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MAY 16 1989

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

Dear Mr. Stein:

SUBJECT: MINUTES OF MARCH 22, 1989 QUALITY ASSURANCE MEETING

The purpose of this letter is to transmit the minutes from the March 22, 1989 U. S. Nuclear Regulatory Commission, U. S. Department of Energy (DOE), and State of Nevada meeting on quality assurance (QA). The minutes were prepared by members of the NRC staff and representatives from the DOE and do not include any items of interest from the State of Nevada.

Besides the monthly QA status, the subject of the meeting was to focus on items regarding QA. The major discussion dealt with the review of the scope of and preparation for the upcoming Fenix and Scisson and Holmes and Narver audits (now completed) and the importance of these audits to the start of design work for the Exploratory Shaft Facility. If you have any questions, please contact Brian 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: G. Gertz, DOE/NV
R. Loux, State of Nevada
S. Bradhurst, Nye County, NV
D. Bechtel, Clark County, NV
D. Baughman, Lincoln County, NV
K. Turner, GAO

DISTRIBUTION AND CONCURRENCE: SEE NEXT PAGE

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PDR
B. Belke
K. Hooks

J. Bunting
On-Site Reps
J. Holonich
B. Thomas
J. Kennedy
J. Conway

OFC : HLPD	: HLPD	: HLPD	: HLPD	:	:	:
NAME: BThomas	/mac: JHolonich	: JLinehan	: JKennedy:	:	:	:
DATE: 05/16/89	: 05/16/89	: 05/11/89	: 05/16/89	:	:	:

OFFICIAL RECORD COPY

MINUTES FOR DOE/NRC
JOINT QUALITY ASSURANCE MEETING
MARCH 22, 1989

On March 22, 1989, representatives of the U. S. Nuclear Regulatory Commission (NRC), the U. S. Department of Energy (DOE), Edison Electric Institute (EEI), the State of Nevada, and local governments met at the DOE offices in Las Vegas, Nevada to discuss items of mutual interest on quality assurance (QA). A list of attendees is shown in Attachment 1.

DOE made a presentation concerning the scope of the upcoming audits of Fenix & Scisson (F&S) and Holmes & Narver (H&N) scheduled for April 10 and April 24, 1989 respectively. During the presentation, DOE stated that although there was no ongoing design work at the time of the meeting, the initiation of design work was expected to be on or about April 3, 1989, and the scope of the audits would include any design work performed after this date. In addition, NRC noted that there would be a technical member on the audit team to review the qualifications of the contractors' staff. The main focus of the audit is readiness to start Exploratory Shaft Facility (ESF), Title II design work. The bases for the audits are the requirements contained in the participants' QA program plan (QAPP) and the "Nevada Nuclear Waste Storage Investigations Quality Assurance Plan" (NNWSI/88-9, Revision 2).

The second DOE presentation provided a status of the surveillances conducted by DOE/HQ and the Yucca Mountain Project (YMP). DOE/HQ conducted a surveillance of HQ and Project Office personnel on the readiness to begin ESF, Title II design activities. In addition, DOE/YMP is performing a 100% surveillance review of the QA procedures of participants in four areas: 1) ESF, Title II design work, 2) long-lead procurement, 3) site preparation, and 4) all other activities necessary for a fully qualified QA program.

NRC staff inquired about what the results were from previously conducted YMP surveillances covering the F&S QA procedures. DOE responded that some procedures are in need of clarification; however, there were no significant problems to prevent the start of ESF, Title II design work. NRC staff further inquired whether more training would be required because of the clarifications to the procedures. DOE responded that due to changes to the procedures resulting from the necessary clarifications, minor changes would necessitate some required training. If there were any major changes to a procedure, classroom training would be done.

NRC staff commented that the checklists for the April 10, 1989 audit of F&S had not yet been received and wanted to know how the audit activities would be different from the previous surveillances. DOE responded that the surveillance covered procedure reviews and was not as comprehensive as the qualification audit. DOE further stated that the upcoming audit would look at changes and activities since the surveillances were performed and at

qualifications of design personnel. NRC requested to know what work had been done recently, and if some of that work was going to be used in the Title II ESF design. In addition, the NRC staff wanted to know if there were QA controls on the work presently being done. DOE responded that all work was being done in accordance with the participants' QA plans and that the work being done did not affect the Title II design work because the Title II design work must stand on its own. DOE further stated that the start of ESF, Title II design work is not being tied to the audit.

The State of Nevada wished to know whether the 13 deficiencies identified during the surveillances of F&S would be corrected before start of Title II design work. DOE responded that there were no fatal flaws for moving ahead; however, it intends to do a summary surveillance prior to the qualification audit.

DOE made a presentation of the draft schedule of planned headquarters QA surveillances (both internal and external). See attachment 2 on "QA Surveillance Schedule." No comments or concerns were raised by the NRC staff.

Next, the status of three outstanding QAPPs were discussed, and DOE reported the status of the Sandia National Laboratory (SNL), U. S. Geological Survey (USGS) and YMP QAPPs. DOE stated that the SNL QAPP was waiting for a page change to close out the last remaining DOE review issue and should be submitted to NRC shortly. The YMP QAPP should be submitted to DOE/HQ in about a month once the description of responsibilities has been finalized. The USGS QAPP has been submitted to the YMP, and DOE expects to provide it to NRC in about two weeks.

The status of Privacy Act issue was presented by DOE. In its discussion, DOE identified the fact that there was a conflict between the Privacy Act and NRC QA recordkeeping requirements concerning files to be kept by employee name. DOE stated that its ability to keep records by employee name must be cleared with Congress, and that it should take about six months to arrange for the exception.

A short presentation was made by DOE on QA controls for scientific notebooks. See attachment 2 - last four pages on "scientific notebooks procedural methods." The State of Nevada inquired whether all the requirements for the control of notebooks applied to all notebooks. DOE responded that requirements were tied back to the Scientific Investigation Plans (SIPs) and that the SIPs specified, through quality levels, what controls were to be applied to those activities covered in an SIP. NRC asked how DOE planned to control the notebooks that were not properly controlled and may need to be "qualified," and how many needed to be qualified. DOE responded that "qualification" would be on a case-by-case basis. However, because site characterization data will be used for a major part of the license application, and because the collection of this data will be under a QA program, there should not be much need to qualify notebooks or data. DOE explained that the need for technical review of the scientific notebooks is to review the use of the data and description of procedures in the notebooks. This would be similar to an independent review of reports for quality. DOE further stated that notebooks will not be used to authorize changes due to the interfaces between experiments.

The agenda item to discuss resolution of QA issues identified by DOE/HQ and YMP that remain open after the start of ESF, Title II design activities carried over to a subsequent QA meeting.

NRC staff then presented the status of its review of the overall DOE QA program for the repository. The Quality Assurance Requirements (QAR) Document Safety Evaluation was expected to be signed by March 24 and the SE for the Quality Assurance Program Description (QAPD) document the following week. The review of the Design Acceptability Analysis (DAA) is ongoing and comments are expected to be ready by mid-April for NRC management review. The status of other reviews was also reported. A copy of the NRC presentation on the status of its review of the QAPPs is given in attachment 3. NRC staff stated that if it does an on-site review of the DAA, DOE will be made aware of the scope of the review so that appropriate technical people can be available.

For the upcoming qualification audits of F&S and H&N, NRC informed DOE that it planned to use its new audit observation procedure for these audits. The NRC staff and State of Nevada will provide feedback on the DOE audits in formal observation reports. An NRC acceptance of the qualification audits for the organization being audited will not be issued until the staff has observed/evaluated the satisfactory implementation of design activities for the ESF.

There were no items of interest for the State of Nevada and local governments reported at this meeting.

A general discussion of the frequency of meetings resulted in agreement by all parties to change to a bi-monthly schedule with the next meeting set for May 9, 1989, at 9:00 a.m. at the NRC building in White Flint.

Potential agenda items discussed were:

- The outcome of the F&S and H&N audits.
- The scope of upcoming audits.
- A summary of verification activities.
- The DAA review results status by NRC.
- A description of quality concerns (allegation management).
- The process for procedure revisions and streamlining the present system.

Other items discussed that may necessitate a separate meeting were:

- A discussion of "best available data".
- The extent of NRC participation in Study Plans and readiness reviews.
- A presentation by EEI on suggestions for streamlining the DOE audit process.



Linda J. Desell
Licensing Branch
Office of Civilian Radioactive Waste
Management
U. S. Department of Energy



James T. Conway
Repository Licensing and Quality
Assurance Project Directorate
U. S. Nuclear Regulatory Commission

QA Monthly Meeting
March 22, 1989

LIST OF ATTENDEES

<u>NAME</u>	<u>ORGANIZATION</u>
J. Conway	NRC
J. Gilray	NRC
L. Barrett	DOE
L. Desell	DOE
J. Jones	DOE
A. Williams	DOE
C. Hampton	DOE
W. Mansel	DOE
R. Murthy	DOE
L. Little	DOE
S. Ailes	SAIC
H. Caldwell	SAIC
E. Ripley	SAIC
S. Metta	SAIC
J. Estella	SAIC
K. Johnson	SAIC
B. Hurley	SAIC
M. Brown	SAIC
J. Madsen	MACTEC
J. Long	MACTEC
M. Diaz	MACTEC
S. Kraft	EEI
T. Colandrea	EEI
C. Johnson	State of Nevada
D. Bechtel	Clark County, Nevada
D. Hoxie	USGS
P. Watters	WESTON
P. Narducci	CER

DOE/NRC MEETING

MARCH 22, 1989

LAS VEGAS, NEVADA

DEPARTMENT OF ENERGY OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT						PLANNED BY _____ DATE _____		THIS CHART LISTS SURVEILLANCE ACTIVITIES GROUPED BY TYPE OF SURVEILLANCE							LOCATION PAGE 1 OF 1 SHEET 1 OF 1 SYMBOLS						
PROJECT SCQA1 RUN CONTROL FILE QMS2						APPROVED BY _____ DATE _____		S1 HQ INTERNAL S2 HQ PROJECT OFFICE							DURATION (NON CRITICAL) [Symbol] DURATION (CRITICAL) [Symbol] ZERO DURATION Δ PROGRESS [Symbol]						
NEW SITE CHARACTERIZATION ACTIVITIES RUN DATE 20MAR89 DATA DATE 17MAR89 QA SURVEILLANCE SCHEDULE																					
ACTIVITY DESCRIPTION	ACTIVITY CODE	SURV TYPE	REFERENCE START	PLANNED DURATION	PLANNED COMPLETE	1989 JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP							
HQ INTERNAL SURVEILLANCE, STUDY PLAN REVIEW		S1	27MAR89	3	29MAR89	[Bar]															
HQ INTERNAL SURVEILLANCE, CRITERIA 2, 3, 5, 8, 17		S1	15MAY89	7	21MAY89																
HQ INTERNAL SURVEILLANCE, CRITERIA 1, 4, 7, 18, 19		S1	29MAY89	7	04JUN89																
HQ INTERNAL SURVEILLANCE, READINESS QUAL AUDIT		S1	10JUL89	7	16JUL89																
HQ PERF SURVEILLANCE, ESF DESIGN ACCEPT. ANALYSIS		S2	05JAN89	10	15JAN89	[Bar]															
HQ PERF SURVEILLANCE YMP TITLE II DES PREPAREDNESS ACT		S2	27FEB89	11	07MAR89		[Bar]														
HQ SURVEILLANCE, YMP SUMMARY SURV OF PARTICIPANTS		S2	29MAR89	170	14SEP89				[Long Bar]												
HQ SURVEILLANCE YMP IMPLEMEN, CRITERIA 2, 5, 8, 17		S2	03APR89	7	09APR89				[Bar]												
HQ SURVEILLANCE, QUAL AUDIT OF FAS		S2	10APR89	7	16APR89				[Bar]												
HQ SURVEILLANCE STUDY PLAN REVIEW & GALS		S2	17APR89	7	23APR89				[Bar]												
HQ SURVEILLANCE, QUAL AUDIT OF HAN		S2	24APR89	7	30APR89				[Bar]												
HQ SURVEILLANCE QUAL AUDIT OF SNL		S2	01MAY89	7	07MAY89				[Bar]												
HQ SURVEILLANCE, YMP IMPLEX, CRITERIA 4, 7, 8, 18, 19		S2	01MAY89	7	07MAY89				[Bar]												
HQ SURVEILL YMP PREPAREDNESS TO START SITE PREP		S2	15MAY89	7	21MAY89				[Bar]												
HQ SURVEILLANCE, QUAL AUDIT OF USGS		S2	22MAY89	14	04JUN89				[Bar]												
HQ SURVEILLANCE QUAL AUDIT OF RECO		S2	03JUN89	7	11JUN89				[Bar]												
HQ SURVEILLANCE, QUAL AUDIT OF LLNL		S2	19JUN89	7	25JUN89				[Bar]												
HQ SURVEILLANCE QUAL AUDIT OF LANL		S2	03JUL89	7	09JUL89				[Bar]												
HQ SURVEILLANCE, YMP READINESS, QUAL AUDIT		S2	17JUL89	7	23JUL89				[Bar]												
HQ SURVEILLANCE YMP PREPAREDNESS TO START MPMH		S2	31JUL89	7	06AUG89				[Bar]												

SURVEILLANCE STATUS

	<u>SCHEDULED</u>	<u>PERFORMED</u>	<u>IN PROCESS</u>	<u>REMAINING</u>	(THRU END OF JULY)
F&S	25	19	0	6	
USGS	15	2	0	13	
H&N	16	4	6	6	
LANL	16	5	0	11	
LLNL	19	11	0	8	
YMP	16	3	1	12	
REECo	16	0	0	16	
SNL	17	6	0	11	
<hr/>					
TOTAL	140	50	7	83	

F&S AND H&N AUDITS

AUDIT SCHEDULE

F&S - 4/19/89

H&N - 4/27/89

AUDIT SCOPE

- o PROGRAMMATIC IN NATURE
- o FOCUS ON READINESS TO START TITLE II DESIGN
- o NO TECHNICAL ACTIVITIES CURRENTLY IN PROGRESS

REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

- o THE REQUIREMENTS TO BE AUDITED ARE CONTAINED IN THE PROGRAMMATIC CHECKLISTS. THESE CHECKLISTS WERE DEVELOPED FROM THE FOLLOWING DOCUMENTS:
 - NNWSI/88-9, REV. 2
 - PARTICIPANT QAPP AND IMPLEMENTING PROCEDURES

REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES (CONT'D)

- o THE CONDUCT OF THE AUDIT WILL BE GUIDED BY THE DOCUMENTS LISTED BELOW:
 - QMP-18-01; "AUDIT SYSTEM FOR THE WASTE MANAGEMENT PROJECT OFFICE," REV. 0
 - QMP-16-03, "STANDARD DEFICIENCY REPORTING SYSTEM," REV. 0
 - YUCCA MOUNTAIN PROJECT AUDIT OBSERVER INQUIRY
 - NRC OBSERVATION OF YUCCA MOUNTAIN PROJECT QA
 - YUCCA MOUNTAIN PROJECT QA AUDIT TASK ORGANIZATION
 - POLICY FOR PARTICIPATION OF STATE, TRIBAL, AND NRC REPRESENTATIVES AS OBSERVERS ON DOE AUDITS (DTD. 7/14/87)

CRITERIA TO BE AUDITED

- 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
- 10.0 INSPECTION
- 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT
- 15.0 CONTROL OF NONCONFORMING ITEMS
- 16.0 CORRECTIVE ACTION
- 17.0 QUALITY ASSURANCE RECORDS
- 18.0 AUDITS

SUMMARY OF SURVEILLANCE RESULTS

- F&S - 13 DEFICIENCY REPORTS WERE GENERATED FOR PROCEDURAL DEFICIENCIES ASSOCIATED WITH 10 OF 64 PROCEDURES REVIEWED; NO IMPLEMENTATION DEFICIENCIES WERE NOTED.
- USGS - 3 OF 6 PROCEDURES WERE FOUND DEFICIENT AND REVISED AS A RESULT OF THIS REVIEW. 1 DEFICIENCY REPORT WAS ISSUED FOR AN IMPLEMENTATION DEFICIENCY.
- H&N - 10 DEFICIENCY REPORTS WERE GENERATED FOR PROCEDURAL AND IMPLEMENTATION DEFICIENCIES ASSOCIATED WITH 21 OF 21 PROCEDURES REVIEWED; (NOTE: 3 OF THE 10 DEFICIENCIES WERE GENERIC AND APPLIED TO ALL H&N PROCEDURES REVIEWED).

- LANL - 11 DEFICIENCY REPORTS WERE GENERATED FOR PROCEDURAL AND IMPLEMENTATION DEFICIENCIES ASSOCIATED WITH 12 OF 17 PROCEDURES REVIEWED.
- LLNL - 16 OF 26 PROCEDURES REVIEWED CONTAINED MINOR DEFICIENCIES; PROCEDURES WERE REVISED IMMEDIATELY; NO IMPLEMENTATION DEFICIENCIES WERE NOTED. NO DEFICIENCY DOCUMENTS WERE ISSUED.
- YMP - 10 DEFICIENCY REPORTS WERE GENERATED FOR PROCEDURAL AND IMPLEMENTATION SURVEILLANCES ASSOCIATED WITH 12 OF 17 PROCEDURES REVIEWED.
- REEC - NO SURVEILLANCES HAVE BEEN PERFORMED TO DATE.
- SNL - 5 DEFICIENCY REPORTS WERE GENERATED FOR PROCEDURAL AND IMPLEMENTATION DEFICIENCIES ASSOCIATED WITH 24 OF 24 PROCEDURES REVIEWED; (NOTE: 1 OF THE 5 DEFICIENCIES WAS GENERIC AND APPLIED TO ALL SNL PROCEDURES REVIEWED).

SCIENTIFIC NOTEBOOKS - PROCEDURAL METHODS

1. DOCUMENTATION

- UNIQUE IDENTIFICATION (ACTIVITY, LOCATION)
- PAGE CONTROL (PAGINATION, REFERENCES NO OPEN/BLANK PAGES)
- GENERAL ENTRY REQUIREMENTS (PERMANENT INK, SIGNATURES/DATES)

2. WORK PLANNING

- EXPERIMENTAL OBJECTIVES (SIP/STUDY PLAN REFERENCE)
- EQUIPMENT FABRICATION AND CALIBRATION REQUIREMENTS
- SPECIAL TRAINING/QUALIFICATION REQUIREMENTS
- POTENTIAL SOURCES OF UNCERTAINTY AND ERROR
- REQUIRED LEVEL OF PRECISION AND ACCURACY

3. IN-PROCESS ENTRIES

- DESCRIPTION OF EXPERIMENT IN PROCESS AND INTERIM CONCLUSIONS
- DESCRIPTION OF CONDITIONS THAT MAY ADVERSELY AFFECT RESULTS
- IDENTIFICATION OF ADDITIONAL EQUIPMENT/MATERIALS USED
- IDENTIFICATION AND TRACEABILITY OF DATA AND/OR INFORMATION
- DEVIATIONS FROM PLANNED EXPERIMENTAL APPROACH

4. QA RECORDS

- INDEX OF CONTENTS
- INTERIM STORAGE
- TECHNICAL REVIEW
- DATA/ANALYSIS SHEETS THAT SUPPORT NOTEBOOK ENTRIES

SCIENTIFIC NOTEBOOKS - IMPLEMENTATION ISSUES

1. DOCUMENT CONTROL

- CONTROLLED DISTRIBUTION
- AUTHORIZATION OF CHANGES

2. QA RECORDS

- SINGLE FACILITY (FIRE-PROOF SAFE)
- PERIODIC REPRODUCTION (90 DAYS)
- INTERIM (FIELD NOTES) VS. FINAL RECORD

3. TRACEABILITY

- REFERENCES (PROCEDURES, PUBLICATIONS)
- ATTACHMENTS (DATA/ANALYSIS SHEETS)

4. VERIFICATION

- PERIODIC TECHNICAL REVIEW
- FINAL TECHNICAL REVIEW

5. IN-PROCESS ENTRIES

- CHRONOLOGY OF EXPERIMENTAL ACTIVITIES
- DAILY ENTRY

NRC REVIEW OF QAPP

F&S - completed (2 open items)
conference call to DOE - 3/2/89
letter to DOE - 4/1/89

H&N - under review
conference call to DOE - 4/5/89
letter to DOE - 4/21/89

SNL - not received

USGS - not received

REECO - under review
conference call to DOE - 5/1/89
letter to DOE - 5/12/89

LLNL - review will start - 4/3/89
conference call to DOE - 5/19/89
letter to DOE - 6/2/89

LANL - review will start - 4/10/89
conference call to DOE - 5/26/89
letter to DOE - 6/9/89

YMP - not received