASSURANCE MEETING
MAY 9-10, 1989

On May 9-10, 1989, staff of the U. S. Nuclear Regulatory Commission (NRC) met with representatives of the U. S. Department of Energy (DOE), and the State of Nevada to discuss items of mutual interest on quality assurance (QA) and the NRC staff's review comments on several QA program plans. Representatives of the affected units of local governments were not present. A list of attendees for the May 9 and 10, 1989 meetings is shown in Attachments 1 and 2 respectively.

DOE's first presentation covered the qualification audits of Holmes and Narver (H&N) and Fenix and Scisson (F&S), the Architect/Engineers for the exploratory shaft facility (ESF) surface and subsurface facilities respectively. Attachment 3 - last 6 pages - on "Summary of H&N and F&S Audits" presents a summary of the audit results. During the presentation, the NRC staff had concerns about the usage of the terms "observation" and "deficiency" and asked DOE for clarification. The staff stated that DOE's definition of the terms observations and deficiencies indicate that not all observations and deficiencies are significant enough to warrant tracking. In response, DOE stated that the results of the audits are reported as "observations" or "deficiencies," both of which deal with procedural or implementation aspects of the participants QA program. Deficiencies are used to describe or identify noncompliances resulting from inadequate implementation of procedural or regulatory requirements. Observations, on the other hand, are used by the DOE audit team to identify a condition that could lead to a deficiency if left uncorrected. It was noted by DOE that the initial summary of observations and deficiencies presented at an audit close-out should be considered as preliminary. As a result, the number and severity of deficiencies and observations are subject to change during final review and analysis.

The State of Nevada inquired if the process of reporting preliminary and then final observations and deficiencies is documented in DOE's procedures. DOE indicated that its system of resolving observations and deficiencies, including screening without further tracking or documentation, may not be in the procedures and the procedures will be reviewed and revised, as needed, to document this system.

DOE's second presentation was on the content and use of corrective action reports (CARs) and deficiency reports (DRs) resulting from DOE surveillances of procedures at the Yucca Mountain Project (YMP) Office and the Office of Civilian Radioactive Waste Management (OCRWM). The surveillances were conducted to determine YMP and OCRWM readiness to start the ESF, Title II design activities. The results are summarized in Attachment 4 entitled "CAR and DR." DOE indicated that they are identifying and tracking problems associated with ongoing actual work and with preparation for starting work related to ESF, Title II design activities and will resolve those problems prior to starting the design.

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DOE's next presentation was on the status of the YMP Office and OCRWM surveillances performed in order to assess the readiness of the participants for the start of ESF, Title II design activities. These results are provided in Attachment 3, "Results of Project Office Programmatic Surveillance." DOE stated that beginning in June 1989, the YMP office conducted the first of a planned 100 programmatic surveillances of project participants and that implementation surveillances of those participants would occur in the future. The staff asked if the surveillances involved a 100% review of the procedure against the requirements in "Nevada Nuclear Waste Storage Investigations Quality Assurance Plan" (NNWSI QAP 88-9), Revision 2. DOE responded that the surveillances are currently done in stages covering procedural adequacy, comparison against requirements, and implementation. However, its goal is to ultimately conduct 100% reviews against NNWSI QAP 88-9, Revision 2.

Next, the status of issues regarding DOE qualifications of program employees and the relationship of the Privacy Act was presented. In its discussion, DOE stated that it is preparing to seek clearance from Congress to keep records by employee name in accordance with the NRC's QA recordkeeping requirements. In addition, DOE headquarters is currently preparing a description of the concerns with the Privacy Act to be available shortly. DOE further commented that it believed the U. S. Geological Survey (USGS) may have to seek separate clearance from Congress because of its federal agency status rather than utilizing the DOE's clearance. DOE indicated that the personnel qualification issue is expected to be resolved in about six months and asked that this item be carried as an open item. The NRC stipulated that this issue must be settled prior to acceptance of DOE's QA program for site characterization.

DOE made a short presentation on its YMP Office and Headquarters (HQ) system for handling quality concerns in which DOE stated that DOE/HQ, like the YMP Office, is developing a "hot-line" system procedure and that HQ is currently seeking management approval for its implementation.

The NRC staff indicated that the NRC has an Allegations Tracking System and encouraged DOE to coordinate the development of its system for handling quality concerns with NRC. DOE indicated that the method for resolving allegations will be made available to the NRC prior to DOE's submittal of the License Application to construct the repository and that this system will apply to DOE and all its contractor organizations, including vendors and suppliers. The NRC staff encouraged DOE to clearly delineate what is to be tracked in the system (i.e. allegations that are reported and/or non-conformances with the regulatory requirements).

DOE's next presentation was on the status of OGR/B-14. OGR/B-14 is a document that outlines the QA requirements for processing high-level radioactive waste into a form suitable for disposal in a geologic repository. DOE commented that it understands the importance of assuring a quality product that meets QA acceptance criteria and will address NRC's comments provided in February 1989 on OGR/B-14. DOE further stated that the Defense Waste Processing Facility (DWPF) at Savannah River currently plans to conduct cold startup in November 1989. Therefore, OCRWM expects to hold a meeting shortly within DOE to review OGR/B-14. DOE explained that it ultimately intends to incorporate the

requirements of OGR/B-14 into the OCRWM Quality Assurance Requirements (QAR) document and the OCRWM Quality Assurance Program Description document. The NRC staff was interested in DOE's method of resolving NRC comments on OGR/B-14. DOE expressed that its preference is to incorporate the resolutions in the QAR document and eliminate OGR/B-14 altogether.

DOE discussed its schedule for qualification audits and indicated that the schedules agreed to in the January 25, 1989 meeting for qualification audits were being reconsidered as part of an evaluation of the schedule for starting the ESF construction. Audits of Lawrence Livermore National Laboratory (LLNL) and Reynolds Electric and Engineering Co., Inc. (REECO) are scheduled for June 1989, but the audit at Sandia National Laboratory previously scheduled for May 22-26, 1989 was postponed and has not been rescheduled.

NRC staff then made a presentation on the definition of the term "selected technical products" and how those products must be part of any QA qualification audit that will support NRC acceptance of a qualified QA program. (See Attachment 5, "Selected Technical Products.") NRC reaffirmed that qualification audits should include an assessment of some implementation of the QA program and stated that this position was the same as previously stated in the January 25, 1989 monthly QA meeting. DOE was reminded that in the January 25, 1989 meeting, the DOE and NRC staffs previously agreed that qualification audits should examine "selected technical products" in order to show that the implementation of the QA program was effective. DOE staff questioned how the audits could examine "implementation" when the staff's Consultation Draft Site Characterization Plan objection recommended that DOE not start new site characterization work until the QA programs were qualified.

In its presentation on selected technical products, the staff indicated that the recommendation to not start new site characterization work applied to the field and laboratory investigations to collect data and construction of the exploratory shaft. Thus, a number of products of the implementation of the program, such as design drawings, design reports, design criteria documents, study plans, and technical procedures for collecting data, would have to be available for auditing and surveilling before new site characterization work occurred. In addition, ongoing data collection activities, such as the seismic monitoring in the vicinity of Yucca Mountain, could be retrofitted for QA and be regarded as a part of any DOE assessment of technical products in a qualification audit.

The staff explained that neither the H&N nor F&S audits addressed implementation of the quality assurance program and for this reason, those audits cannot be considered complete qualification audits. In the January 25, 1989 monthly status meeting, the NRC and DOE staff agreed on five essential characteristics of a qualification audit, one of which was evaluation of implementation of the program into selected technical products by the audit team. The staff agreed that the audits conducted in April 1989 at these two organizations were generally acceptable and that credit could be taken for them in qualifying the program, but that a supplemental audit or surveillance would need to be conducted to assess whether the implemented QA programs were producing acceptable technical products. The NRC staff would work with DOE to

incrementally accept the QA program. This incremental acceptance could be used up to the start of site characterization.

Statement by the State of Nevada

The following is the State of Nevada's written statement regarding the May 9, 1989 Quality Assurance meeting in Rockville with the NRC and the DOE.

"The State thought the meeting was beneficial. Bi-monthly meetings appear more efficient and effective than monthly meetings.

Important issues were raised at this meeting that should be resolved prior to the acceptance of the QA programs governing site characterization. The Privacy Act issue has been an open item for more than 18 months and DOE should resolve this issue as soon as possible. The allegation process should be firmly in place prior to the start of any activities at the site, including site preparation.

The NRC explanation of their term 'selected technical products' and the relationship to the NRC acceptance of the DOE QA plans was beneficial. This term and its role was discussed at the January QA meeting and is in the NRC handouts for that meeting. DOE's statement that the NRC is 'changing the rules on them again' is incorrect.

The State strongly urges the NRC staff to be cautious in accepting any QA programs incrementally. The 'selected technical products' that are to be used to verify effective implementation of the programs should be picked with care to ensure that these technical products are indicative of the program's effectiveness. Reviewing only technical procedures and/or study plans will not give enough evidence of effective implementation."

May 10, 1989 Meeting

During the continuation of the meeting on May 10, 1989, the participants engaged in a working session to review DOE's responses to NRC review comments on the H&N, F&S, and REECO QA Program Plans (QAPPs).

DOE provided responses to two NRC review comments on the F&S QAPP (QAPP-002), Revision 6. Both responses were accepted by NRC. See Attachment 6, "Response to NRC Review Comments - F&S QAPP (QAPP-002), Revision 6."

Next, DOE provided responses to six NRC review comments on the REECO QAPP (568-DOC-115), Revision 7 that were all considered acceptable as written; however, it was agreed that comment number 3 was resolved and comment numbers 1, 2, 4, 5, and 6 would be carried as open items pending DOE's revisions to language contained in the QAPP and in NNWSI QAP 88-9, Revision 2. Attachment 7, "Response to NRC Review Comments - REECO QAPP (568-DOC-115), Revision 7" provides the details of the revisions.

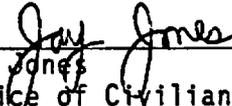
DOE then provided responses to all (19) NRC review comments on the H&N QAPP,

Revision 3 that were accepted by NRC and considered closed with the exception of four comments. These are comment numbers 3, 4, 11, and 18, which are considered open items pending further evaluation and revision by DOE. Details of the comments can be seen in Attachment 8, "Response to NRC Review Comments - H&N QAPP Revision 3." DOE and NRC agreed that the accepted comments must be incorporated into the document before final NRC acceptance.

At the end of the meeting, all the participants agreed the next meeting will be scheduled for July 11, 1989.



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



Jay Jones
Office of Civilian Radioactive
Waste Management
U. S. Department of Energy

QA Bimonthly Meeting
May 9, 1989

LIST OF ATTENDEES

<u>NAME</u>	<u>ORGANIZATION</u>
J. Holonich	NRC
B. Thomas	NRC
J. Kennedy	NRC
C. Cameron	NRC
T. Verma	NRC
J. Conway	NRC
J. Gilray	NRC
B. Belke	NRC
K. Hooks	NRC
W. Mansel	DOE
J. Blaylock	DOE
D. Shelor	DOE
T. Gutmann	DOE
L. Desell	DOE
R. Edwards	DOE
B. Lemeshevsky	DOE
J. Lowry	DOE
J. Jones	DOE
S. Skuchko	DOE
S. Zimmerman	State of Nevada
H. Caldwell	Science Application International, Corporation (SAIC)
J. Estella	SAIC
S. Metta	SAIC
C. Wright	H&N
H. Tuthill	H&N
M. Regenda	F&S
D. Tunney	F&S
P. Watters	DOE/WESTON
G. Faust	DOE/WESTON
T. Colandrea	Edison Electric Institute (EEI)
C. Henkel	EEI
T. Chaney	USGS
G. Roseboom	USGS

QA Bimonthly Meeting
May 10, 1989

LIST OF ATTENDEES

<u>NAME</u>	<u>ORGANIZATION</u>
B. Thomas	NRC
J. Kennedy	NRC
B. Belke	NRC
J. Conway	NRC
K. Hooks	NRC
K. Sommer	DOE
J. Blaylock	DOE
L. Desell	DOE
W. Mansel	DOE
J. Jones	DOE
B. Lemeshewsky	DOE
S. Zimmerman	State of Nevada
J. Estella	SAIC
S. Metta	SAIC
D. Tunney	F&S
M. Regenda	F&S
C. Wright	H&N
H. Tuthill	H&N
J. Marchand	DOE/WESTON

**DOE/NRC
QA MEETING**

MAY 9, 1989

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

- 7 SURVEILLANCES HAVE BEEN PERFORMED
- 7 IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED
- 17 OF 31 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

- 4 SURVEILLANCES HAVE BEEN PERFORMED
- 13 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 11 OF 17 PROCEDURES REVIEWED

RESULTS OF PROJECT OFFICE PROGRAMMATIC SURVEILLANCE

(CONTINUED)

LLNL

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

YMP

- 4 SURVEILLANCES HAVE BEEN PERFORMED
- 10 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 11 OF 17 PROCEDURES REVIEWED

RESULTS OF PROJECT OFFICE PROGRAMMATIC SURVEILLANCE

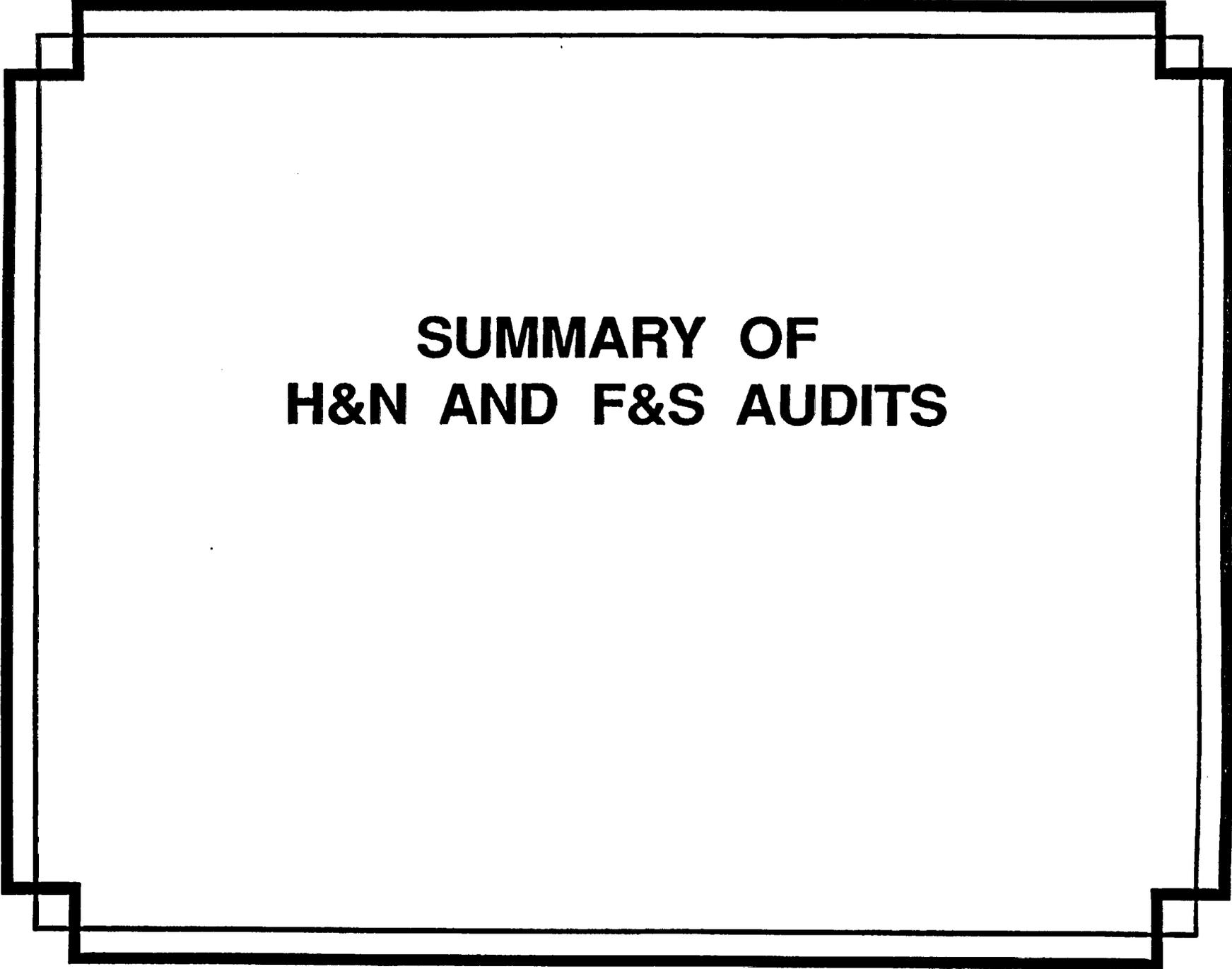
(CONTINUED)

REECo

- 6 SURVEILLANCES HAVE BEEN PERFORMED
- 1 PROCEDURAL DEFICIENCY WAS IDENTIFIED ASSOCIATED WITH 20 OF 21 PROCEDURES REVIEWED

SNL

- 9 SURVEILLANCES HAVE BEEN PERFORMED
- 13 PROCEDURAL AND IMPLEMENTATION DEFICIENCIES WERE IDENTIFIED ASSOCIATED WITH 45 OF 45 PROCEDURES REVIEWED;
(NOTE: 1 OF THE 5 DEFICIENCIES WAS GENERIC - LACK OF QA RECORDS SECTION - AND APPLIED TO ALL SNL PROCEDURES REVIEWED)



**SUMMARY OF
H&N AND F&S AUDITS**

SUMMARY OF H&N AND F&S AUDITS

H&N AUDIT SCOPE 89-2

PROGRAMMATIC ELEMENTS:

- 1.0 - ORGANIZATION**
- 2.0 - QUALITY ASSURANCE PROGRAM**
- 3.0 - DESIGN CONTROL**
- 4.0 - PROCUREMENT DOCUMENT CONTROL**
- 5.0 - INSTRUCTIONS, PROCEDURES AND DRAWINGS**
- 6.0 - DOCUMENT CONTROL**
- 7.0 - CONTROL OF PURCHASED ITEMS AND SERVICES**
- 8.0 - IDENTIFICATION AND CONTROL OF ITEMS**
- 9.0 - CONTROL OF PROCESS**
- 10.0 - INSPECTION**
- 11.0 - TEST CONTROL**
- 12.0 - CONTROL OF MEASURING AND TEST EQUIPMENT**
- 13.0 - HANDLING, STORAGE AND SHIPPING**
- 14.0 - INSPECTION, TEST AND OPERATING STATUS**
- 15.0 - CONTROL OF NON-CONFORMING ITEMS**
- 16.0 - CORRECTIVE ACTION**
- 17.0 - QUALITY ASSURANCE RECORDS**
- 18.0 - AUDITS**

TECHNICAL ELEMENTS:

- TECHNICAL QUALIFICATIONS OF DESIGN PERSONNEL**
- DESIGN PERSONNEL UNDERSTANDING OF THE DESIGN CONTROL PROCESS**
- DESIGN PERSONNEL UNDERSTANDING OF THE PROCEDURAL REQUIREMENTS AS THEY PERTAIN TO DESIGN**
- PROCEDURAL ADEQUACY FROM A TECHNICAL STANDPOINT**

SUMMARY OF H&N AND F&S AUDITS

F&S AUDIT SCOPE 89-1

PROGRAMMATIC ELEMENTS:

- 1.0 - ORGANIZATION**
- 2.0 - QUALITY ASSURANCE PROGRAM**
- 3.0 - SCIENTIFIC INVESTIGATION AND DESIGN CONTROL**
- 4.0 - PROCUREMENT DOCUMENT CONTROL**
- 5.0 - INSTRUCTIONS, PROCEDURES , PLANS AND DRAWINGS**
- 6.0 - DOCUMENT CONTROL**
- 7.0 - CONTROL OF PURCHASED ITEMS AND SERVICES**
- 10.0 - INSPECTION**
- 12.0 - CONTROL OF MEASURING AND TEST EQUIPMENT**
- 13.0 - HANDLING, STORAGE AND SHIPPING**
- 16.0 - CORRECTIVE ACTION**
- 17.0 - QUALITY ASSURANCE RECORDS**
- 18.0 - AUDITS**

ELEMENTS NOT COVERED (NOT CURRENTLY AND F&S RESPONSIBILITY):

- 8.0 - IDENTIFICATION AND CONTROL OF ITEMS**
- 9.0 - CONTROL OF PROCESS**
- 11.0 - TEST CONTROL**
- 13.0 - HANDLING, STORAGE AND SHIPPING**
- 14.0 - INSPECTION, TEST AND OPERATING STATUS**

TECHNICAL ELEMENTS:

- TECHNICAL QUALIFICATIONS OF DESIGN PERSONNEL**
- DESIGN PERSONNEL UNDERSTANDING OF THE DESIGN CONTROL PROCESS**
- DESIGN PERSONNEL UNDERSTANDING OF THE PROCEDURAL REQUIREMENTS AS THEY PERTAIN TO DESIGN**
- PROCEDURAL ADEQUACY FROM A TECHNICAL STANDPOINT**

H&N AND F&S DEFICIENCIES

H&N:

- H&N'S QAPP DOES NOT ADDRESS LINES OF COMMUNICATION OR AUTHORITY AND DUTIES ASSIGNED TO NTSO OR EG&G WHILE H&N IMPLEMENTING PROCEDURES DO
- H&N DOES NOT HAVE SUFFICIENT AUTHORITY OR ORGANIZATIONAL FREEDOM TO CONTROL NON-CONFORMING CONDITIONS WITHIN THEIR AREA(S) OF RESPONSIBILITY. SDR ISSUED TO YMP.

F&S:

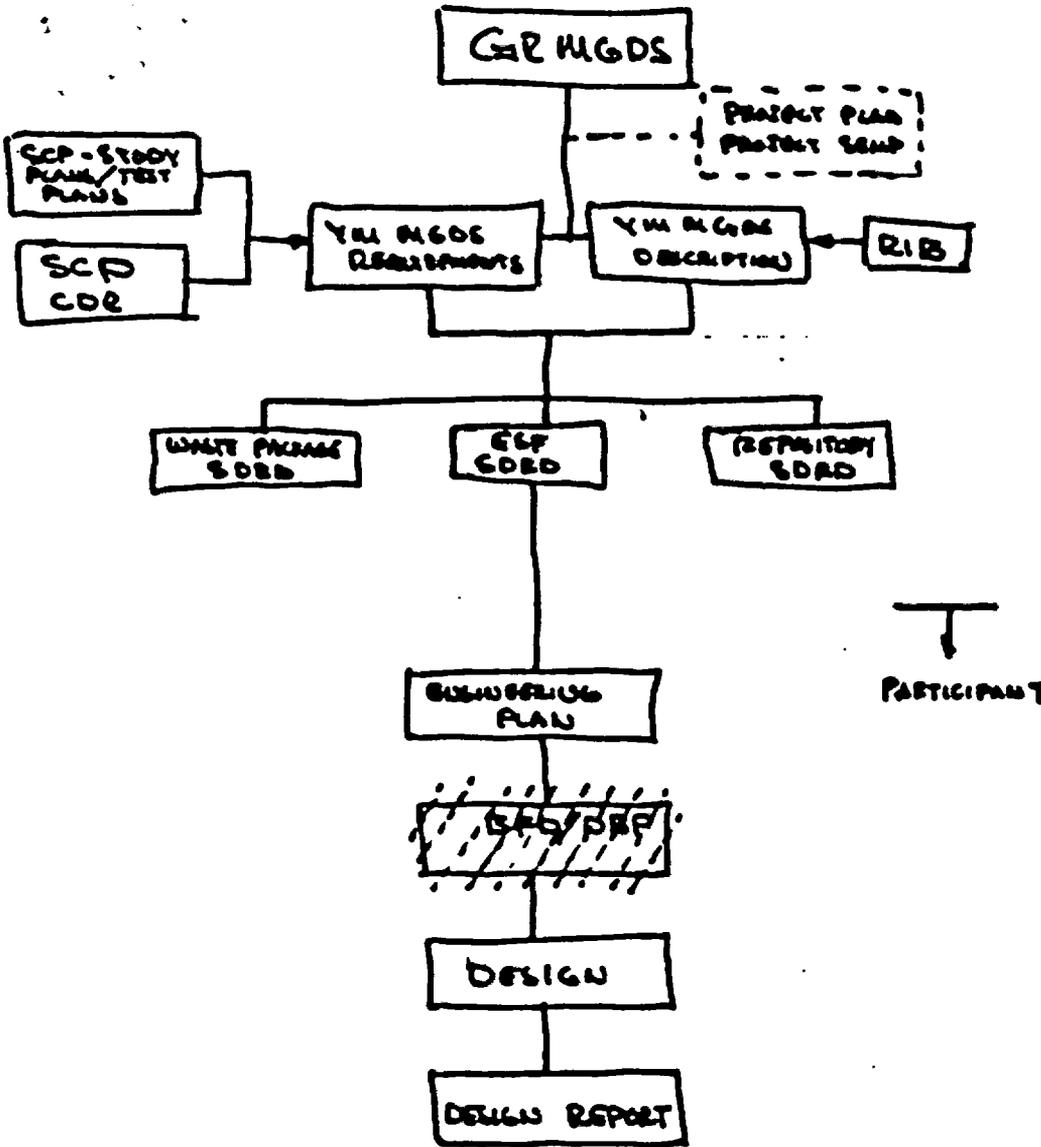
- F&S RECORDS PERSONNEL ARE LOGGING IN ONLY THE TRANSMITTAL SHEETS...RECORDS ARE NOT READILY TRACEABLE OR RETRIEVABLE
- F&S ISSUED A DESIGN CONTROL PROCEDURE PRIOR TO COMPLETION OF ALL REQUIRED INTERNAL REVIEWS

F&S OBSERVATIONS

- **PROCEDURE INADEQUACY - 9**
- **DESIGN - 6**
- **DEFICIENCY REPORTING - 1**
- **TREND ANALYSIS - 1**
- **TRAINING - 1**
- **PROCUREMENT - 1**

H&N OBSERVATIONS

- **TREND ANALYSIS** - 1
- **PERSONNEL CERTIFICATION** - 1
- **PROCEDURE INADEQUACY** - ~~1~~ 3
- **DESIGN** - 1
- **TEST CONTROL** - 1
- **RECORDS** - 1
- **REQUIREMENTS DOCUMENT (QAPP)** - 1



SYSTEM STUDY EFFORTS
FUNCTIONAL ANALYSIS
PERFORMANCE ASSESSMENT
SAFETY & RISK ANALYSIS
DESIGN ANALYSIS
OPERABILITY
IMPACT ANALYSIS

DEFINE FUNCTIONS, PERFORMANCE
CRITERIA, CONSTRAINTS AND
INTERFACES
IDENTIFY METHODS OF EMPT
CONSTRAINTS

CAR-89-002
YMP

DESCRIPTION OF CONDITION AND REMEDIAL ACTION:

CONTRARY TO PROGRAM REQUIREMENTS:

- (D OF C) THERE ARE NO QA PROCEDURES TO CONTROL PREPARATION OF TECHNICAL DOCUMENTS, NOR DOCUMENTED DIRECTION IDENTIFYING REQUIRED INPUTS, STUDIES OR ANALYSES FOR ESTABLISHING SITE SPECIFIC MDGS REQUIREMENTS.

- (RA) A PROCEDURE FOR HOLD POINTS WILL BE PREPARED. HOLD POINTS WILL BE ESTABLISHED DURING THE DESIGN TO ASSURE THAT THE RELEASE OF A DESIGN PACKAGE CANNOT OCCUR PRIOR TO THE VERIFICATION OF ALL RELATED DESIGN INPUTS.

- (C OF D) THE REVIEW PLAN FOR YMP ESF SUBSYSTEMS DESIGN REQUIREMENTS DOCUMENT (BENCHMARK 4) DOES NOT ADEQUATELY IDENTIFY THE TECHNICAL REVIEW CRITERIA AND TECHNICAL INPUT DOCUMENTS NECESSARY TO ASSURE CONSIDERATION OF ALL REFERENCES AND REPOSITORY INTERFACES WITH THE ESF AND THE REQUIRED LEVEL OF DETAIL.

- (RA) REVIEW CRITERIA FOR THE TECHNICAL ASSESSMENT REVIEW OF THE SDRD WILL BE REVISED TO INCLUDE A REFERENCE LETTER; GUIDANCE FOR ACD REQUIREMENTS DOCUMENTS (GERTZ, YMPO TO RAMSPOTT, LLNL).

CAR-89-002

YMP

CONTINUED

- (C OF D) THE EXISTING ESTABLISHED MGDS BASELINE DOCUMENT HIERARCHY IS NOT CONSISTENT WITH THE DOCUMENT HIERARCHY IN OGR/B-7 (SEMP), REV. 1 OR THE NNWSI/88-3 (PROJ. SEMP) IN THAT THE YMP MGDS SITE SPECIFIC DESCRIPTION AND REQUIREMENTS DOCUMENT HAVE NOT YET BEEN APPROVED AND ISSUED.

- (RA) THE SEMP WILL BE MODIFIED TO REFLECT THE INTERIM TECHNIQUES TO BE USED FOR CONTROL OF THE ESF REQUIREMENTS IN THE ABSENCE OF A COMPLETE SET OF REQUIREMENT DOCUMENTS. THE INTERFACE CONTROL, AS DESCRIBED IN THE NNWSI SEMP, WILL BE MAINTAINED.

- (C OF D) PROJECT ORGANIZATIONAL RESPONSIBILITIES FOR DEVELOPMENT OF ESF DESIGN REQUIREMENTS, TEST REQUIREMENTS AND ASSOCIATED DESIGN AND TESTING INTERFACES ARE NOT ADEQUATELY IDENTIFIED AND DOCUMENTED IN THE WBS DICTIONARY FOR CONTROL OF DESIGN INTERFACES.

- (RA) THE WBS DICTIONARY WILL BE REVISED TO INCLUDE ADDITIONAL RESPONSIBILITIES AND INTERPRETATIONS AS DEFINED IN LETTERS PREVIOUSLY SENT TO THE PARTICIPANTS.

CAR-89-001
OCRWM-HQ

DESCRIPTION OF CONDITION AND REMEDIAL ACTIONS:

CONTRARY TO THE PROGRAM REQUIREMENT:

- (D OF C) THERE ARE NO QA PROCEDURES TO CONTROL PREPARATION OF TECHNICAL DOCUMENTS, NOR DOCUMENTED DIRECTION IDENTIFYING REQUIRED INPUTS, STUDIES OR ANALYSES FOR ESTABLISHING THE MGDS REQUIREMENTS.

- (RA) QAAP 3.1, "TECHNICAL DOCUMENT REVIEW", HAS BEEN ISSUED WITH AN EFFECTIVE DATE OF MARCH 27, 1989. QAAP 3.5, "PREPARATION OF TECHNICAL DOCUMENTS" IS SCHEDULED TO BE ISSUED ON JUNE 28, 1989. SUPPLEMENTAL READING MATERIALS AND CLASSROOM INSTRUCTION ON QAAP 3.1 HAVE BEEN COMPLETED. SPECIAL EMPHASIS WILL BE PLACED ON VERIFICATION OF INPUT SOURCES TO REQUIREMENT DOCUMENTS.

- (D OF C) THE TECHNICAL REVIEW PLANS FOR THE OCRWM-HQ 10CFR60 AND NON-10CFR60 TECHNICAL FLOWDOWN REVIEW DID NOT INCLUDE OR REQUIRE THE DEVELOPMENT AND DOCUMENTATION OF THE REVIEW CRITERIA OR THE BASIS TO BE USED FOR DETERMINING ESF REQUIREMENT APPLICABILITY.

- (RA) QAAP 3.1, "TECHNICAL DOCUMENT REVIEW" HAS BEEN ISSUED WITH AN EFFECTIVE DATE OF MARCH 27, 1989. SUPPLEMENTAL READING MATERIALS AND CLASSROOM INSTRUCTION ON QAAP 3.1 HAVE BEEN COMPLETED. SPECIAL EMPHASIS WILL BE PLACED ON VERIFICATION OF INPUT SOURCES TO REQUIREMENT DOCUMENTS.

CAR-89-001
OCRWM-HQ
CONTINUED

- (D OF C) THE EXISTING ESTABLISHED MGDS BASELINE DOCUMENT HIERARCHY IS NOT CONSISTENT WITH THE DOCUMENT HIERARCHY ON OGR/B-7 (SEMP), REV. 1 OR THE NNWSI/88-3 (PROJ. SEMP), REV. 0 IN THAT THE YMP MGDS SITE SPECIFIC DESCRIPTION HAVE NOT YET BEEN APPROVED AND ISSUED.

- (RA) THE SR AND OTHER SUBTIER REQUIREMENTS WILL BE IN-PLACE IN FY89. FORMAL READINESS REVIEWS WILL BE PERFORMED IN ACCORDANCE WITH QAAP 2.6, EFFECTIVE MARCH 27, 1989.

DR-89-005

YMP

DESCRIPTION OF CONDITION:

CONTRARY TO THE PROGRAM REQUIREMENTS, THERE ARE NO YMP QA PROGRAM PROCEDURES IN-PLACE TO CONTROL THE PREPARATION OF THE YMP TECHNICAL BASELINE DOCUMENTS OR THE TECHNICAL BASIS DOCUMENTS USED TO ESTABLISH DESIGN INPUT.

REMEDIAL ACTION:

- THE OCRWM AND THE PROJECT LETTERS OF DIRECTION FOR THE PREPARATION OF THESE DOCUMENTS WILL BE INCORPORATED INTO A FORMAL YMP PROCEDURE FOR "TECHNICAL DOCUMENT PREPARATION".

DR-89-006

YMP

DESCRIPTION OF CONDITION:

CONTRARY TO THE PROGRAM REQUIREMENTS, NO OBJECTIVE EVIDENCE WAS AVAILABLE TO SUBSTANTIATE INDOCTRINATION AND TRAINING OF APPLICABLE PERSONNEL INVOLVED IN THE DEVELOPMENT AND IMPLEMENTATION OF THE MGDS TECHNICAL BASELINE DOCUMENTS AND THE YMP TECHNICAL BASELINE CONTROL SYSTEM.

REMEDIAL ACTION:

- ALL APPROPRIATE STAFF WILL BE TRAINED TO THE APPLICABLE PROCEDURES.
- IT SHOULD BE RECOGNIZED THAT UNTIL THE PRIVACY ACT CONCERNS ARE RESOLVED, RECORDS WILL NOT BE MADE AVAILABLE FOR QA ACTIVITIES.

DR-89-004

OCRWM-HQ

DESCRIPTION OF CONDITION:

CONTRARY TO THE PROGRAM REQUIREMENTS, NO OBJECTIVE EVIDENCE WAS AVAILABLE TO SUBSTANTIATE INDOCTRINATION AND TRAINING OF APPLICABLE PERSONNEL INVOLVED IN THE DEVELOPMENT AND IMPLEMENTATION OF THE MGDS TECHNICAL BASELINE DOCUMENTS AND THE OCRWM-HQ TECHNICAL BASELINE CONTROL SYSTEM.

REMEDIAL ACTION:

- THE OSIR AND OFSD WILL ASSIST THE OCRWM TRAINING OFFICER IN THE DESIGN AND CONDUCT OF APPROPRIATE INDOCTRINATION AND TRAINING

DR 89-003

OCRWM-HQ

DESCRIPTION OF CONDITION:

CONTRARY TO THE PROGRAM REQUIREMENTS, RESPONSIBILITIES AND REQUIREMENTS FOR RECORD TRANSMITTAL, DISTRIBUTION, RETENTION, MAINTENANCE AND DISPOSITION HAS NOT BEEN ESTABLISHED, DOCUMENTED OR IMPLEMENTED.

REMEDIAL ACTION:

- PREPARE AND ISSUE QAAP 17.1, "QA RECORDS MANAGEMENT".
- REVISE AND PE CCP PROCEDURE TO ADDRESS QA RECORDS REQUIREMENTS.

DR-89-002.

OCRWM-HQ

DESCRIPTION OF CONDITION:

CONTRARY TO THE PROGRAM REQUIREMENTS, THERE ARE NO OCRWM-HQ QA PROGRAM PROCEDURES IN-PLACE TO CONTROL THE PREPARATION OF THE OCRWM-HQ TECHNICAL BASELINE DOCUMENTS OR THE TECHNICAL BASIS DOCUMENTS USED TO ESTABLISH DESIGN INPUT.

REMEDIAL ACTION:

- PREPARE AND ISSUE QAAP 3.1, "TECHNICAL DOCUMENT REVIEW".
- PREPARE AND ISSUE QAAP 3.5, "PREPARATION OF TECHNICAL DOCUMENTS".

DESCRIPTION OF CONDITION:

CONTRARY TO THE PROGRAM REQUIREMENTS:

- OGR/B-1 HAS NOT BEEN UPDATED TO REFLECT CURRENT OCRWM-HQ REORGANIZATION.
- THERE IS AN INCONSISTENCY IN THE CURRENT ORGANIZATIONAL RESPONSIBILITIES FOR REVIEW AND APPROVAL OF TECHNICAL BASELINE DOCUMENTS, AND CHANGES THERETO, WITHIN THE TECHNICAL BASELINE DOCUMENT PROCEDURES.
- THE DISTRIBUTION LIST OF CONTROLLED DOCUMENTS HAS NOT BEEN MAINTAINED CURRENT.
- A FORMALIZED QA RECORDS MANAGEMENT SYSTEM HAS NOT BEEN DEVELOPED FOR THE COLLECTION AND MAINTENANCE OF QA RECORDS INITIATED DURING THE OGR/B-1 PROCESS.

REMEDIAL ACTIONS:

- THE PE-CCP (PROGRAM ELEMENTS CHANGE CONTROL PROCEDURE) WILL BE REVISED ACCORDINGLY AND WILL REPLACE THE OGR/B-1.
- ISSUANCE OF THE REVISED PE-CCP WILL RESOLVE ORGANIZATIONAL RESPONSIBILITIES.
- A REVISED DISTRIBUTION LIST WILL BE DEVELOPED FOR CONTROLLED DOCUMENTS RELATED TO THE PE-CCP.
- A FORMALIZED RECORDS MANAGEMENT SECTION WILL BE INCLUDED IN THE REVISED PE-CCP, TO RESOLVE THE CURRENT CONDITION.
- A SURVEY WILL BE PERFORMED OF CCB RECORDS FROM THE OGR/B-1 PERIOD, TO ASSURE COMPLETENESS.

OCRWM SURVEILLANCE NO.
OCRWM-HQ-SR-89-002

SCOPE:

THE SURVEILLANCE FOCUSED ON AN EVALUATION OF THE STATUS OF THE QA PROGRAM DEVELOPMENT AND IMPLEMENTATION ACTIVITIES TO SUPPORT THE INITIATION OF THE EXPLORATORY SHAFT FACILITY (ESF) TITLE II DESIGN PHASE. THE APPLICABLE PORTIONS OF THE QA PROGRAM EVALUATED INCLUDED THE FOLLOWING PROGRAMMATIC ELEMENTS:

I	ORGANIZATION
II	QA PROGRAM
III	DESIGN CONTROL
V	INSTRUCTIONS, PROCEDURES AND DRAWINGS
VI	DOCUMENT CONTROL
XVI	CORRECTIVE ACTION
XVII	QA RECORDS
XVIII	AUDITS

REQUIREMENTS SURVEILLED:

1. OGR/B-7 - SYSTEMS ENGINEERING MANAGEMENT PLAN FOR THE OGR, REV. 1.
2. OGR/B-1 - PROGRAM BASELINE PROCEDURES NOTEBOOK, REV. 7.1.
3. OGR/B-2 - GENERIC REQUIREMENTS FOR A MINED GEOLOGIC DISPOSAL SYSTEM, REV. 3.
4. OGR/B-3 - OGR QA PLAN, REV. 1.
5. NNWSI/88-3 - NNWSI PROJECT SYSTEMS ENGINEERING MANAGEMENT PLAN, REV. 0.
6. YMP ESF SUBSYSTEMS DESIGN REQUIREMENTS DOCUMENT, (DRAFT-BENCHMARK 4).
7. NNWSI/88-1 - YMP QA PROGRAM PLAN, REV. 0.
8. ANSI/ASME NQA-1 - APPLICABLE BASIC REQUIREMENTS AND SUPPLEMENT.

OCRWM-HQ-SR-89-002

DEFICIENCIES:

OCRWM-HQ

YMP

DR-89-001 TECHNICAL BASELINE DOCUMENT
CONTROL PROCEDURE
DEFICIENCIES.

DR-89-005 LACK OF A PROCEDURE FOR
CONTROLLING THE PREP-
ARATION OF TECHNICAL
DOCUMENTS.

DR-89-002 LACK OF A PROCEDURE FOR
CONTROLLING PREPARATION OF
TECHNICAL DOCUMENTS.

DR-89-006 LACK OF OBJECTIVE
EVIDENCE OF TRAINING
OF PERSONNEL.

DR-89-003 LACK OF PROCEDURES TO
ESTABLISH REQUIRED
RECORDS MANAGEMENT
CONTROLS.

CAR-89-002 INADEQUATE CONTROL OF
MGDS TECHNICAL BASELINE.

DR-89-004 LACK OF OBJECTIVE
EVIDENCE OF TRAINING
OF PERSONNEL.

CAR-89-001 INADEQUATE CONTROL OF MGDS
TECHNICAL BASELINE.

OCRWM-HQ-SR-89-002

LOCATION:

OCRWM-HQ
YMP

MARCH 1 - 2, 1989
MARCH 6 - 9, 1989

RESULTS:

OCRWM-HQ

BASED ON THE SURVEILLANCE ACTIVITIES, QA PROGRAM DEFICIENCIES WERE IDENTIFIED IN THE AREAS OF CONTROL OF THE MGDS TECHNICAL BASELINE, RECORDS MANAGEMENT AND TRAINING.

YMP

BASED ON THE SURVEILLANCE ACTIVITIES, QA PROGRAM DEFICIENCIES WERE IDENTIFIED IN THE AREAS OF TECHNICAL BASELINE CONTROL SYSTEM AND THE YMP COMPLETION AND/OR VERIFICATION OF TITLE II PREREQUISITES.

"SELECTED TECHNICAL PRODUCTS"

J. KENNEDY

MAY 9, 1989

BACKGROUND

- o **DOE COMMITTED TO HAVING QUALIFIED QA PROGRAM IN PLACE FOR NEW SITE CHARACTERIZATION ACTIVITIES AND ES CONSTRUCTION IN SCP 8.6.1**

- o **FULFILLMENT OF DOE COMMITMENT WOULD SATISFY STAFF'S OBJECTION ON CDSCP**

- o **STAFF INDICATED ON JANUARY 25, 1989 THAT QA PROGRAM SHOULD BE IMPLEMENTED INTO TECHNICAL PRODUCTS BEFORE BEING QUALIFIED**

DOE CONCERN

- o HOW TO ACHIEVE PROGRAM QUALIFICATION (WHICH REQUIRES "PRODUCTS") WHILE NOT STARTING NEW SITE CHARACTERIZATION WORK OR ES CONSTRUCTION (WHICH MAY APPEAR TO PRECLUDE "PRODUCTS")

STAFF POSITION

- o AGREEMENT TO NOT START NEW SITE CHARACTERIZATION WORK OR ES CONSTRUCTION DOES NOT PRECLUDE IMPLEMENTATION OF PROGRAM
- o SITE CHARACTERIZATION = FIELD AND LAB INVESTIGATIONS
& collection of data.
- o IMPLEMENTATION COULD INCLUDE ES DESIGN AND PLANNING AND PROCEDURES FOR SITE CHARACTERIZATION ACTIVITIES
- o EXAMPLES:

DESIGN DRAWINGS

DESIGN REPORTS

DESIGN CRITERIA DOCUMENTS

STUDY PLANS

TECHNICAL PROCEDURES FOR COLLECTING DATA

RESPONSE TO NRC REVIEW COMMENTS
F&S QAPP (QAPP-002), REV. 6

NRC COMMENT NO. 1

Criterion 1.11 of the 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 requirement is not addressed in the QAPP.

RESPONSE TO COMMENT NO. 1

FSN has adopted and implemented the following Yucca Mountain Project Administrative Procedures:

- a. AP-5.4Q, "Assignment of Quality Assurance Levels" adopted in PP-70-03, same title
- b. AP-5.17Q, "Application of Graded Quality Assurance" adopted in PP-70-04, same title

These procedures address the requirements of Section 1.11. Revision 6 of FSN QAPP did not fulfill those requirements because it was developed and approved prior to the issuance of the above Administrative Procedures which assigned FSN the responsibility for lower-tier QA Level Assignment and QA Grading. FSN has revised Section 2.0 of QAPP-002 (Change Notice A to Revision 6) to incorporate QA level Assignment and QA Grading for QA Levels 1 and 2. These requirements provide the means for the QA controls to be determined by the QA staff in combination with the line staff. (Reference QAPP-002, Rev. 6, Change Notice A, Para. 2.2.1.2)

OK per NRC
(Conway)
JWE
5/10/89

OPEN
(pending issuance
of Change Notice
to F&S QAPP.) ~~Closed~~

NRC COMMENT NO. 2

Criterion 1.18 of the RP states, "Provisions are established for resolving allegations of adequate 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 1.18 was not included in NWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) FSN did not address this subject.

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

Additionally, at the Yucca Mountain Project (Project) level, a procedure is being developed to deal with internal and external quality concerns. The procedure, AP-5.8Q, Reporting and Resolution of Quality Concerns, will describe the system that will provide all Project personnel the means to express quality concerns with assurance that those concerns will be investigated and resolved. Project personnel are those personnel of all the organizations, including Subcontractors.

OK per NRC
(Jim Conway)
JWC
5/10/89

OPEN

ITEM

DRAFT

**QAPP-002, REV. 6
CHANGE NOTICE A**

FENIX & SCISSON OF NEVADA

INTRODUCTION

QUALITY ASSURANCE PROGRAM PLAN

STATEMENT OF POLICY AND AUTHORITY

It is the policy of Fenix & Scisson of Nevada, (FSN) (formerly known as Fenix & Scisson, Inc., (F&S) Las Vegas Branch) to establish and maintain a documented Quality Assurance Program. The purpose of the FSN Quality Assurance Program is to provide confidence that FSN will continually achieve satisfactory quality of performance in all areas of its operational activities through the application of effective management systems that assure conformance to programmatic objectives.

This Quality Assurance Program Plan (QAPP-002, Revision 6 and Change Notice A), describes the Fenix & Scisson of Nevada, Quality Assurance Program for the DOE Yucca Mountain Project (YMP). This plan is a revision to the FSN Quality Assurance Program Plan, QAPP-002, Rev. 5. The program is based upon and satisfies the applicable requirements of the Yucca Mountain Project Quality Assurance Plan, NNWSI/88-9, Rev. 2.

The Quality Assurance Program includes controls to verify conformance of all elements of the program including personnel, organization, work assignments, procedures, calibration requirements, documentation, nonconformances, and corrective action. Where project management plans are required, this Quality Assurance Program Plan shall be incorporated.

All FSN personnel involved in the performance of quality-related functions shall comply with the policies and requirements of this Quality Assurance Program Plan and procedures that implement the Quality Assurance Program. Each member of FSN Management is responsible to assure that all quality-related work performed under their cognizance is in compliance with the requirements of this Quality Assurance Program Plan.

Quality Assurance personnel have the responsibility to recognize and reveal problems pertaining to the quality of FSN programs, projects and activities; to initiate, recommend, or provide solutions to such problems; and to verify implementation of corrective action.

DRAFT

QAPP-002, REV. 6
CHANGE NOTICE A

INTRODUCTION

The Manager of Quality Assurance is responsible for the establishment, implementation and verification of the Quality Assurance Program to assure compliance with the policies and requirements set forth herein. The Manager of Quality Assurance is responsible for keeping management informed as to the status of the FSN Quality Program.

Approved by:

M. J. Legenda
Manager of Quality Assurance

Date:

5/2/89

Approved by:

D. L. Howard
General Manager

Date:

5/2/89

CHANGE NOTICE A

2.0 QUALITY ASSURANCE PROGRAM

2.1 Extent of the Quality Assurance Program

FSN has developed a Quality Assurance Program Plan which provides the description of the FSN QA program and commits to the applicable Yucca Mountain Project QA requirements given in NNWSI/88-9. This Quality Assurance Program Plan (QAPP) includes consideration of the activities affecting quality and generated by the Quality Assurance Division with assistance from the technical staff. The QAPP provides instruction to implement and apply the QA requirements to the technical activities of the YMP. It is planned, implemented, and maintained in accordance with NNWSI/88-9 and is consistent with and addresses all of the applicable requirements of this Yucca Mountain Project QA Plan.

Management above or outside of the QA organization regularly receives information as to the scope, status, adequacy, compliance, etc. of the QA Program by means of audits, surveillances, weekly reports and quarterly reports. Management shall perform readiness reviews, as deemed appropriate. Readiness reviews shall apply to major scheduled/planned activities which could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified prior to starting a major activity.

The hierarchy of criteria applicable to FSN are in Figure 2, see Section II. Where deviations between the requirements of these documents exist, the requirements of NNWSI/88-9 shall prevail.

- 2.1.1 The QA criteria and specific requirements associated with these criteria have been adapted to the Yucca Mountain Project activities through NNWSI/88-9 and are addressed in QAPP-002. When a specific criteria is not applicable to FSN activities, it will be noted in the QAPP and recorded on the checklist required in Paragraph 2.1.2 below with justification.
- 2.1.2 The FSN Quality Assurance Program consists of QAPP-002 plus appropriate implementing procedures required to provide and implement control over activities affecting quality. FSN has three types of implementing procedures as follows:
 - a. Project Procedures controlled by the Project Manager which apply to Project personnel, and in specific instances to QA personnel (for example, Quality Assurance Records, Personnel Qualification Evaluations, Training, etc.)
 - b. Design Control Procedures controlled by the Project Manager which apply to FSN design personnel and other personnel involved in the design process including QA personnel.

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- c. Quality Assurance Procedures controlled by the QA Manager which apply primarily to QA Personnel but also apply to other personnel performing work on the project.

The control is consistent with the importance of the activity. These procedures are developed by qualified personnel and reviewed and approved by Quality Assurance prior to implementation to assure they meet all the requirements of QAPP-002.

The QAPP is submitted to YMPO for review prior to implementation and includes a checklist based on NNWSI/88-9 which identifies how and where each of its requirements are addressed. YMPO comments will be resolved and YMPO approval will be obtained. Editorial changes to the QAPP and those which have no effect on the Quality Program will be issued without YMPO approval. These will be in the form of Change Notices in lieu of Revisions. Change Notices will be incorporated in the subsequent Revisions.

- 2.1.3 FSN Management will monitor QAPP-002 through internal audits to assess the adequacy of the program and assure its effective implementation.
- 2.1.4 As an NTS Support Contractor, FSN is not responsible for the acceptance of data or data interpretations for the use in licensing activities that were not generated under the controls of the Yucca Mountain Project QA Plan (QAP). When requested, FSN will provide Participating Organizations primary data or primary data interpretations and reports that were generated by FSN.
- 2.1.5 FSN does not have responsibility for the development of "Q" Lists.
- 2.1.6 FSN uses the Yucca Mountain Project approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation, and those that do not. The approach is designed to ensure that each item and activity is assigned a QA Level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, non-radiological health and safety, the U. S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, cost, and schedules. The Participating Organizations or YMPO will identify the appropriate upper-tier QA Level, or a lower-tier QA Level will be assigned by FSN in accordance with YMP Administrative Procedures for all items and activities that affect quality associated with site characterization, facility and equipment construction, and facility operations. Once assigned, the QA Level for a particular item or activity will be applied by FSN.

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- 2.1.7 QAPP-002 which complies with the requirements of NNWSI/88-9 has been established by FSN consistent with the schedule for accomplishing the activities. QAPP-002 assures that procedures required to implement the requirement of NNWSI/88-9 are properly documented, controlled, and are mandated by the General Manager in the policy statement. QAPP-002 will be applied throughout the life of the Yucca Mountain Project in accordance with established policies, procedures and instructions. QAPP-002 applies to all items and activities identified as QA Level I and II affecting quality. It also identifies the major organizations participating in the project and designated functions of these organizations. QAPP-002 provides control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. The activities that affect quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. The program takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. The program provides for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

The YMPO will regularly assess the status and adequacy of the FSN QA Program by overview, surveillance and audit activities.

2.2 Application of Graded Quality Assurance

2.2.1 SCOPE

2.2.1.1 EXTENT OF APPLICATION

The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. The preparation of administrative and management planning documents shall not require QA Level assignments, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA Level assignments. The YMPO shall develop a Project administrative procedure for the application of graded QA. The procedure shall be in consonance with the QA requirements specified herein. It may

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be necessary to exempt certain YMP items and activities from QA Level assignment. Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions shall be approved by the YMPO PQM.

2.2.1.2 PURPOSE OF A GRADED QA PROGRAM

The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Repository Program consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of QA applied, depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations. The FSN QA organization is involved in portions of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the FSN QA Staff in combination with the line staff in accordance with YMP Administrative Procedures.

2.2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY

This approach involves (1) identifying those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses, or both, and (2) ensuring that these items and activities are covered by a commensurate QA program. Alternatively, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon the delivery of the item. Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.

2.2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION

The graded approach set forth here provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity as it relates to radiological safety or waste isolation that is commensurate with the relative importance of the role or function assigned to the item or activity.

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2.2.2 Requirements

The requirements specified in this section are to be used to apply the graded quality philosophy to all YMP QA Level I and II items and activities.

2.2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

FSN is not responsible for the selection of upper-tier Quality Assurance Levels. If FSN subdivides upper-tier QA Levels to lower-tier QA Levels, this will be accomplished in accordance with YMP Administrative Procedures. The appropriate Quality Assurance Level for any item or activity shall be determined by the application of decision criteria as provided by the YMP Administrative Procedures. The basis for the selection of the Quality Assurance Level and assigned QA requirements shall be documented. The assigned Quality Assurance Levels and QA requirements must be submitted to the YMPO for review, resolution of comments, and approval prior to implementation or use. This review and approval shall be performed by the YMPO PQM and appropriate YMPO Branch Chiefs.

2.2.2.2 SELECTION OF SPECIFIC QA LEVELS

This approach incorporates three Quality Assurance Levels (QA Level) of which one will be assigned to each technical task that affects the quality of the Yucca Mountain Project. The definition, application, and assignment to each of the three QA Levels are described in the following discussion.

- 2.2.2.2.1 QA Level I - are those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10 CFR 60, and 40 CFR 191.

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2.2.2.2.2 QA Level II - are those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and YMPO concerns, and the environment.

2.2.2.2.3 QA Level III - are those activities and items not classified as QA Levels I and II.

2.2.2.3 Application of Levels

FSN will apply upper-tier QA Levels as assigned by the Participating Organization. If it is necessary to subdivide a QA Level, lower-tier QA Levels will be assigned in accordance with YMP Administrative Procedures consistent with the requirements that follow.

2.2.2.3.1 QA Level I

QA Level I is the most stringent level of quality assurance. It is to be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. QA Level I activities which are on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard.

To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety as well as long term isolation as per the following:

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- o Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.
- o Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. These data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance.
- o Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.
- o Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.
- o Where items and activities that, having failed, could cause a failure of a QA Level I item, or irretrievable loss of QA Level I data.
- o The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.

2.2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to the Yucca Mountain Project activities, and items that are specifically concerned with nonradiological operation of the

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exploratory shaft facilities and repository, and the radiological safety of the repository worker. The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled.

Therefore, Quality Assurance Level II must be applied to activities and items as follows:

- o Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.
- o Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.
- o Where items and activities could affect the retrievability of waste up to the time of repository closure.
- o Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.
- o The Design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/methods/equipment is preferred, shall be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.
- o Where items and activities that, having failed, could result in a major cost overrun.
- o Where items and activities that, if failed, could result in a major schedule slippage.

CHANGE NOTICE A

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with YMP AP 5.9Q "Acceptance of Data and Data Interpretations Not Developed Under the YMP Project QA Program."

2.2.2.3.3 QA LEVEL III

QA Level III is the least stringent Level of Quality Assurance. Level III Quality Assurance items and activities are such that they have no major function in the characterization of the site and design of the repository, but they require good practices for the intended use. Design phases which are purely preliminary and are conducted to define the range of alternatives/methods/equipment which are felt to be worthy of more detailed study shall be assigned a QA Level of III prior to execution. Those activities controlled in accordance with a Quality Assurance Level III program cannot subsequently be used to directly support Quality Assurance Level I activities.

In some cases, data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the Yucca Mountain Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.

- 2.2.2.4 The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by FSN.

2.3 QA Activities2.3.1 Overview

FSN shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. This excludes other project participants (see Para. 7.5.2.1). Overview is to include the following as appropriate:

CHANGE NOTICE A

- o The review and approval of QAPPs.
- o Surveillance of activities affecting quality to verify compliance with requirements.
- o Performance of quality audits to verify the adequacy and compliance of QA programs.

2.3.2 Review and Approval of QA Programs

Procedures are to be established by FSN for the review of QA program documentation of those organizations under their purview for adequacy, completeness and relevance. The procedures shall identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action. Reviews of QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

2.4 Management Assessment

2.4.1 Frequency of Management Assessments Management assessments will be conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) the adequacy of resources and personnel provided to the QA Program. Management is to verify that the QA Program is being effectively implemented and that personnel are trained to the QA requirements of the program.

2.4.2 Performance of Management Assessment Management assessments are performed by FSN in accordance with procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and tracking of recommendations. Copies of management assessments are to be provided to the Project Manager, YMPO and the YMPO PQM. Management above or outside the QA Organization shall be responsible for the Management Assessment activity.

2.5 Personnel Selection, Indoctrination, and Training Procedures

2.5.1 Establishment of Requirements FSN has established requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. The requirements establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, etc), are certified in accordance with the detailed requirements specified in Appendix C, D or F, as applicable.

CHANGE NOTICE A

- 2.5.1.1 Position Description Minimum education and experience requirements are established and documented in position descriptions for each position involved in the performance of activities that affect quality.
- 2.5.1.2 Personnel Qualification Evaluation Personnel selected will have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience will be verified. This verification will be documented. The initial capabilities of an individual will be based upon an evaluation of their education, experience, and training and compared to those established for the position. Evaluations will be documented by managers or supervisors responsible for the activities to be performed.
- 2.5.1.3 Indoctrination Prior to assigning personnel to perform activities affecting quality, they will be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished.
- Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.
- o FSN QAPP
 - o Implementing Procedures and Work Instructions (applicable to the individual's responsibilities)
 - o Regulations
 - o Project Level Documents
- 2.5.1.4 Training Prior to assigning personnel to perform quality affecting activities training if needed, will be conducted to gain the required proficiency. The training (in-depth instruction) will include the principles, techniques, and requirements of the activity. Such in-depth instructions may be internal or external class room sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.
- 2.5.1.5 Proficiency Evaluation After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality will be evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations. Proficiency evaluations will be performed by managers or supervisors who have responsibility for the activities being performed or verified.

CHANGE NOTICE A

- 2.5.1.6 Records Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations will be retained as lifetime QA records. These records will include, as a minimum, the items listed below:
- o Personnel Qualification Evaluation Records Records of the verification and evaluation of a candidates education, experience, and training, compared to those for the position.
 - o Indoctrination Records Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.
 - o Training Records Records of training which include the objective and content of the training, name of the instructor, attendees, dates of attendance and results of proficiency evaluations (where applicable), and other applicable information.
 - o Proficiency Evaluation Records Records of proficiency evaluation will include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

APPENDIX A

CHANGE NOTICE A

OBSERVATION: The recognition of a weakness in a Quality Assurance program that if left uncorrected could result in a condition adverse to quality.

OPERATIONS, PERIOD OF: Includes the time during which emplacement of waste occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing of shafts.

OVERVIEW: An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness, assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

OWNER: The person, group, company, agency, or corporation that has or will have title to the repository.

PARTICIPATING ORGANIZATION: This term applies to the following: (1) The government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in Yucca Mountain Project activities.

PEER: A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

PEER REVIEW: A documented critical review performed by peers who are independent of the work being reviewed but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art.

A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

PEER REVIEW GROUP: A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

PEER REVIEW REPORT: A documented in-depth report of the proceedings and findings of a peer review.

PERFORMANCE ALLOCATION: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components.

RESPONSE TO NRC REVIEW COMMENTS
REECO QAPP (568-DOC-115), REV. 7

The following representation of the NRC comments on the REECO QAPP are based on the NRC/DOE teleconference which took place on May 4, 1989.

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 QAPP.

RESPONSE TO COMMENT NO. 1

Since Section 1.17 was not included in NNWSI/88-9, Rev. 2 (i.e., new NRC review plan requirement) REECO 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 REECO QAPP will be revised to contain the provision.

Additionally, at the Yucca Mountain Project (Project) level, a procedure is being developed to deal with internal and external quality concerns. The procedure, AP-5.8Q, Reporting and Resolution of Quality Concerns, will describe the system that will provide all Project personnel the means to express quality concerns with assurance that those concerns will be investigated and resolved. Project personnel are those personnel of all the organizations, including Subcontractors.

OK per NRC
(Belke)
JWE
5/10/89

OPEN
ITEM

NRC COMMENT NO. 2

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 REECO QAPP does not meet this requirement.

RESPONSE TO COMMENT NO. 2

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

OK per NRC
- Belke
JML
5/10/89

OPEN

ITEM

NRC COMMENT NO. 3

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. 3

REECo has no responsibility for exploratory investigations associated with the site characterization program. Requirements for controlling change to the procedures that REECo will be implementing on the Yucca Mountain Project are defined in Section VI of the REECo QAPP.

OK per NRC
- Belke
JME
5/10/89

Closed

NRC COMMENT NO. 4

Criterion 14.5 of the RP states, in part, "Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety."

This criterion does not appear to be addressed in the REECO QAPP.

RESPONSE TO COMMENT NO. 4

This requirement is not contained in the REECO QAPP since it is not presently contained in the YMP QA Plan, NNWSI/88-9 (i.e., new NRC review plan requirement). However, the REECO QAPP, Section X, Paragraph 3.0 includes a requirement for hold points when needed to control an activity. Upon revision of the YMP QA Plan to include this requirement, the REECO QAPP will be revised accordingly.

OK per NRC
- Belke
JME
5/10/85

OPEN
ITEM

NRC COMMENT NO. 5

Criterion 17.3 of the RP states, "Inspection and test records contain the following, where applicable:

- a. Identification of procedure and item inspected or tested.
- b. A description of the type of observation.
- c. the date and results of the inspection or test.
- d. Information related to conditions adverse to quality.
- e. Inspector or data recorder identification.
- f. Evidence as to the acceptability of the results, with signature and organization.
- g. Action taken to resolve any discrepancies noted."

This criterion does not appear to be addressed in the REECO QAPP.

RESPONSE TO COMMENT NO. 5

Item a. (in its entirety) and Item f., the words "... with signature and organization." are new NRC review plan requirements which are not contained in the YMP QA Plan (NWSI/88-9). During the next general revision to the YMP QA Plan, these requirements will be added and the REECO QAPP will be revised accordingly. The remainder of the above items are addressed in Section X, Paragraph 9.1 (Page 50) for inspection records and Section XI, Paragraph 5.0, (Page 56) for test records.

OK per NRC
- Belke
JMR
5/10/89

OPEN

ITEM

NRC COMMENT NO. 6

Criterion 17.7 of the RP states, "Suitable facilities for the storage and security of records are described and used to preclude deterioration, damage, loss and misuse of records." Paragraph 10.2.1 of Section 17 of the REECO QAPP does not include requirements for forced air circulation with a filtration system as required by the UMP QA Plan, NNWSI/88-9.

RESPONSE TO COMMENT NO. 6

This bullet was inadvertently omitted from the REECO QAPP. The REECO QAPP will be revised to reflect this requirement.

OK per NRC
— Balke
JWE
5/10/89

OPEN
ITEM

RESPONSE TO NRC REVIEW COMMENTS
H&N QAPP REV. 3

NRC COMMENT NO. 1

In the Introduction Section of the 88-9 QAP, Paragraph 2.8 requires the YMP Project Quality Manager to approve the Project Participant QAPP's and changes thereto. The NRC staff does not see any information whereby this has been accomplished by the YMP Project Quality Manager for the H&N QAPP.

RESPONSE TO COMMENT NO. 1

Although the YMP Project Quality Manager is required to approve the Project Participant QAPPs and changes thereto, there is no requirement that this approval be by signature on the actual document. The typical practice has been to provide this approval via letter. (See attached approval letter).

OK per NRC
- Belke
JRE
5/10/89

Closed



Department of Energy

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

NBS 1.2.9
"QA: N/A"

FEB 03 1989

Joseph C. Calovini
Technical Project Officer for Yucca Mountain Project
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Las Vegas, NV 89109

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) APPROVAL OF THE HOLMES & NARVER, INC. (H&N) YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE PROGRAM PLAN (QAPP) REVISION 3 (NN1-1989-1142)

Reference: Letter, Wright to Blaylock, dtd. 1/31/89

The Project Office has completed its review of Revision 3 to the H&N QAPP. The Project Office has found the subject QAPP revision to be consistent with the requirements of the Yucca Mountain Project Quality Assurance (QA) Plan (88-9), Revision 2, and approves it for use on the Yucca Mountain Project.

Upon receipt of this letter, please submit a controlled copy of the H&N QAPP and all controlled documents that implement this plan (e.g., instructions, procedures, and drawings) and revisions thereto to the QA Support Contractor and Yucca Mountain Project QA Office for reference and use.

Your cooperation regarding this matter is appreciated. Should you have any questions, please contact Albert C. Williams of my staff at 794-7591 or Kent B. Johnson of Science Applications International Corporation at 794-7751.

N Valdura for
James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-1913

Joseph C. Calovini

-2-

FEB 03 1989

cc:

Ralph Stein, HQ (RW-30) FORS
L. H. Barrett, HQ (RW-3) FORS
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A. C. Williams, YMP, NV
N. A. Voltura, YMP, NV



NRC COMMENT NO. 2

Criterion 1.5 of the Review Plan (RP) states, "DOE and prime contractors describe major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations."

Section 1, Page 1, Paragraph III.B of the H&N Quality Assurance Program Plan (QAPP) indicates the TPO is the prime interface with the YMPO, participating organizations, and supporting contractors. Section 7, Page 1, Paragraph II.C of the H&N QAPP indicates that procurement of equipment and subcontracts is the responsibility of Reynolds Electrical and Engineering Co. Inc. with H&N supporting these activities. The H&N QAPP needs to provide in more detail, a description of the major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations.

RESPONSE TO COMMENT NO. 2

Holmes & Narver does not delegate any work. As noted in the H&N QAPP, Section 1, Paragraph I, last sentence, H&N directly performs all work within their scope. The responsibilities for work performed on the Yucca Mountain Project is delegated by the Project Office for the various contractors via the Work Breakdown Structure, (Ref. Sect. 1, II.B). In the area of procurement, detailed responsibilities for the various contractors will be further defined in a Project-level Administrative Procedure on procurement.

OK per NRC
- Belke
DRL
5/10/85

Closed

NRC COMMENT NO. 3

Criterion 1.15 of the RP states, "Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel."

Section 1, Page 2, Paragraph C.1 states that the Chief, Quality Assurance has direct access to responsible management including, if necessary, the YMPO Project Quality Manager, to resolve quality problems. It is not clear whether this responsibility includes provisions to resolve disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

RESPONSE TO COMMENT NO. 3

H&N's QAPP, Section 1, Paragraph III.C.1, states "The CQA has direct access to responsible management including, if necessary, the YMPO Project Quality Manager, to resolve quality problems." Since this is a program requirement there will be a procedure which will be more detailed in meeting the program requirements. The intent of this requirement is to resolve any quality problems regardless of where it originates.

OK per NRC
- Belke

per
5/11/89

However, QAPP must
be clarified by
adding 88-9 verbage

OPEN

NRC COMMENT NO. 4

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 does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 4

During the next general revision of 88-9, provisions will be added for requiring that internal and external allegations of inadequate quality be resolved at all organizational levels. When the Project revises the 88-9 document, then H&N will revise the QAPP to meet the new requirements.

Additionally, at the YMP level, a procedure is being developed to deal with internal and external quality concerns. Procedure AP-5.8Q, Reporting and Resolution of Quality Concerns, will describe 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 per NRC
- Balke
JRE
5/10/85

OPEN

NRC COMMENT NO. 5

Criterion 2.2 of the RP states, in part, "The QA Program provides a commitment to comply with NQA-1," Quality Assurance Program Requirements for Nuclear Facilities," and the following position, relative to the NQA-1 standard; Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," provides guidance on the qualifications of inspection and test personnel.

In the Policy Statement and Section 2, Paragraph II.B of the H&N QAPP, it is stated that the H&N QAPP complies with the NWSI/88-9 QAP. It is the NRC staff interpretation that H&N completely complies with the 88-9 QAP including a commitment to implement the requirements of ANSI/ASME NQA-1-1986. This should be clearly stated in the H&N QAPP to avoid future misinterpretations of this commitment.

RESPONSE TO COMMENT NO. 5

It is the Project Office position that the YMP QA Plan (NWSI/88-9), Rev. 2, is the governing document since the YMP QA Plan establishes the QA requirements for the Yucca Mountain Project. It is imperative that the Project participants commit to NWSI/88-9 rather than to NQA-1 directly since the YMP QA Plan describes certain NRC approved deviations to NQA-1 requirements (i.e., applicability of Criterion IX, X, XI and XIV to scientific investigations, additional requirements for scientific investigations etc.). The YMP QA Plan, Section II, Paragraph 1.0 states: "The hierarchy of criteria applicable to the Project are shown in Figure 1 of the Introduction of this document. With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in that Figure and this QAP exist, the requirements of this document shall prevail."

The relationship between NQA-1, the YMP QA Plan and the Project participant QA Program Plans (QAPPs) is clearly shown in Figure 1 of the YMP QA Plan (Introduction) and in the "Hierarchy of QA Criteria" figure presented in the H&N QAPP, Section 2, Attachment A.

OK per NRC
- Belke
Jue
5/10/89

Closed

NRC COMMENT NO. 6

Criterion 2.7 of the RP states, "Provisions are established which demonstrate through a matrix system or other means that each criterion of Appendix B is properly documented and covered by implementing procedures and/or instructions."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 6

Although not presently required by the YMP QA Plan (and therefore not a part of the H&N QA Plan), the Project Office does require each participant to complete a matrix which describes where each of the QA requirements of the participant QAPP are addressed in implementing procedures. In addition, a listing of implementing procedures is contained (and periodically updated) in Chapter 8.6 of the Site Characterization Plan (SCP).

OK per NRC
- Belke
5/16/88
JRE

Closed

NRC COMMENT NO. 7

Criterion 3.1 of the RP states, in part, "The definitions of design, design information, and design activities used in the design control program are defined... Design information and design activities refer to data collection and analyses activities and computer codes 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 analyses."

"Design information" and "design activities" are not addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 7

As noted in the H&N QAPP Section 3, Paragraph I, "Purpose", Design Activity requirements are established and described in this section. The term "Design Information" is not used in H&N's QAPP, but the applicable portions of the term as described in the NRC Review Plan are included in this section, i.e., design analyses, computer codes relative to activities, and design documentation. Data collection, (part of the laboratory requirements) per se, is not included in the H&N design responsibilities.

OK per NRC
- Belke
JME
5/10/89

Closed

NRC COMMENT NO. 8

Criterion 3.5 of the RP states, "Design Control measures are established and applied to conceptual design, or parts thereof, which may at a later time become part of the final design."

The H&N QAPP, Section 3, Scope, states, in part, "This section applies to all design activities performed in support of the project."

Clarify what is meant by "all design activities" and whether they apply to conceptual through final design.

RESPONSE TO COMMENT NO. 8

The H&N QAPP Rev. ²~~X~~, Section ³~~X~~, Paragraph II.A, states "This section applies to all design activities performed in support of the project." Design activities includes conceptual to final design.

OK per NRC
- Belke
JRE
5/10/88

Closed

NRC COMMENT NO. 9

Criterion 3.6 of the RP states, "Organizational responsibilities are prescribed for preparing, reviewing, approving, verifying, and validating design and design information documents."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 9

The H&N QAPP Rev. 3, Section 1, Paragraphs III.B, III.B.2 and III.C.2; Section 2, Paragraph III.C; Section 3, Paragraphs III.A.3, III.B.1, III.D.1, III.D.6, III.G.3, III.H.4.a, and III.H.9; Section 5, Paragraph III.C, and Section 6, Paragraphs II and III.A.2 describes the H&N Organization responsibilities for preparing, reviewing, approving, verifying, and validating (computer codes/software) design and design information documents. These requirements are more specifically presented in the H&N implementing procedures.

OK per NRC
- Belke
5/10/89
Jue

Closed

NRC COMMENT NO. 10

Criterion 3.12 of the RP states, in part, "Procedures for a design or technical review require, where applicable...the resolution methods for resolving comments."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 10

In accordance with H&N's QAPP Section 5, all requirements established in the QAPP are covered by procedures. This would also include any requirements for resolution of comments. Additionally, at the YMPO level, Procedure AP-5.14Q entitled "Design Review" has been issued that addresses Design Reviews and describes resolution methods for resolving comments.

Deferred
NRC Action Item
to review and
discuss in-house
JME
5/10/89

closed
~~OPEN~~

NRC COMMENT NO. 11

Criterion 3.13 of the RP states, in part, "Design Verification procedures assure the following:

- a. Criteria for determining the method of verification are established;...
- b. The responsibilities of the persons performing the verification or validation are defined;..."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 11

- a. This requirement is not presently contained in the H&N QAPP since it is a new NRC review plan requirement and thus is not reflected in the YMP QA Plan (NWSI/88-9). This new requirement was apparently derived from NUREG-0800, USNRC Standard Review Plan, Rev. 2 - July 1981, "Quality Assurance During the Design and Construction Phases" (power plants). Criterion 3E3 of this document reads as follows:

3E3. The following provisions are included if the verification method is only by test:

- a. Procedures provide criteria that specify when verification should be by test.
- b. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.
- c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

Based on Item (a) above, it appears that the original intent was to provide criteria for when verification should be by test and not necessarily to establish criteria for when other verification methods are selected. Items (b) and (c) of this criterion are already contained in the YMP QA Plan (Reference Section III, Paragraph 2.4.2 and 2.4.6.3). The Project Office agrees that a requirement should be incorporated into the YMP QA Plan to specify when verification should be by test. This will be incorporated into the next general revision of the YMP QA Plan at which time the H&N QAPP will be revised accordingly.

Pending further
DOE impact
evaluation
JVE 5/10/88

OPEN

b. Item (d) of review plan Criterion 3.13.

All of Section 3 of the H&N QAPP applies to the Design Organization. Implementing procedures describe the details necessary to define further responsibilities and duties. (Also see response to Comment #9).

NRC COMMENT NO. 12

Criterion 4.3 of the RP states, in part, "Organizational responsibilities are described for: (1) procurement planning;....(3) supplier selection;..."

(See above NRC Comment #1). In Section 7, Paragraph ^{II}IX.C of the H&N QAPP, it appears that Reynolds Electric & Engineering Co., Inc., has total responsibility for all procurement of equipment and contracts with H&N providing the oversight of these activities through surveillances and audits. If the NRC staff interpretation of the above is correct, it should be clearly described to avoid future misinterpretations.

RESPONSE TO COMMENT NO. 12

The H&N QAPP, Rev. 3, Section 7, Paragraph III.A describes procurement planning and the requirements to be defined and implemented by H&N procedure(s). Section 7, Paragraph III.B describes the basic requirements for supplier selection that are to be incorporated into H&N implementing procedure(s). In addition, upon issuance of Project direction via AP-4.10Q entitled "Procurement"; specific organizational responsibilities will be more specifically defined and clarified and subsequently incorporated into respective H&N implementing procedures. H&N has no responsibility to provide oversight of REECO procurement activities through audits and surveillance. This is the responsibility of the Project Office. The YMP QA Plan, NWSI/88-9, Rev. 2, Section VII, Paragraph 1.4.2.1 states: "When a Participating Organization, or Nevada Test Site (NTS) Support Contractor, utilizes another Participating Organization or NTS Support Contractor for NWSI activities for which they are responsible, the user organization shall initiate a request to WMPO to conduct a WMPO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize NTS Support Contractor or Participating Organization personnel as technical advisors."

OK per NRC
- Belke
per 5/10/85

Closed

NRC COMMENT NO. 13

Criterion 5.2 of the RP states, "Organizational responsibilities are described assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 13

The H&N QAPP, Rev. 3, Section 1, Paragraph III.B, describes that the Technical Project Officer "is responsible for directing the activities performed in support of the Project and ensuring that these activities are performed in accordance with this QAPP and implementing procedures."

Section 2 of the QAPP, Paragraph II.C, defines that "Implementing procedures, developed by qualified personnel, are reviewed and approved by the TPO and CQA, to ensure they meet the requirements of the QAPP, prior to implementation.

Section 5 of the QAPP, Paragraph II.A, requires that "Activities affecting quality shall be prescribed by and performed in accordance with written instructions, procedures, plans or drawings, as appropriate.

And, Section 1 of the QAPP, Paragraph III.C, defines the specific H&N Organization Responsibilities relating to assurance that the items specified in instructions, procedures or drawings are properly implemented.

OK per NRC
- Belke
JWB
5/10/89

Closed

NRC COMMENT NO. 14

Criterion 9.1 of the RP states, in part, "The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes is provided...."

Section IX, Paragraph 2.2.1 of the 88-9 QAP requires the Participating Organization and Support Contractor to identify which portions of its activities involve the use of special processes. This criterion and the 88-9 QAP requirements do not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 14

The H&N QAPP, Rev. 3, Appendix B, defines the term "Special Process,"; in addition, Section 9, Paragraph ^{III} (D), A, C, and E further clarify the minimum requirements or criteria description for special processes. H&N's work scope does not include any special process activities directly. H&N is only responsible to provide NDT as a service to the other participants.

OK per NRC
- Belke
5/10/89 JRE

Closed

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Criterion 9.2 of the RP states, "Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel."

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RESPONSE TO COMMENT NO. 15

The H&N QAPP, Rev. 3, Section 1, Paragraph IV.C, and Attachment B describes the Nondestructive Testing section responsibilities and organizational reporting lines. The QA organization is responsible to review and approve all H&N procedures including special processes as stated in Section 1, Paragraph C.

OK per NRC
- Belka
JVL
5/10/89

Closed

NRC COMMENT NO. 16

Criterion 10.2 of the RP states, in part, "Organizational responsibilities for inspection are described."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 16

The H&N QAPP, Rev. 3, Section 1, Paragraph III.B.4, and Attachment B, describes the inspection responsibilities and organization reporting relationship.

OK per NRC
- Belke
5/10/89
JMR

Closed

NRC COMMENT NO. 17

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

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 17

The H&N QAPP, Rev. 3, Section 12, Paragraph II.C, requires that each H&N support organization ensure compliance with the requirements of this section, including the responsibility for establishing and implementing the M&TE Calibration Program. The effectiveness of this program is measured by audits and surveillances of each department, as noted in Section 18 by QA.

OK per NRC
- Belke
QML
5/10/89

Closed

NRC COMMENT NO. 18

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RESPONSE TO COMMENT NO. 18

This requirement is not contained in the H&N QAPP since it is not presently contained in the YMP QA Plan, NNWSI/88-9 (i.e., new NRC review plan requirement). However, the H&N QAPP, Paragraph III.C includes a requirement for hold points when needed to control an activity. Upon revision of the YMP QA Plan to include this requirement, the H&N QAPP will be revised accordingly.

OK per NRC
- Belke
5/10/89
JMR

OPEN
ITEM

NRC COMMENT NO. 19

Criterion 17.2 of the RP states, "QA and other organizations are identified and their responsibilities are described for defining and implementing record activities, particularly in the retention, duration, and safe storage of records."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 19

Section 1 of the H&N QAPP, Paragraph III.B.3, defines the organization responsible for record processing. Also the H&N QAPP, Rev. 3, Section 17, Paragraph III.A, requires that the records system be defined and implemented in accordance with written procedures and shall include requirements and responsibilities for record transmittal, distribution, retention, maintenance, storage, disposition, retrievability, and for the prevention of delays between record completion and storage at the Project Record Center.

OK per NRC
- Belke
5/16/89
JRE

closed

RESPONSE TO NRC REVIEW COMMENTS
H&N QAPP REV. 3

NRC COMMENT NO. 1

In the Introduction Section of the 88-9 QAP, Paragraph 2.8 requires the YMP Project Quality Manager to approve the Project Participant QAPP's and changes thereto. The NRC staff does not see any information whereby this has been accomplished by the YMP Project Quality Manager for the H&N QAPP.

RESPONSE TO COMMENT NO. 1

Although the YMP Project Quality Manager is required to approve the Project Participant QAPPs and changes thereto, there is no requirement that this approval be by signature on the actual document. The typical practice has been to provide this approval via letter. (See attached approval letter).

OK per NRC
- Belke
Jue
5/10/89

Closed



Department of Energy

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

NBS 1.2.9
"QA: N/A"

FEB 03 1989

Joseph C. Calovini
Technical Project Officer for Yucca Mountain Project
Holmes & Narver, Inc.
101 Convention Center Drive
Phase II, Suite P-280
Las Vegas, NV 89109

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) APPROVAL OF THE HOLMES & NARVER, INC. (H&N) YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE PROGRAM PLAN (QAPP) REVISION 3 (NN1-1989-1142)

Reference: Letter, Wright to Blaylock, dtd. 1/31/89

The Project Office has completed its review of Revision 3 to the H&N QAPP. The Project Office has found the subject QAPP revision to be consistent with the requirements of the Yucca Mountain Project Quality Assurance (QA) Plan (88-9), Revision 2, and approves it for use on the Yucca Mountain Project.

Upon receipt of this letter, please submit a controlled copy of the H&N QAPP and all controlled documents that implement this plan (e.g., instructions, procedures, and drawings) and revisions thereto to the QA Support Contractor and Yucca Mountain Project QA Office for reference and use.

Your cooperation regarding this matter is appreciated. Should you have any questions, please contact Albert C. Williams of my staff at 794-7591 or Kent B. Johnson of Science Applications International Corporation at 794-7751.

N. Valdeira for
James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-1913

Joseph C. Calovini

-2-

FEB 03 1989

cc:

Ralph Stein, HQ (RW-30) FORS
L. H. Barrett, HQ (RW-3) FORS
S. H. Klein, SAIC, Las Vegas, NV
J. W. Estella, SAIC, Las Vegas, NV
K. B. Johnson, SAIC, Las Vegas, NV
R. K. Ramsgate, SAIC, Las Vegas, NV
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L. P. Skousen, YMP, NV
M. B. Blanchard, YMP, NV
W. R. Dixon, YMP, NV
E. L. Wilmot, YMP, NV
A. L. Baca, YMP, NV
A. C. Williams, YMP, NV
N. A. Voltura, YMP, NV



NRC COMMENT NO. 2

Criterion 1.5 of the Review Plan (RP) states, "DOE and prime contractors describe major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations."

Section 1, Page 1, Paragraph III.B of the H&N Quality Assurance Program Plan (QAPP) indicates the TPO is the prime interface with the YMPO, participating organizations, and supporting contractors. Section 7, Page 1, Paragraph II.C of the H&N QAPP indicates that procurement of equipment and subcontracts is the responsibility of Reynolds Electrical and Engineering Co. Inc. with H&N supporting these activities. The H&N QAPP needs to provide in more detail, a description of the major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations.

RESPONSE TO COMMENT NO. 2

Holmes & Narver does not delegate any work. As noted in the H&N QAPP, Section 1, Paragraph I, last sentence, H&N directly performs all work within their scope. The responsibilities for work performed on the Yucca Mountain Project is delegated by the Project Office for the various contractors via the Work Breakdown Structure, (Ref. Sect. 1, II.B). In the area of procurement, detailed responsibilities for the various contractors will be further defined in a Project-level Administrative Procedure on procurement.

OK per NRC
- Belke
JRL
5/10/85

Close

NRC COMMENT NO. 3

Criterion 1.15 of the RP states, "Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel."

Section 1, Page 2, Paragraph C.1 states that the Chief, Quality Assurance has direct access to responsible management including, if necessary, the YMPO Project Quality Manager, to resolve quality problems. It is not clear whether this responsibility includes provisions to resolve disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

RESPONSE TO COMMENT NO. 3

H&N's QAPP, Section 1, Paragraph III.C.1, states "The CQA has direct access to responsible management including, if necessary, the YMPO Project Quality Manager, to resolve quality problems." Since this is a program requirement there will be a procedure which will be more detailed in meeting the program requirements. The intent of this requirement is to resolve any quality problems regardless of where it originates.

OK per NRC
- Belke

gpc
5/10/89

However, QAPP must
be clarified by
adding 88-9 verbage

OPEN

NRC COMMENT NO. 4

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 does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 4

During the next general revision of 88-9, provisions will be added for requiring that internal and external allegations of inadequate quality be resolved at all organizational levels. When the Project revises the 88-9 document, then H&N will revise the QAPP to meet the new requirements.

Additionally, at the YMP level, a procedure is being developed to deal with internal and external quality concerns. Procedure AP-5.8Q, Reporting and Resolution of Quality Concerns, will describe 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 per NRC
- Belke
JRE
5/10/89

OPEN

NRC COMMENT NO. 5

Criterion 2.2 of the RP states, in part, "The QA Program provides a commitment to comply with NQA-1," Quality Assurance Program Requirements for Nuclear Facilities," and the following position, relative to the NQA-1 standard; Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," provides guidance on the qualifications of inspection and test personnel.

In the Policy Statement and Section 2, Paragraph II.B of the H&N QAPP, it is stated that the H&N QAPP complies with the NNWSI/88-9 QAP. It is the NRC staff interpretation that H&N completely complies with the 88-9 QAP including a commitment to implement the requirements of ANSI/ASME NQA-1-1986. This should be clearly stated in the H&N QAPP to avoid future misinterpretations of this commitment.

RESPONSE TO COMMENT NO. 5

It is the Project Office position that the YMP QA Plan (NNWSI/88-9), Rev. 2, is the governing document since the YMP QA Plan establishes the QA requirements for the Yucca Mountain Project. It is imperative that the Project participants commit to NNWSI/88-9 rather than to NQA-1 directly since the YMP QA Plan describes certain NRC approved deviations to NQA-1 requirements (i.e., applicability of Criterion IX, X, XI and XIV to scientific investigations, additional requirements for scientific investigations etc.). The YMP QA Plan, Section II, Paragraph 1.0 states: "The hierarchy of criteria applicable to the Project are shown in Figure 1 of the Introduction of this document. With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in that Figure and this QAP exist, the requirements of this document shall prevail."

The relationship between NQA-1, the YMP QA Plan and the Project participant QA Program Plans (QAPPs) is clearly shown in Figure 1 of the YMP QA Plan (Introduction) and in the "Hierarchy of QA Criteria" figure presented in the H&N QAPP, Section 2, Attachment A.

OK per NRC
- Belke
JUL 5/10/89

Closed

NRC COMMENT NO. 6

Criterion 2.7 of the RP states, "Provisions are established which demonstrate through a matrix system or other means that each criterion of Appendix B is properly documented and covered by implementing procedures and/or instructions."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 6

Although not presently required by the YMP QA Plan (and therefore not a part of the H&N QA Plan), the Project Office does require each participant to complete a matrix which describes where each of the QA requirements of the participant QAPP are addressed in implementing procedures. In addition, a listing of implementing procedures is contained (and periodically updated) in Chapter 8.6 of the Site Characterization Plan (SCP).

OK per NRC
- Belke
5/10/89
Jr2

Closed

NRC COMMENT NO. 7

Criterion 3.1 of the RP states, in part, "The definitions of design, design information, and design activities used in the design control program are defined... Design information and design activities refer to data collection and analyses activities and computer codes 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 analyses."

"Design information" and "design activities" are not addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 7

As noted in the H&N QAPP Section 3, Paragraph I, "Purpose", Design Activity requirements are established and described in this section. The term "Design Information" is not used in H&N's QAPP, but the applicable portions of the term as described in the NRC Review Plan are included in this section, i.e., design analyses, computer codes relative to activities, and design documentation. Data collection, (part of the laboratory requirements) per se, is not included in the H&N design responsibilities.

OK per NRC
- Belke
JME
5/10/89

Closed

NRC COMMENT NO. 8

Criterion 3.5 of the RP states, "Design Control measures are established and applied to conceptual design, or parts thereof, which may at a later time become part of the final design."

The H&N QAPP, Section 3, Scope, states, in part, "This section applies to all design activities performed in support of the project."

Clarify what is meant by "all design activities" and whether they apply to conceptual through final design.

RESPONSE TO COMMENT NO. 8

The H&N QAPP Rev. ² ~~2~~, Section ³ ~~2~~, Paragraph II.A, states "This section applies to all design activities performed in support of the project." Design activities includes conceptual to final design.

OK per NRC
- Belke
JRE
5/10/88

Closed

NRC COMMENT NO. 9

Criterion 3.6 of the RP states, "Organizational responsibilities are prescribed for preparing, reviewing, approving, verifying, and validating design and design information documents."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 9

The H&N QAPP Rev. 3, Section 1, Paragraphs III.B, III.B.2 and III.C.2; Section 2, Paragraph III.C; Section 3, Paragraphs III.A.3, III.B.1, III.D.1, III.D.6, III.G.3, III.H.4.a, and III.H.9; Section 5, Paragraph III.C, and Section 6, Paragraphs II and III.A.2 describes the H&N Organization responsibilities for preparing, reviewing, approving, verifying, and validating (computer codes/software) design and design information documents. These requirements are more specifically presented in the H&N implementing procedures.

OK per NRC
- Belka
5/10/89
gme

Closed

NRC COMMENT NO. 10

Criterion 3.12 of the RP states, in part, "Procedures for a design or technical review require, where applicable....the resolution methods for resolving comments."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 10

In accordance with H&N's QAPP Section 5, all requirements established in the QAPP are covered by procedures. This would also include any requirements for resolution of comments. Additionally, at the YMPO level, Procedure AP-5.14Q entitled "Design Review" has been issued that addresses Design Reviews and describes resolution methods for resolving comments.

Deferred
NRC Action Item
to review and
discuss in-house
JMC
5/10/89

~~OPEN~~
Accepted by NRC and closed after
further discussion on
5/10/89
D. J. Thomas

NRC COMMENT NO. 11

Criterion 3.13 of the RP states, in part, "Design Verification procedures assure the following:

- a. Criteria for determining the method of verification are established;...
- b. The responsibilities of the persons performing the verification or validation are defined;..."

This criterion does not appear to be addressed in the H&N QAPP.

RESPONSE TO COMMENT NO. 11

- a. This requirement is not presently contained in the H&N QAPP since it is a new NRC review plan requirement and thus is not reflected in the YMP QA Plan (NWSI/88-9). This new requirement was apparently derived from NUREG-0800, USNRC Standard Review Plan, Rev. 2 - July 1981, "Quality Assurance During the Design and Construction Phases" (power plants). Criterion 3E3 of this document reads as follows:

3E3. The following provisions are included if the verification method is only by test:

- a. Procedures provide criteria that specify when verification should be by test.
- b. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.
- c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

Based on Item (a) above, it appears that the original intent was to provide criteria for when verification should be by test and not necessarily to establish criteria for when other verification methods are selected. Items (b) and (c) of this criterion are already contained in the YMP QA Plan (Reference Section III, Paragraph 2.4.2 and 2.4.6.3). The Project Office agrees that a requirement should be incorporated into the YMP QA Plan to specify when verification should be by test. This will be incorporated into the next general revision of the YMP QA Plan at which time the H&N QAPP will be revised accordingly.

Pending further
DOE impact
evaluation
JVE 5/10/89

OPEN

b. Item (d) of review plan Criterion 3.13.

All of Section 3 of the H&N QAPP applies to the Design Organization. Implementing procedures describe the details necessary to define further responsibilities and duties. (Also see response to Comment #9).

NRC COMMENT NO. 12

Criterion 4.3 of the RP states, in part, "Organizational responsibilities are described for: (1) procurement planning;....(3) supplier selection;..."

(See above NRC Comment #1). In Section 7, Paragraph ~~IX~~^{II}.C of the H&N QAPP, it appears that Reynolds Electric & Engineering Co., Inc., has total responsibility for all procurement of equipment and contracts with H&N providing the oversight of these activities through surveillances and audits. If the NRC staff interpretation of the above is correct, it should be clearly described to avoid future misinterpretations.

RESPONSE TO COMMENT NO. 12

The H&N QAPP, Rev. 3, Section 7, Paragraph III.A describes procurement planning and the requirements to be defined and implemented by H&N procedure(s). Section 7, Paragraph III.B describes the basic requirements for supplier selection that are to be incorporated into H&N implementing procedure(s). In addition, upon issuance of Project direction via AP-4.10Q entitled "Procurement"; specific organizational responsibilities will be more specifically defined and clarified and subsequently incorporated into respective H&N implementing procedures. H&N has no responsibility to provide oversight of REECo procurement activities through audits and surveillance. This is the responsibility of the Project Office. The YMP QA Plan, NNWSI/88-9, Rev. 2, Section VII, Paragraph 1.4.2.1 states: "When a Participating Organization, or Nevada Test Site (NTS) Support Contractor, utilizes another Participating Organization or NTS Support Contractor for NNWSI activities for which they are responsible, the user organization shall initiate a request to WMPO to conduct a WMPO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize NTS Support Contractor or Participating Organization personnel as technical advisors."

OK per NRC
- Belke
per 5/10/85

Closed

NRC COMMENT NO. 13

Criterion 5.2 of the RP states, "Organizational responsibilities are described assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents."

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OK per NRC
- Belke
Jue
5/10/89

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OK per NRC
- Belke
5/10/89 JRE

Closed

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OK per NRC
- Belka
DRL
5/10/89

Closed

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OK per NRC
- Belke
5/10/89
JMR

Closed

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OK per NRC
- Belke
Jvt.
5/10/89

Closed

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OK per NRC
- Belke
5/10/89
gmc

OPEN
ITEM

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OK per NRC
- Belke
5/16/89
GME

closed