

JUL 13 1993

MEMORANDUM FOR: John T. Larkins, Acting Executive Director
Advisory Committee on Nuclear Waste

FROM: B. J. Youngblood, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety and Safeguards

SUBJECT: TRANSMITTAL OF VIEWGRAPHS

In accordance with the Memorandum of Understanding between the Advisory Committee on Nuclear Waste (ACNW) and the Executive Director for Operations (EDO) enclosed for your information and use are five copies of the viewgraphs for the July 21, 1993, briefing on quality assurance by the Division of High-Level Waste Management (HLWM).

If you have any questions regarding these viewgraphs you may contact Kenneth Hooks of my staff on 504-2447.

B. J. Youngblood, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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ENCLOSURE

**PRESENTATION TO THE
ADVISORY COMMITTEE ON NUCLEAR WASTE**

ON

**QUALITY ASSURANCE IN THE HIGH-LEVEL
NUCLEAR WASTE REPOSITORY PROGRAM**

BY

KENNETH R. HOOKS, QA SECTION LEADER, (301) 504-2447

**DIVISION OF HIGH-LEVEL WASTE MANAGEMENT
OFFICE OF NUCLEAR MATERIAL SAFETY & SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION**

JULY 21, 1993

PRESENTATION

- * WHAT IS QUALITY ASSURANCE (QA)**
- * DIVISION OF HIGH-LEVEL WASTE MANAGEMENT (HLWM) QA ACTIVITIES**
- * CONCLUSIONS**

WHAT IS QA

- * SOME BASIC PRINCIPLES OF QA
- * 18 CRITERIA OF TITLE 10 CODE OF FEDERAL REGULATIONS (10 CFR) PART 50, APPENDIX B
- * HLWM STAFF PERCEPTION OF QA
- * LEVELS OF SPECIFICITY IN QA REQUIREMENTS

SOME BASIC PRINCIPLES OF QA

- * PLAN ACTIVITIES (AND DOCUMENT PLANNING PROCESS)**
- * FOLLOW THE PLAN (AND DOCUMENT THE WORK PROCESS)**
- * DOCUMENT RESULTS**
- * AUDIT TO VERIFY ADEQUACY OF ABOVE STEPS (AND DOCUMENT AUDITS)**
- * TAKE CORRECTIVE ACTION TO CORRECT DEFICIENCIES**

18 CRITERIA OF 10 CFR PART 50, APPENDIX B

- I. ORGANIZATION**
- II. QUALITY ASSURANCE PROGRAM**
- III. DESIGN CONTROL**
- IV. PROCUREMENT DOCUMENT CONTROL**
- V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS**
- VI. DOCUMENT CONTROL**
- VII. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES**
- VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS**

18 CRITERIA OF 10 CFR PART 50, APPENDIX B (CONTINUED)

- IX. CONTROL OF SPECIAL PROCESSES**
- X. INSPECTION**
- XI. TEST CONTROL**
- XII. CONTROL OF MEASURING AND TEST EQUIPMENT**
- XIII. HANDLING, STORAGE AND SHIPPING**
- XIV. INSPECTION, TEST, AND OPERATING STATUS**
- XV. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS**
- XVI. CORRECTIVE ACTION**
- XVII. QUALITY ASSURANCE RECORDS**
- XVIII. AUDITS**

HLWM STAFF PERCEPTION OF QA **

- * 10 CFR PART 50, APPENDIX B QA PROGRAM CAN BE IMPLEMENTED ON EARTH SCIENCES, BASED ON EXPERIENCE WITH NUCLEAR POWER PLANT SITE INVESTIGATIONS.
 - NRC REGULATORY GUIDE 1.132 "SITE INVESTIGATION FOR FOUNDATIONS OF NUCLEAR POWER PLANTS," REVISION 1, MARCH 1979.
 - ANSI/ASME NQA-2, PART 2.20 "QUALITY ASSURANCE REQUIREMENTS FOR SUBSURFACE INVESTIGATIONS FOR NUCLEAR POWER PLANTS."
 - ANSI/ASME N45.2.20-1979 "SUPPLEMENTARY QUALITY ASSURANCE REQUIREMENTS FOR SUBSURFACE INVESTIGATIONS FOR NUCLEAR POWER PLANTS," SEPTEMBER 30, 1979.
- * IMPLEMENTING PROCEDURES AT THE WORKING LEVEL ARE BEST DEFINED BY EXPERIENCED SCIENTISTS/ENGINEERS WHO UNDERSTAND THE INTENT OF QA REQUIREMENTS.
- * THE APPLICATION OF A MEANINGFUL QA PROGRAM TO ANY COMPLEX ACTIVITY WILL REQUIRE SUCCESSIVE ITERATIONS.

** LETTER LINEHAN (NRC) TO STEIN (DOE), AUGUST 15, 1990, "MAY 22, 1990 MEETING ON THE QUALITY ASSURANCE WORKSHOP."

LEVELS OF SPECIFICITY IN QA REQUIREMENTS

GENERAL



SPECIFIC

- * **NRC REQUIREMENTS AND GUIDANCE**
 - 10 CFR PART 60, SUBPART G
 - 10 CFR PART 50, APPENDIX B
 - NQA-1
 - NRC REVIEW PLAN
 - NUREGS

- * **DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) REQUIREMENTS**
 - OCRWM QA REQUIREMENTS AND DESCRIPTION
 - PARTICIPANTS QA PROGRAM DESCRIPTIONS
 - OCRWM QA ADMINISTRATIVE PROCEDURES
 - PARTICIPANT QA PROCEDURE(S)
 - PARTICIPANT TECHNICAL PROCEDURE(S)
 - SCIENTIFIC INVESTIGATION (ACTUAL WORK)

HLWM QA ACTIVITIES

- * EVALUATION OF OCRWM QA PROGRAM**
- * OVERSIGHT OF CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES (CNWRA) QA PROGRAM**
- * IMPLEMENTATION OF HLWM INTERNAL QA (IOA) PROGRAM**

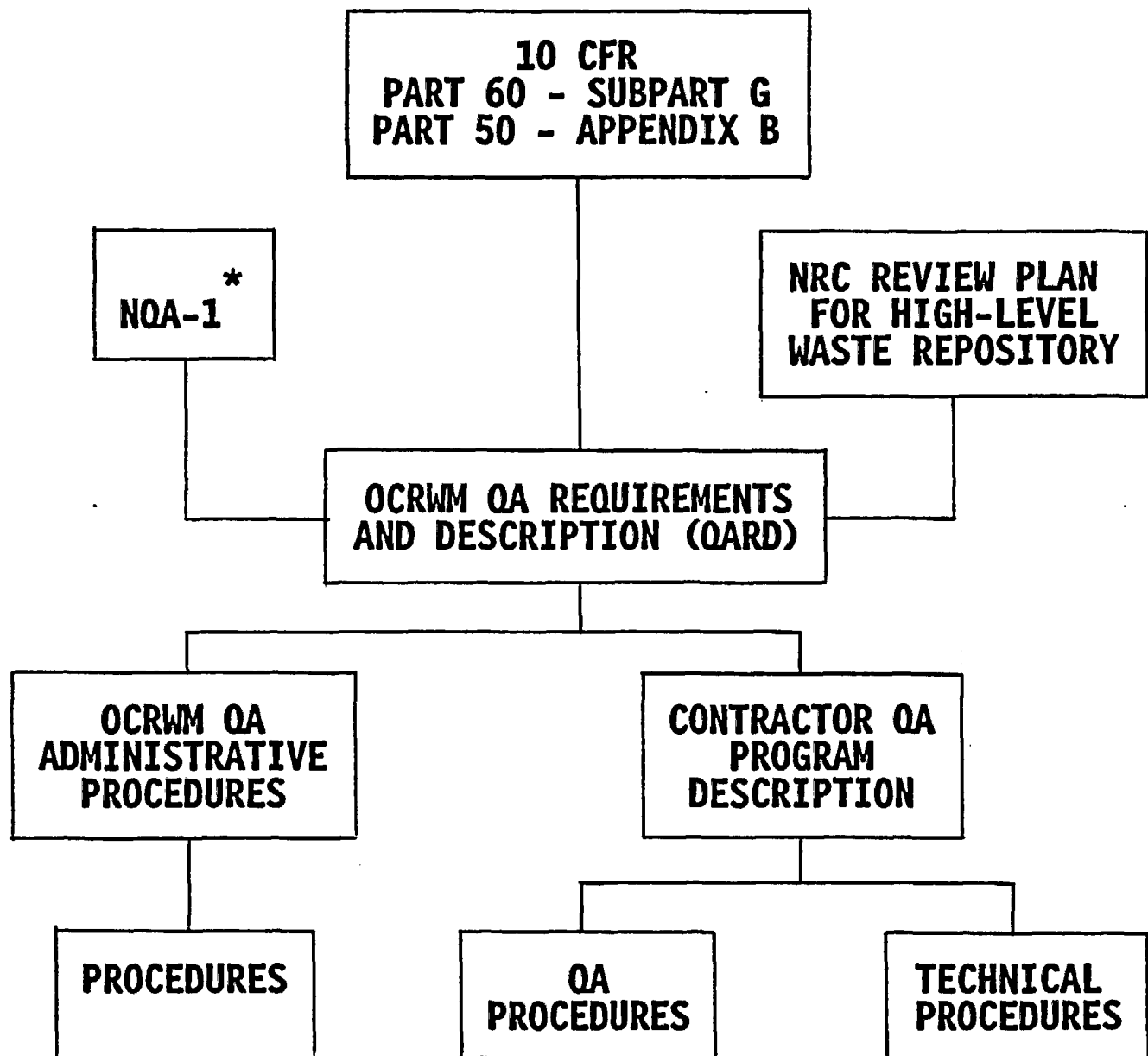
EVALUATION OF OCRWM QA PROGRAM

- * 10 CFR PART 60, SUBPART G**
- * HIERARCHY OF OCRWM QA PROGRAM**
- * HLWM QA GUIDANCE PROVIDED TO OCRWM**
- * STEPS LEADING TO NRC ACCEPTANCE OF OCRWM QA PROGRAM**
- * STATUS OF OCRWM & PARTICIPANT QA PROGRAMS**
- * HLWM METHODS OF EVALUATING OCRWM QA PROGRAM**
- * SUMMARY OF HLWM QA ACTIVITIES**
- * EVENTS LEADING TO OCRWM QA PROGRAM ACCEPTANCE**
- * SITE CHARACTERIZATION ANALYSIS (SCA) OBJECTION NO. 2**
- * 10 CFR PART 50 APPENDIX B REQUIREMENTS AS APPLIED TO SCIENTIFIC INVESTIGATIONS**
- * RESOURCE ESTIMATES FOR QA PROGRAM**

10 CFR PART 60, SUBPART G

- * QA PROGRAM BASED ON 10 CFR PART 50, APPENDIX B AS APPLICABLE AND APPROPRIATELY SUPPLEMENTED BY ADDITIONAL CRITERIA**
- * QA PROGRAM APPLIES TO SYSTEMS, STRUCTURES, AND COMPONENTS IMPORTANT TO SAFETY AND BARRIERS IMPORTANT TO WASTE ISOLATION**
- * QA PROGRAM APPLIES TO SITE CHARACTERIZATION, FACILITY AND EQUIPMENT CONSTRUCTION, FACILITY OPERATION, PERFORMANCE CONFIRMATION, PERMANENT CLOSURE, AND DECONTAMINATION AND DISMANTLING OF SURFACE FACILITIES**

HIERACHY OF OCRWM QA PROGRAM



* AMERICAN NATIONAL STANDARDS INSTITUTE/AMERICAN SOCIETY OF MECHANICAL ENGINEERS, "QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR NUCLEAR FACILITIES"

HLWM QA GUIDANCE PROVIDED TO OCRWM

- * REVIEW PLAN FOR HIGH-LEVEL WASTE REPOSITORY QUALITY ASSURANCE PROGRAM DESCRIPTIONS**
- * TECHNICAL POSITIONS (NUREGS)**
- * QUALIFICATION OF EXISTING DATA**
- * REVIEW AND COMMENT ON OCRWM WRITTEN QA PROGRAM DOCUMENTS**
- * PERIODIC HLWM/OCRWM QA MEETINGS**
- * FEEDBACK BASED ON OBSERVATIONS OF OCRWM AUDITS AND SURVEILLANCES**

TECHNICAL POSITIONS

- * FINAL TECHNICAL POSITION ON DOCUMENTATION OF COMPUTER CODES FOR HIGH-LEVEL WASTE MANAGEMENT (NUREG-0856-F) JUNE 1983**
- * PEER REVIEW FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES (NUREG-1297) FEBRUARY 1988**
- * QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES (NUREG-1298) FEBRUARY 1988**
- * TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS (NUREG-1318) APRIL 1988**

QUALIFICATION OF EXISTING DATA

- * NUREG-1298 PROVIDES GUIDANCE ON METHODS OF QUALIFYING DATA NOT COLLECTED UNDER A 10 CFR PART 60, APPENDIX G, QA PROGRAM:
 - PEER REVIEW IN ACCORDANCE WITH NUREG-1297
 - USE OF CORROBORATING DATA
 - USE OF CONFIRMATORY TESTING
 - USE OF AN EQUIVALENT QA PROGRAM
- * YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE (YMP0) ADMINISTRATIVE PROCEDURE 5.9Q, "QUALIFICATION OF DATA OR DATA ANALYSES NOT DEVELOPED UNDER THE YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE PLAN"
- * LETTER ROBERTS (DOE) TO HOLONICH (NRC) 9/3/92: "... WHEN DOE DETERMINES THAT SUFFICIENT INFORMATION HAS BEEN DEVELOPED TO APPROACH RESOLUTION OF AN ISSUE, THE NEED FOR QUALIFICATION OF DATA TO SUPPORT THE TECHNICAL BASIS OF A DOE POSITION WOULD BE ADDRESSED AT THAT TIME. ..."

STEPS LEADING TO NRC ACCEPTANCE OF OCRWM QA PROGRAM

- * OCRWM DEVELOPS AND APPROVES WRITTEN QA PROGRAM DOCUMENT(S)**
- * OCRWM REQUESTS NRC ACCEPTANCE OF QA PROGRAM DOCUMENT(S)**
- * NRC REVIEWS AND, IF APPROPRIATE, ACCEPTS OCRWM QA PROGRAM DOCUMENT(S)**
- * OCRWM IMPLEMENTS QA PROGRAM**
- * OCRWM EVALUATES QA PROGRAM IMPLEMENTATION (AUDITS, SURVEILLANCES, DOCUMENT REVIEWS)**
- * NRC OBSERVES SELECTED AUDITS AND SURVEILLANCES**
- * OCRWM APPROVES QA PROGRAM IMPLEMENTATION**
- * OCRWM REQUESTS NRC ACCEPTANCE OF QA PROGRAM IMPLEMENTATION**
- * NRC EVALUATES QA PROGRAM IMPLEMENTATION BASED ON OBSERVATIONS**
- * IF APPROPRIATE, NRC ACCEPTS QA PROGRAM IMPLEMENTATION**

**EXAMPLE - ACCEPTANCE OF LAWRENCE LIVERMORE
NATIONAL LABORATORY (LLNL) QA PROGRAM**

MARCH 1989	OCRWM APPROVES LLNL QA PROGRAM PLAN (QAPP)
MARCH 1989	LLNL IMPLEMENTS QA PROGRAM
MARCH 1989	OCRWM REQUESTS NRC ACCEPTANCE OF LLNL QAPP
JUNE 1989	NRC TRANSMITS COMMENTS ON LLNL QAPP TO OCRWM
JUNE 1989	OCRWM AUDIT 89-6 OF LLNL QA PROGRAM
OCTOBER 1989	NRC ACCEPTS LLNL QAPP
APRIL 1990	OCRWM ACCEPTS LLNL QA PROGRAM
APRIL 1990	OCRWM REQUESTS NRC ACCEPTANCE OF LLNL QA PROGRAM
MAY 1990	OCRWM AUDIT 90-02 OF LLNL QA PROGRAM
OCTOBER 1990	NRC ACCEPTS LLNL QA PROGRAM

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT PROGRAM PARTICIPANTS

- * FELIX & SCISSON (F&S)**
- * HOLMES & NARVER (H&N)**
- * REYNOLDS ELECTRICAL & ENGINEERING COMPANY, INC. (REECO)**
- * U. S. GEOLOGICAL SURVEY (USGS)**
- * SANDIA NATIONAL LABORATORIES (SNL)**
- * LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL)**
- * LOS ALAMOS NATIONAL LABORATORY (LANL)**
- * SCIENCE APPLICATIONS INTERNATIONAL CORPORATION (SAIC)/TECHNICAL & MANAGEMENT SUPPORT SERVICES (T&MSS)**
- * RAYTHEON SERVICES NEVADA (RSN)**
- * OCRWM/HEADQUARTERS (HQ)**
- * OCRWM/YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE (YMP0)**
- * CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (M&O)**

STATUS OF OCRWM & PARTICIPANT QA PROGRAMS

ORGANIZATION	DATE OF NRC ACCEPTANCE	
F&S	10/24/90 *	**
H&N	10/24/90 *	**
REECO	10/24/90 *	8/15/91
USGS	10/24/90 *	8/16/91
SNL	10/24/90	
LLNL	10/24/90	
LANL	05/29/91	
SAIC/T&MSS	10/09/91	
RSN	01/27/92	
OCRWM/HQ	01/18/91 *	12/20/91
OCRWM/YMPO	01/18/91 *	12/20/91
M&O	ONGOING REVIEW	

* ACCEPTED WITH EXCEPTIONS

** SCOPE OF WORK ASSUMED BY RSN

HLWM METHODS OF EVALUATING OCRWM QA PROGRAM

- * REVIEWS OF DOE QA DOCUMENTS**
 - NRC REVIEW PLAN**
 - FORWARDED REVISION 0 IN JUNE 1984**
 - FORWARDED REVISION 1 IN DECEMBER 1988**
 - FORWARDED REVISION 2 IN MARCH 1989**
- * PERIODIC MEETINGS WITH DOE**
 - BEGUN JANUARY 1989**
 - INITIALLY HELD BI-MONTHLY, NOW AS REQUIRED**
- * EVALUATION OF PROGRAM IMPLEMENTATION**
 - OBSERVATIONS**
 - BEGUN FEBRUARY 1988**
 - DOE QA AUDITS**
 - DOE QA SURVEILLANCES**
 - DESIGN REVIEWS**
 - READINESS REVIEWS**
 - ON-SITE LICENSING REPRESENTATIVES**
 - QA ON-SITE VISITS**
 - NRC INDEPENDENT QA AUDITS**
- * NRC CONTINUES TO EVALUATE PREVIOUSLY ACCEPTED PROGRAMS THROUGH OBSERVATIONS OF DOE'S AUDITS AND SURVEILLANCES**

OBSERVATIONS OF OCRWM QA AUDITS/SURVEILLANCES

ADVANTAGES

- * EVALUATE BOTH AUDIT PROCESS AND THE PROGRAM BEING AUDITED**
- * REQUIRES SUBSTANTIALLY LESS HLWM RESOURCES FOR BOTH PREPARATION AND PARTICIPATION**

DISADVANTAGES

- * LITTLE CONTROL OF SCHEDULE OR SCOPE OF INDIVIDUAL AUDITS/SURVEILLANCES**

EVALUATION

- * CURRENTLY PROVIDES ADEQUATE CONFIDENCE**

DESIGN REVIEWS

- * ONE OF METHODS FOR DESIGN CONTROL DISCUSSED IN PARAGRAPHS 3.10 AND 3.12 OF NRC REVIEW PLAN**
- * REQUIRED BY SECTION 3.2.5 OF OCRWM QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION**
- * OBSERVED BY HLWM PERSONNEL (AS OF 7/16/93)**
 - EXPLORATORY STUDIES FACILITY (ESF) NORTH AREA DESIGN STUDIES REVIEW, JUNE 1991**
 - 50% DESIGN REVIEW OF DESIGN PACKAGE 1A FOR THE ESF, APRIL 1992 (BY ON-SITE LICENSING REPRESENTATIVES)**
 - 90% INDEPENDENT TECHNICAL REVIEW OF DESIGN PACKAGE 1A FOR THE ESF, JULY 1992**
 - 50% INDEPENDENT TECHNICAL REVIEW OF ESF TITLE II DESIGN PACKAGES 1B AND 2 , APRIL 1993**
 - 90% INDEPENDENT TECHNICAL REVIEW OF ESF TITLE II DESIGN PACKAGE 2, JULY 1993**

READINESS REVIEWS (RRs)

- * REQUIRED BY PARAGRAPH 2.15 OF NRC REVIEW PLAN**
- * COMMITTED TO, AS NEEDED, BY OCRWM QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION, SECTION 2.27**
- * HLWM PERSONNEL HAVE OBSERVED OCRWM AND M&O RRs**
 - MIDWAY VALLEY STUDY PLAN, DECEMBER 1990**
 - M&O FY92 QUALITY AFFECTING ACTIVITIES, DECEMBER 1991**
 - M&O MONITORED RETRIEVABLE STORAGE ACTIVITIES, FEBRUARY 1992**
 - M&O FY92 QUALITY AFFECTING ACTIVITIES, APRIL 1992**

SUMMARY OF HLWM QA ACTIVITIES (AS OF 7/16/93)

QA MANUALS REVIEWED/ACCEPTED - 12

QA AUDITS OF DOE OBSERVED

CY 88 - 11
CY 89 - 7
CY 90 - 8
CY 91 - 16
CY 92 - 16
CY 93 - 11

QA SURVEILLANCES OF DOE OBSERVED

CY 89 - 0
CY 90 - 8
CY 91 - 10
CY 92 - 2
CY 93 - 3

HLWM STAFF AUDITS OF DOE - 2 (LANL, USGS)

EVENTS LEADING TO OCRWM QA PROGRAM ACCEPTANCE

- * SEPTEMBER 1985: DOE COMMITS TO HAVING A FULLY QUALIFIED QA PROGRAM WHEN SITE CHARACTERIZATION PLAN (SCP) IS ISSUED - LTR PURCELL (DOE) TO BROWNING (NRC), 9/3/85
- * JUNE 1986: NRC EXPRESSES CONCERN ABOUT LACK OF AN EFFECTIVE DOE QA PROGRAM IN MANAGEMENT MEETING WITH DOE - MEMO KENNEDY (NRC) TO BROWNING (NRC), 12/12/86
- * SEPTEMBER 1987: DOE REITERATES ITS COMMITMENT TO HAVE FULLY QUALIFIED QA PROGRAM WHEN SCP IS ISSUED - LTR KNIGHT (DOE) TO YOUNGBLOOD (NRC), 9/18/87
- * MARCH 1988: NRC COMMENTS ON CONSULTATION DRAFT SCP THAT DOE QA PROGRAM IS INADEQUATE TO SUPPORT SITE CHARACTERIZATION - LTR BROWNING (NRC) TO KALE (DOE), 3/7/88
- * NOVEMBER 1988: DOE REPORTS TO NRC THAT DEVELOPMENT & IMPLEMENTATION OF QA PROGRAM IS BEHIND SCHEDULE - LTR STEIN (DOE) TO LINEHAN (NRC), 11/4/88
- * JULY 1989: NRC RAISES OBJECTION NO. 2 TO DOE LACK OF ADEQUATE QA PROGRAM IN SCA - LTR BERNERO (NRC) TO ROUSSO (DOE), 7/31/89

EVENTS LEADING TO OCRWM QA PROGRAM ACCEPTANCE (CONTINUED)

- * APRIL 1990: NRC MEETS WITH DOE, SECURES DOE AGREEMENT TO HOLD WORKSHOPS WITH PROGRAM PARTICIPANTS TO DISCUSS PROBLEMS IN QA PROGRAM IMPLEMENTATION - MINUTES ISSUED BY LTR LINEHAN (NRC) TO STEIN (DOE), 5/30/90**
- * AUGUST 1990: DOE QA WORKSHOP WITH PROGRAM PARTICIPANTS - MINUTES ISSUED BY LTR DESELL (DOE) TO LINEHAN (NRC), 9/24/90**
- * OCTOBER 1990: NRC ACCEPTS SIX PROGRAM PARTICIPANTS' QA PROGRAMS, TWO WITH NO EXCEPTIONS - LTR LINEHAN (NRC) TO SHELOR (DOE), 10/24/90**
- * DECEMBER 1991: NRC ACCEPTS OCRWM QA PROGRAM WITHOUT EXCEPTIONS (LTR HOLONICH (NRC) TO ROBERTS (DOE), 12/20/91**
- * MARCH 1992: NRC LIFTS SCA OBJECTION NO.2 - LTR BERNERO (NRC) TO BARTLETT (DOE), 3/2/92**
- * OCRWM HAS DEVELOPED AND IMPLEMENTED A QA PROGRAM WHICH IS ACCEPTABLE TO THE NRC, AND IS, IN GENERAL, SUCCESSFULLY APPLYING THIS PROGRAM TO SITE CHARACTERIZATION ACTIVITIES.**

SCA OBJECTION NO. 2

*** OCRWM COMMITTED TO HAVING AN APPROPRIATE QA PROGRAM IN PLACE PRIOR TO STARTING SITE CHARACTERIZATION ACTIVITIES**

*** OCRWM HAD NOT DEMONSTRATED AN ACCEPTABLE QA PROGRAM**

- OCRWM AND PARTICIPANTS' WRITTEN QA PROGRAM DOCUMENTS HAD NOT BEEN ACCEPTED BY OCRWM OR THE NRC**
- OCRWM AND PARTICIPANTS' QA PROGRAM IMPLEMENTATION HAD NOT BEEN ACCEPTED BY OCRWM OR THE NRC**

LACK OF FULL TIME QUALIFIED QA MANAGER

QA FOR DESIGN ACCEPTABILITY ANALYSIS

*** BASIS FOR LIFTING**

- REMAINING ORGANIZATIONS PARTICIPATING IN SITE CHARACTERIZATION HAVE ACCEPTABLE QA PROGRAMS**
- QA MANAGEMENT POSITIONS FILLED WITH FULL TIME PERSONNEL**
- OCRWM DEMONSTRATED ACCEPTABLE DESIGN CONTROL PROGRAM**

10 CFR PART 50, APPENDIX B, REQUIREMENTS
AS APPLIED TO SCIENTIFIC INVESTIGATIONS

CRITERION III, DESIGN CONTROL

"DESIGN CHANGES, INCLUDING FIELD CHANGES, SHALL BE SUBJECT TO DESIGN CONTROL MEASURES COMMENSURATE WITH THOSE APPLIED TO THE ORIGINAL DESIGN AND BE APPROVED BY THE ORGANIZATION THAT PERFORMED THE ORIGINAL DESIGN UNLESS THE APPLICANT DESIGNATES ANOTHER RESPONSIBLE ORGANIZATION."

NQA-1-1986, DESIGN CONTROL

"DESIGN CHANGES, INCLUDING FIELD CHANGES, SHALL BE COVERED BY CONTROL MEASURES COMMENSURATE WITH THOSE APPLIED TO THE ORIGINAL DESIGN."

(CONTINUED)

OCRWM COMMITS TO MEET THE REGULATORY QA REQUIREMENTS OF CRITERION III AND NQA-1, "DESIGN CONTROL" FOR SCIENTIFIC INVESTIGATIONS IN SUPPLEMENT III OF THE QARD. IN SUPPLEMENT III, OCRWM STATES;

III.2.3 PERFORMING SCIENTIFIC INVESTIGATIONS

- A. SCIENTIFIC INVESTIGATIONS SHALL BE PERFORMED USING SCIENTIFIC NOTEBOOKS, TECHNICAL IMPLEMENTING DOCUMENTS, OR A COMBINATION OF BOTH.**
- B. SCIENTIFIC NOTEBOOKS SHALL CONTAIN THE FOLLOWING:**
 - 1. A DESCRIPTION OF WORK TO BE PERFORMED, OR REFERENCE TO AN APPROVED PLAN THAT DESCRIBES THE WORK.**
 - 2. METHOD(S) TO BE USED.**
 - 3. DESCRIPTION OF THE WORK PERFORMED AND RESULT(S) OBTAINED.**
 - 4. DESCRIPTION OF CHANGES MADE TO METHOD(S) USED, AS APPROPRIATE.**
- C. SCIENTIFIC NOTEBOOKS SHALL BE REVIEWED BY AN INDEPENDENT QUALIFIED INDIVIDUAL TO VERIFY THERE IS SUFFICIENT DETAIL TO RETRACE THE INVESTIGATION AND CONFIRM THE RESULTS, IF FEASIBLE, OR REPEAT THE INVESTIGATION AND ACHIEVE COMPARABLE RESULTS, WITHOUT RECOURSE TO THE ORIGINAL INVESTIGATOR.**

EXAMPLES OF OCRWM QA SURVEILLANCES OF FIELD ACTIVITIES

ACTIVITY	ORGANIZATION
GEOLOGIC INVESTIGATIONS	LANL
TRACER GAS INJECTION	USGS
DRILL HOLE ACTIVITIES	YMPO/RSN
GEOPHYSICAL LOGGING ACTIVITIES NRG-1	US BUREAU OF RECLAMATION
GEOLOGIC MAPPING	USGS
SAMPLE HANDLING	YMPO
FIELD VERIFICATION ACTIVITIES	RSN
FIELD DOCUMENT CONTROL	YMPO
CONTROL OF BOREHOLE SAMPLES	YMPO

SURVEILLANCE OF LANL GEOLOGIC INVESTIGATIONS

- * SURVEILLANCE YMP-SR-92-006, JULY 9-14, 1992, OF FIELD AND LABORATORY LOGS AND NOTEBOOKS FOR SCIENTIFIC ACTIVITIES CONDUCTED BY LANL UNDER STUDY PLANS 8.3.1.8.1.1, "PROBABILITY OF MAGMATIC DISRUPTION OF THE REPOSITORY," AND 8.3.1.8.5.1, "CHARACTERIZATION OF VOLCANIC FEATURES"
- * AUDITOR AND TECHNICAL SPECIALIST REVIEWED DOCUMENTATION AND INTERVIEWED PRINCIPAL INVESTIGATOR AND OTHER LANL PERSONNEL
- * DETERMINED THAT IMPLEMENTATION OF PROGRAMMATIC AND TECHNICAL REQUIREMENTS WAS SATISFACTORY
- * ISSUED CORRECTIVE ACTION REQUEST FOR FAILURE TO PERFORM INDEPENDENT REVIEW OF LOGS AND NOTEBOOKS

RESOURCE ESTIMATES FOR QA PROGRAM

- * 10 - 15% OF TIME CHARGES FOR ESTABLISHED PROGRAM (GENERALLY AGREED TO BY QA PROGRAM MANAGERS)
- * 20 - 45% OF LLNL YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT RESOURCES LAST YEAR (NUCLEAR WASTE TECHNICAL REVIEW BOARD MEETING AT LLNL, JANUARY 1990)
- * APPROXIMATELY 12% OF TOTAL PROJECT IN FY89 AND FY90 FOR "DIRECT" QA, APPROXIMATELY 6% WAS QA STAFF (L.J. JARDINE, LLNL TECHNICAL PROJECT OFFICER, AMERICAN SOCIETY FOR QUALITY CONTROL ENERGY DIVISION 2ND INTERNATIONAL WASTE MANAGEMENT CONFERENCE, MARCH 1991)

OVERSIGHT OF CNWRA QA PROGRAM

- * CNWRA QA REQUIREMENTS**
- * OVERSIGHT OF CNWRA QA PROGRAM**

CNWRA QA REQUIREMENTS

- * CONTRACT NRC-02-88-005, SECTION E.2**
 - ALL WORK IN ACCORDANCE WITH 10 CFR PART 50, APPENDIX B AND THE NRC REVIEW PLAN FOR HIGH-LEVEL WASTE REPOSITORY QUALITY ASSURANCE PROGRAM DESCRIPTIONS, AS APPLICABLE**
- * CNWRA QUALITY ASSURANCE MANUAL, REVISION 2, CHANGE 2 (ACCEPTED BY NRC MAY 29, 1991)**
- * CNWRA QUALITY ASSURANCE PROCEDURES (QAPs)**
- * CNWRA TECHNICAL OPERATING PROCEDURES (TOPs)**
- * CNWRA PROGRAM**
 - APPLIES TO QUALITY AFFECTING ACTIVITIES**
 - MANUAL PREPARED IN CONFORMANCE WITH 10 CFR PART 50**
 - QAPs AND TOPs ISSUED AND FOLLOWED**
 - AUDITS CONDUCTED FOR COMPLIANCE**

OVERSIGHT OF CNWRA QA PROGRAM

- * REVIEWS OF CNWRA QA DOCUMENTS**
- * IMPLEMENTATION**
 - OBSERVATION OF SIX CNWRA INTERNAL AUDITS**
 - OBSERVATION OF CNWRA QA PERSONNEL**

IMPLEMENTATION OF HLWM IOA PROGRAM

*** MAJOR PROGRAM ACTIVITIES ARE CONTROLLED**

*** EXAMPLES OF PROCEDURES**

- SCP REVIEW PLAN**
- QA REVIEW PLAN**
- STUDY PLAN REVIEW PLAN**
- STAFF TECHNICAL POSITION PREPARATION GUIDANCE**
- STAFF RECEIVES TRAINING ON PROCEDURES BEFORE USE**

*** CONDUCT INTERNAL AUDITS/SURVEILLANCES**

- COMPLIANCE EVALUATED**
- FINDINGS ISSUED**
- SIX CONDUCTED TO DATE**

*** STAFF TRAINING**

- TECHNICAL STAFF AUDIT TRAINING**
- SOFTWARE QA TRAINING**
- REQUIREMENTS OF HLWM PROCEDURES**

HLWM IOA AUDITS/SURVEILLANCES

- * REVIEW PROCESS FOR THE CONSULTATION DRAFT SITE CHARACTERIZATION PLAN (SCP), FEBRUARY 1988**
- * REVIEW PROCESS FOR THE SCP, MAY 1989**
- * REVIEW PROCESS FOR STUDY PLANS, JUNE 1991**
- * REVIEW PROCESS FOR SCP PROGRESS REPORT NO. 5, SEPTEMBER 1992**
- * REVIEW OF IMPLEMENTATION OF DOCUMENT CONTROL PROCEDURE, DECEMBER 1992**
- * REVIEW OF IMPLEMENTATION OF TRIP REPORT PROCEDURE, JULY 1993**

CONCLUSIONS

- * OCRWM AND ORIGINAL PARTICIPANTS HAVE ACCEPTABLE QA PROGRAMS**
- * M&O QA PROGRAM DESCRIPTION HAS BEEN ACCEPTED BY OCRWM AND IS BEING REVIEWED BY THE NRC**
- * M&O QA PROGRAM IMPLEMENTATION IS BEING REVIEWED BY OCRWM AND NRC**
- * OCRWM AND PARTICIPANTS' QA PROGRAMS ARE GENERALLY IMPROVING**
- * QA IS BEING SUCCESSFULLY APPLIED TO SITE CHARACTERIZATION ACTIVITIES**
- * CNWRA HAS ACCEPTABLE QA PROGRAM**
- * HLWM HAS AN ACCEPTABLE IQA PROGRAM**