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MINUTES OF THE MAY 22, 1990 NRC/DOE MEETING
ON THE QUALITY ASSURANCE WORKSHOP

On May 22, 1990, the United States Nuclear Regulatory Commission (NRC) staff and representatives of: the United States Department of Energy (DOE), the State of Nevada (NV), and Nye County, NV met in Bethesda, Maryland to discuss the proposed quality assurance (QA) workshop. Representatives of the other Affected Units of Local Government were informed of this meeting but did not send representatives. The workshop has been proposed as a way of identifying and resolving questions about problems (perceived or real) in the implementation of QA programs by participants in DOE's high-level waste (HLW) repository program. An attendance list is included as Attachment 1.

In opening remarks, the NRC staff discussed the problems (perceived or real) which have been voiced by those inside and outside of the repository program. These include statements that QA is counterproductive or that work is being impeded by problems caused by the implementation of QA programs. Listed below are several sources of these statements:

- o National Academy of Sciences, August 1988 Colloquium, "Aspects of Geotechnical Practices for Underground Radioactive Waste Repositories"
- o Comments of Dr. Don U. Deere, Chairman of the Nuclear Waste Technical Review Board (NWTRB) in an interview with Radioactive Exchange, December 1989
- o Statement of Dr. C. Frederick Sears, Chairman of the Steering Committee of Edison Electric Institute (EEI) Utility Nuclear Waste and Transportation Program to the NWTRB, December 1989
- o Statements by Dr. L. Jardine, Lawrence Livermore National Laboratory (LLNL) Technical Project Officer (TPO) at NWTRB meeting at LLNL, January, 1990
- o Paper by Dr. Frank L. Parker, Chairman of the Board on Radioactive Waste Management of the National Research Council at the International Conference on Waste Management at Tucson, Arizona, February, 1990.*

It was noted that most of the statements attributed to these sources were based on information provided by individuals involved in DOE's HLW repository program.

*Extracts of these statements are included in Attachment 2 which is an expansion of Attachment 6 of the minutes of the February 15, 1990 QA Meeting Minutes.

ENCLOSURE

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In addition, comments have been made at DOE audits and surveillances in the presence of both DOE audit team members and NRC and NV audit observers. It is the opinion of the NRC staff that the workshop should be a forum for the exchange of ideas which will allow DOE to determine which of the problems are simply perceptions and to begin the resolution of any real problems which are found. The NRC staff also stated its view that problems probably do not exist with NRC regulations and requirements relative to QA since 10 CFR Part 50, Appendix B and associated requirements have been successfully implemented in earth science applications for siting and design of nuclear power reactors.

DOE expressed interest in the opportunity to discuss the perceived QA problems and to determine their current sources and accuracy. It was noted that some of the problems mentioned have been the subject of discussion for several years and may have long since been resolved. It was also stated that development and implementation of a QA program which meets the requirements of 10 CFR Part 50, Appendix B is a challenge which DOE accepts.

In its presentation on the problems (perceived or real) (Attachment 3), the NRC staff discussed why the perception problem is a serious one. The reasons include the importance of an effective QA program to the geologic repository program and the increased difficulty that perceived problems will have on implementing an effective QA program. The NRC staff's position on QA program implementation was also discussed during this presentation. The main points were that experience in reactor applications shows that a 10 CFR Part 50, Appendix B QA program can be implemented on earth science projects, that the implementing procedures are best defined at the working level by experienced scientists and engineers, and that application of a meaningful QA program will require successive iterations. The NRC staff believes that it has made a determination that the DOE program participant's QA Program Plans meet 10 CFR 50 Appendix B and other regulatory requirements, as applicable. Both DOE and the representative from EEI expressed their agreement that the NRC regulations and requirements were sufficiently general to permit adequate flexibility in scientific investigations. DOE also agreed with the need to work with program participants by providing policy guidance, but allowing procedures to be developed at the working level.

The NRC staff continued its presentation with a discussion of NRC's logic to resolve the problems (perceived or real). It was noted that generalities cannot be resolved, rather root causes must be identified. Root causes of a problem cannot be determined without specific details. The best place to identify these is at the working level. A workshop would be one way to start this process. DOE noted that there were different ways of getting to the root causes. According to DOE, it might be more effective for DOE to hold discussions with individual program participants before a workshop to determine the details.

The NRC staff also discussed specific issues which have been identified as possible problems with regard to QA program implementation (Attachment 4). These were problems (perceived or real) identified over the last nine months, based on conversations with participant TPOs, QA Managers, and working level scientists and engineers. The NRC staff pointed out that its requirements were flexible and therefore should not be the source of the problems (perceived or real). The

problems (perceived or real) tend to reflect difficulty in implementing procedures and instructions. For example, graded QA has been perceived as a problem because of the difficulty that the DOE program participants have had in assigning QA levels to various activities. DOE stated that the problem here was one of program start-up. DOE further stated that changes in the procedure for grading had probably changed this perception.

In general, DOE's perception was that program participants needed to realize that while NRC's requirements were not overly prescriptive, there needs to be a limit to the flexibility in the QA program. It was stated that there will be times when program participants must wait for procedures to be reviewed, that this is inevitable. DOE also made the point that quality is achieved by the individuals who carry out the work. Its current revision of the QA Requirements Document was discussed by DOE as an example of management actions being taken to improve QA program implementation.

The NRC staff discussed examples of successful implementation of 10 CFR Part 50, Appendix B QA programs in the earth sciences (Attachment 5). One important lesson learned from the successful applications is the importance of appropriate delegation, particularly the delegation of writing QA procedures to the program participants. The ability to make needed revisions to procedures when unexpected obstacles appear was also noted as an important tool for successful QA implementation.

In discussing follow-up activities to this meeting, DOE stated that its preferred approach would be to meet with individual program participants to determine whether or not the problems (perceived or real) were a concern. After these meetings a general workshop would be held to discuss the results. After concerns were raised by NRC, NV, and EEI about this approach DOE suggested that an acceptable approach was potentially having two tiers of workshops. The first workshop would be a meeting for DOE program participants to air problems. DOE could use NRC as a resource to assist in facilitating the process, with other interested parties invited to observe. The second workshop would be held to resolve problems identified at the first workshop. Again, NRC could be a resource, with other interested parties invited to observe.

In closing remarks, the NV representative stated that the program participants have varying degrees of resentment toward the DOE Office of Civilian Radioactive Waste Management headquarters (OCRWM) and Yucca Mountain Project Office (YMPO) staff because the program participants feel as if they have been "guinea pigs" with regard to QA, while OCRWM and YMPO have not been as rigorous with their own QA programs. This problem has been exacerbated by the recent postponement of the OCRWM and YMPO audits. The NV representative also stated that some scientists working for the program participants were unhappy with QA staff in their organizations who did not seem knowledgeable about QA. Another NV observation was that the individual meetings with program participants could be used (or could be perceived to be used) to filter out subjects DOE does not want discussed at the general meeting.

The representative from EEI remarked that he concurred with NRC's approach of a

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workshop for all participants in which there would be an opportunity for open discussions.

DOE's closing remarks included a statement that its policy is not to suppress any concerns of program participants in any forum. It was further stated that the postponement of the OCRWM and YMPO audits might enable DOE to support a workshop earlier than they had previously thought possible.

The NRC staff's closing remarks urged a workshop in the near-term to resolve the problems (perceived or real) now, as the QA programs are being implemented. NV and EEI concurred in this. It was noted by NRC that the problems (perceived or real) discussed in this meeting continue to be discussed at various meetings, thus reinforcing them, whether they are accurate or not.

Since this meeting did not meet its objective of developing an agenda for the QA workshop, DOE's progress toward holding a workshop (and any related meetings) shall remain a regular agenda item at the NRC/DOE QA meetings.

NV did not submit a written statement for inclusion in these minutes.



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Repository Licensing and Quality
Assurance Project Directorate
Office of Nuclear Material Safety
and Safeguards, NRC



Corinne Macaluso
Repository Licensing Branch
Office of Civilian Radioactive
Waste Management, DOE

NRC/DOE QA WORKSHOP MEETING

May 22, 1990

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TELEPHONE</u>
Charlotte Abrams	NRC/ACNW	FTS 492-8371
William Belke	NRC/HLWM	FTS 492-0445
Robert E. Browning	NRC/HLWM	FTS 492-3408
J. R. Caldwell	MACTEC/YMP	(702) 794-2559
Woody Chu	NWTRB	(202) 254-4792
Robert Clark	DOE/HQ OQA	(202) 586-1238
Tom Colandrea	EEl-U Waste	(619) 487-7510
Jim Conway	NRC/HLWM	FTS 492-0453
Scott Dam	Weston/DOE HQ	(202) 646-6660
Mark Delligatti	NRC/HLWM	FTS 492-0430
Linda Desell	DOE	(202) 586-1462
Gary Faust	Weston/UE&C	646-6729
Charles Head	DOE/RW 30	(202) 586-9606
Chris Henkel	EEl-U Waste	(202) 778-6693
Kenneth R. Hooks	NRC/HLWM	FTS 492-0447
Donald G. Horton	DOE/YMP	FTS 544-7504
Rose Konouck	SAIC	(703) 827-4887
John Linehan	NRC/HLWM	FTS 492-3387
Corinne Macaluso	DOE/HQ	586-2837
		FTS 896-2837
Paul P. Narducci	CER	(703) 276-9300
Phillip Niedzielski-Eichner	Nye County, NV	(703) 818-2434
Gene Roseboom	USGS-Dir. Off.	(703) 648-4423
Ralph Stein	DOE/RW-30	FTS 896-6046
Dwight Shelor	DOE	586-7220
John S. Trapp	NRC/HLWM	FTS 492-0509
Larry D. Vaughan	DOE	(301) 353-3137
Tilak R. Verma	NRC/HLWM	FTS 492-3465
Nancy Voltura	DOE/YMP QA	(702) 794-7972
Dermot Winters	Def. Nuc. Fac. Safety Board	(202) 376-5074
Joe Youngblood	NRC/HLWM	FTS 492-3410
Susan Zimmerman	State of Nevada	(702) 687-3744

PROBLEM

- Implementation of QA requirements during site characterization is viewed as being counterproductive to the repository program
 - "My view is that there may well have been an overemphasis." Response to the following "in your view has NRC overemphasized QA aspects?" [DR. DEERE'S INTERVIEW WITH RADIOACTIVE EXCHANGE - DECEMBER 1989]
 - "...DOE appears to have developed a quality assurance program that has become a management obstacle rather than a management tool." [Dr. Sear's statement before NWTRB - December 1989].
 - QA consumed 25 - 40% of the LLNL resources last year. [NWTRB meeting at LLNL - January 1990].
 - QA requirements are using UP significant amounts of technical and management personnel time. As an example, review and approval of one study plan requires about 25 signatures. [NWTRB meeting in Denver - February 1990].
 - "The Boards warned that though everyone was in favor of quality work that disoriented, disorganized, or mismatched quality assurance could be the program's nemesis." [Dr. Parker's paper presented at Waste Management '90, Tucson, Arizona - February 1990].

NRC/DOE QA WORKSHOP PLANNING MEETING

MAY 22, 1990

PERCEIVED PROBLEM

Kenneth R. Hooks
NRC

GENERAL STATEMENT OF THE PROBLEM

PERCEPTION THAT APPLICATION OF QA REQUIREMENTS DURING SITE

CHARACTERIZATION IS COUNTERPRODUCTIVE TO THE REPOSITORY PROGRAM.

WHY WORRY ABOUT THIS PROBLEM

AN EFFECTIVE QA PROGRAM IS AN ESSENTIAL PART OF A GEOLOGIC REPOSITORY PROGRAM.

PERCEPTION OF QA PROBLEMS, WHETHER CORRECT OR INCORRECT, WILL MAKE SUCCESSFUL IMPLEMENTATION OF AN EFFECTIVE QA PROGRAM MORE DIFFICULT.

THERE MAY BE QA PROBLEMS WHICH ARE ADVERSELY AFFECTING THE REPOSITORY PROGRAM.

IF QA IS THE BASIS OF THESE PROBLEMS, THE ROOT CAUSE MUST BE IDENTIFIED AND RESOLVED.

IF NOT, CONFIRMATION OF THE LACK OF QA PROBLEMS WILL AID FOCUSING ON REAL PROBLEMS.

NRC PERCEPTIONS 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 QA REQUIREMENTS ARE SUFFICIENTLY GENERAL TO PERMIT ADEQUATE FLEXIBILITY IN SCIENTIFIC INVESTIGATIONS.

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.

NRC LOGIC TO RESOLVE THE PERCEIVED PROBLEM

THERE MAY BE PROBLEMS WITH QA AS APPLIED TO THE REPOSITORY PROGRAM.

IT IS NOT POSSIBLE TO RESOLVE GENERALITIES; THE ROOT CAUSE MUST BE IDENTIFIED TO RESOLVE SPECIFIC PROBLEMS.

PROBLEMS INITIALLY IDENTIFIED AS RESULTING FROM QA REQUIREMENTS MAY BE DUE TO QA, OR MAY BE DUE TO SOMETHING ELSE. THE ROOT CAUSE OF THE PROBLEMS CANNOT BE DETERMINED WITHOUT SPECIFIC DETAILS.

QA (AND TECHNICAL) PROBLEMS ARE BEST IDENTIFIED AT THE WORKING LEVEL.

THE WORKING LEVEL IN THE REPOSITORY PROGRAM IS THE DOE PARTICIPANTS.

THEREFORE, NRC RECOMMENDS THAT DOE DETERMINE WHAT SPECIFIC QA PROBLEMS HAVE BEEN IDENTIFIED BY THEIR PROGRAM PARTICIPANTS.

ONE WAY TO START THIS PROCESS IS A "WORKSHOP" INVOLVING THE PROGRAM PARTICIPANTS.

QUESTIONS TO CONSIDER AT THIS MEETING

HAVE ANY PROBLEMS WITH GEOLOGIC REPOSITORY PROGRAM IMPLEMENTATION BEEN TRACED TO OVERLY RESTRICTIVE (UNREALISTIC) QA REQUIREMENTS?

IF SO, ARE THE REQUIREMENTS IMPOSED BY NRC REGULATIONS, OR BY DOCUMENTS WHICH IMPLEMENT THESE REGULATIONS?

AFTER ALLOWING FOR THE EFFORT REQUIRED TO START UP A QA PROGRAM, HAVE THE RESOURCES REQUIRED FOR QA PROGRAM IMPLEMENTATION BEEN EXCESSIVE?

NRC/DOE QA WORKSHOP PLANNING MEETING

MAY 22, 1990

FLEXIBILITY IN NRC REQUIREMENTS

Kenneth R. Hooks,
NRC

ESSENCE 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.

LEVELS OF SPECIFICITY IN QA REQUIREMENTS

10 CFR PART 60, SUBPART G

10 CFR PART 50, APPENDIX B

NRC REVIEW PLAN

NRC REQUIREMENTS

NUREGS

NQA-1

DOE REQUIREMENTS

OCRWM QAR

OCRWM QAPD

PARTICIPANT QAPP

YMPO QUALITY MANAGEMENT PROCEDURES

PARTICIPANT QA PROCEDURE(S)

PARTICIPANT TECHNICAL PROCEDURE(S)

SCIENTIFIC INVESTIGATION (ACTUAL WORK)

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

CONTINUED

CONTINUED

18 CRITERIA OF 10 CFR PART 50, APPENDIX B

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

TRANSLATION OF 10 CFR PART 50, APPENDIX B REQUIREMENTS
AS APPLIED TO SCIENTIFIC (FIELD) INVESTIGATIONS

CRITERION III, DESIGN CONTROL (FIELD CHANGES)

"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 (FIELD CHANGES)

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

CONTINUED..

CONTINUED

OCRWM QAR REV.2, DESIGN CONTROL

"THE PROVISIONS OF NQA-1 BASIC REQUIREMENT 3 AND SUPPLEMENT 35-1 SHALL APPLY TO DESIGN, FROM CONCEPTUAL DESIGN THROUGH FINAL DESIGN."

"OCRWM QAPD REV.1, DESIGN CONTROL

"3.1.2 SCIENTIFIC INVESTIGATIONS

THE ADEQUACY OF THE GEOLOGIC REPOSITORY DESIGN IS HEAVILY DEPENDENT UPON THE RESULTS OF THE SCIENTIFIC INVESTIGATIONS CONDUCTED FOR THE CHARACTERIZATION OF THE GEOLOGIC REPOSITORY SITE. THEREFORE, THE PERFORMANCE OF THESE SCIENTIFIC INVESTIGATIONS WILL BE CONTROLLED.

SCIENTIFIC INVESTIGATIONS WILL BE CONDUCTED BY OCRWM - OR PROJECT OFFICE - MANAGED PROGRAM PARTICIPANTS. PROVISIONS OF THE QAR FOR CONTROLLING SCIENTIFIC INVESTIGATIONS WILL BE IMPOSED UPON THE PROGRAM PARTICIPANTS."

CONTINUED..

CONTINUED

NNWSI/88-9, REV.2, SCIENTIFIC INVESTIGATION CONTROL AND DESIGN
CONTROL

"1.6.1 DOCUMENTATION

THERE ARE TWO METHODS WHICH CAN BE USED FOR THE QUALITY ASSURANCE, DOCUMENTATION AND CONTROL OF SCIENTIFIC WORK. THESE ARE THE SCIENTIFIC NOTEBOOK SYSTEM AND THE TECHNICAL IMPLEMENTING PROCEDURE SYSTEM.

THE SCIENTIFIC NOTEBOOK SYSTEM WILL GENERALLY BE USED BY QUALIFIED INDIVIDUALS WHO ARE USING A HIGH DEGREE OF PROFESSIONAL JUDGEMENT, TRIAL AND ERROR METHODS, OR DEVELOPING

THE METHODOLOGY BY WHICH AN ACTIVITY WILL BE ACCOMPLISHED. WHEN THE SCIENTIFIC NOTEBOOK SYSTEM IS USED, THE STUDY PLAN OR SCIENTIFIC INVESTIGATION PLANNING DOCUMENT SHALL BE THE CONTROLLING DOCUMENT USED TO PERFORM THE ACTIVITY SINCE IT DESCRIBES THE PROPOSED APPROACH OR GENERAL PROCEDURE FOR ACCOMPLISHING THE WORK.

LANL YMP QAPP, R4.3 SCIENTIFIC INVESTIGATION AND DESIGN CONTROL

3.1.1 PREPARATION OF SCIENTIFIC INVESTIGATION PLANNING DOCUMENTS

SCIENTIFIC INVESTIGATIONS AFFECTING QUALITY SHALL BE PLANNED AND DOCUMENTED TO ENSURE A SYSTEMATIC APPROACH. BEFORE THE START OF ANY SCIENTIFIC INVESTIGATION, THE RESPONSIBLE PI SHALL DEVELOP A SCIENTIFIC INVESTIGATION PLANNING DOCUMENT FOR THAT INVESTIGATION THAT OUTLINES THE WORK TO BE PERFORMED AND DELINEATES THE INSTRUCTIONS FOR COMPLYING WITH THE REQUIREMENTS OF THE DEFINED SCOPE OF WORK. SCIENTIFIC INVESTIGATIONS CATEGORIZED AS SITE CHARACTERIZATION ACTIVITIES, AS DEFINED IN THE NUCLEAR WASTE POLICY ACT (AS AMENDED), SHALL USE STUDY PLANS AS THE SCIENTIFIC INVESTIGATION PLANNING DOCUMENT. THE REQUIREMENTS FOR THE FORMAT AND CONTENT OF STUDY PLANS ARE INCLUDED IN APPENDIX K OF THIS QAPP. QA LEVEL ASSIGNMENTS WILL BE MADE IN ACCORDANCE WITH APS.

3.1.6 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF DETAILED PROCEDURES

THERE ARE TWO KINDS OF DOCUMENTATION THAT CAN BE USED FOR THE QA DOCUMENTATION AND CONTROL OF SCIENTIFIC WORK: THE SCIENTIFIC NOTEBOOK AND THE DETAILED TECHNICAL PROCEDURE (DP). SCIENTIFIC NOTEBOOKS GENERALLY ARE USED BY QUALIFIED INDIVIDUALS WHO ARE LARGELY GUIDED BY PROFESSIONAL JUDGEMENT AND WHO USE TRIAL AND ERROR METHODS IN THEIR WORK. A DP GENERALLY IS USED WHEN A QUALIFIED INDIVIDUAL PERFORMS REPETITIVE WORK THAT IS NOT GUIDED BY PROFESSIONAL JUDGEMENT AND DOES NOT INVOLVE TRIAL AND ERROR METHODS. DPS SHALL BE REQUIRED WHEN DEVIATION FROM A PRESCRIBED SEQUENCE OF ACTIONS ENDANGERS THE VALIDITY OF THE RESULTS. BOUND NOTEBOOKS, LOGBOOKS, OR APPROPRIATE FORMS SHALL BE USED TO DOCUMENT THE PERFORMANCE OF DPS AND THE CONTROL OVER ALL OTHER ASPECTS OF THE WORK. DOCUMENTATION OF SCIENTIFIC WORK, I.E., EXPERIMENTS AND RESEARCH, SHALL BE PERFORMED TO PROVIDE A WRITTEN RECORD OF THE EXPERIMENT OR RESEARCH.

WHAT DOES THIS EXAMPLE SHOW

THERE IS A GENERAL REQUIREMENT IN 10 CFR PART 50, APPENDIX B, CRITERION III, FOR CONTROL OF DESIGN ACTIVITIES.

OCRWM QAPD SAYS SCIENTIFIC INVESTIGATIONS ARE DESIGN ACTIVITIES AND WILL BE CONTROLLED.

NNWSI/88-9 SAYS SCIENTIFIC NOTEBOOKS CAN BE USED FOR NON-REPETITIVE WORK REQUIRING A HIGH DEGREE OF PROFESSIONAL JUDGEMENT OR TRIAL AND ERROR METHODS. IN SUCH CASES, THE CONTROL IS PROVIDED BY THE STUDY PLAN OR SCIENTIFIC INVESTIGATION PLANNING DOCUMENT. USE OF DETAILED TECHNICAL PROCEDURES IS NOT REQUIRED.

WHO CAN SOLVE THE PROBLEM OF RESTRICTIVE QA REQUIREMENTS?

REQUIREMENTS DOCUMENTS WHICH ARE IMPOSED UPON PARTICIPANTS ARE USUALLY GENERAL IN NATURE.

SPECIFIC DETAILS MAY BE SPELLED OUT IN OWRWM, YMPO OR PARTICIPANT PROCEDURES.

IN GENERAL, AUTHORITY TO DEVELOP, REVISE, APPROVE AND IMPLEMENT PARTICIPANT PROCEDURES IS ASSIGNED TO THE USING ORGANIZATION.

IN MOST CASES, WORKING LEVEL PROCEDURES ARE DEVELOPED BY THE PEOPLE WHO WILL BE USING THE PROCEDURES IN THEIR WORK.

THUS, IN MOST CASES, THE SOLUTION TO A PROBLEM OF IMPRACTICAL, OVERLY RESTRICTIVE PROCEDURES IS IN THE HANDS OF THE USER, PROVIDED THAT HIGHER LEVEL REQUIREMENTS ARE NOT TOO RESTRICTIVE.

NRC/DOE QA WORKSHOP PLANNING MEETING

MAY 22, 1990

QUALITY ASSURANCE PROGRAM IMPLEMENTATION

SPECIFIC ISSUES

James T. Conway,
NRC

° GRADED QUALITY ASSURANCE.

NRC REQUIREMENT/GUIDANCE:

THE QA PROGRAM SHALL PROVIDE CONTROL OVER ACTIVITIES AFFECTING THE QUALITY OF THE IDENTIFIED STRUCTURES, SYSTEMS AND COMPONENTS TO AN EXTENT CONSISTENT WITH THEIR IMPORTANCE TO SAFETY.

GRADED APPLICATION OF QA MEASURES ARE DESCRIBED IN SECTION 2.4 ~~4.5~~ (NUREG-1318 "TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS).

NQA-1 REQUIREMENT:

SAME AS THE CRITERIA II APPENDIX B REQUIREMENT.

- DOCUMENTATION OF THE CREDENTIALS OF EVERYBODY ON THE PROGRAM.

NRC REQUIREMENT/GUIDANCE:

THE PROGRAM SHALL PROVIDE FOR INDOCTRINATION AND TRAINING OF
PERSONNEL PERFORMING ACTIVITIES AFFECTING QUALITY AS
NECESSARY TO ASSURE THAT SUITABLE PROFICIENCY IS ACHIEVED
AND MAINTAINED.

NQA-1 REQUIREMENT:

SAME AS CRITERION II APPENDIX B REQUIREMENT.

- CONTENTS OF SCIENTIFIC NOTEBOOKS AND SCIENTIFIC INVESTIGATION PLANNING (SIP) DOCUMENTS.

NRC REQUIREMENTS:

APPLICABLE REGULATORY REQUIREMENTS AND DESIGN BASIS ARE TRANSLATED INTO SPECIFICATIONS, DRAWINGS, PROCEDURES AND INSTRUCTIONS.

ACTIVITIES AFFECTING QUALITY SHALL BE PRESCRIBED BY DOCUMENTED INSTRUCTIONS, PROCEDURES, OR DRAWINGS OF A TYPE APPROPRIATE TO THE CIRCUMSTANCES.

NQA-1 REQUIREMENT:

SAME AS CRITERION V APPENDIX B REQUIREMENT.

- CHANGES TO DOCUMENTS IN THE FIELD AND/OR LABORATORY.

NRC REQUIREMENT/GUIDANCE:

- CHANGES TO DOCUMENTS SHALL BE REVIEWED AND APPROVED BY THE SAME ORGANIZATIONS THAT PERFORMED THE ORIGINAL REVIEW AND APPROVAL UNLESS THE APPLICANT DESIGNATES ANOTHER RESPONSIBLE ORGANIZATION.
- CHANGES TO FIELD AND LABORATORY PROCEDURES ARE SUBSEQUENTLY DOCUMENTED AND VERIFIED IN A TIMELY MANNER BY AUTHORIZED PERSONNEL.

NQA-1 REQUIREMENT:

- SAME AS CRITERION VI APPENDIX B REQUIREMENT.

- REVIEW AND APPROVAL OF SIPs AND STUDY PLANS.

NRC REQUIREMENT/GUIDANCE:

DOCUMENTS ARE REVIEWED FOR ADEQUACY.

PLANS FOR DATA COLLECTION AND ANALYSES SHOULD BE COMPLETED
BEFORE PERFORMING THE ACTIVITIES.

NQA-1 REQUIREMENT:

SAME AS CRITERION VI APPENDIX REQUIREMENT.

- AUDITS OF VENDORS SUPPLYING ITEMS AND SERVICES.

NRC REQUIREMENT:

MEASURES USED TO ASSURE THAT PURCHASED MATERIAL, EQUIPMENT,
AND SERVICES CONFORM TO THE PROCUREMENT DOCUMENTS INCLUDE,
AS APPROPRIATE, SOURCE EVALUATION AND SELECTION, OBJECTIVE
EVIDENCE OF QUALITY FURNISHED BY THE VENDOR SOURCE INSPECTION
AND EXAMINATION OF PRODUCTS UPON DELIVERY.

NQA-1 REQUIRMENT:

SAME AS CRITERION VII APPENDIX B REQUIREMENT.

° IDENTIFICATION AND CONTROL OF SAMPLES.

NRC GUIDANCE:

CONTROLS ARE ESTABLISHED TO IDENTIFY AND CONTROL SAMPLES AS APPLICABLE TO ASSURE THAT THE IDENTITY IS MAINTAINED AND TRACEABLE TO TECHNICAL AND QUALITY-RELATED DOCUMENTS.

NQA-1 REQUIREMENT:

SECTION 8 ADDRESSES THE "IDENTIFICATION AND CONTROL OF ITEMS."

- ° TRACEABILITY OF M&TE TO NATIONAL INSTITUTE OF STANDARDS & TECHNOLOGY.

NRC REQUIREMENT/GUIDANCE:

M&TE USED FOR ACTIVITIES AFFECTING QUALITY SHALL BE CONTROLLED, CALIBRATED, AND ADJUSTED AT SPECIFIED PERIODS TO MAINTAIN ACCURACY WITHIN NECESSARY LIMITS.

CALIBRATION STANDARDS ARE TRACEABLE TO NATIONALLY RECOGNIZED STANDARDS. WHERE NATIONAL STANDARDS DO NOT EXIST, THE ACCEPTABILITY OF THE CALIBRATION STANDARD USED SHOULD BE DOCUMENTED.

NQA-1 REQUIREMENT:

SAME AS CRITERION XII APPENDIX B AND SUBSECTION 12.6 NRC REVIEW PLAN REQUIREMENTS.

◦ QA RECORDS PROGRAMS.

NRC REQUIREMENT:

SUFFICIENT RECORDS SHALL BE MAINTAINED TO FURNISH EVIDENCE OF ACTIVITIES AFFECTING QUALITY. THE RECORDS SHOULD BE IDENTIFIABLE AND RETRIEVABLE. REQUIREMENTS FOR RECORD RETENTION SUCH AS DURATION, LOCATION, AND ASSIGNED RESPONSIBILITY SHOULD BE ESTABLISHED.

NQA-1 REQUIREMENT:

SAME AS CRITERION XVII APPENDIX B REQUIREMENT PLUS THE FOLLOWING. RECORDS SHALL BE PROTECTED AGAINST DAMAGE, DETERIORATION, OR LOSS. REQUIREMENTS AND RESPONSIBILITIES FOR RECORD TRANSMITTAL AND DISTRIBUTION SHALL BE ESTABLISHED AND DOCUMENTED.

- SOFTWARE QA PROGRAM.

NRC GUIDANCE:

DEVELOPMENT, CONTROL, AND/OR USE OF COMPUTER PROGRAMS WILL BE CONDUCTED IN ACCORDANCE WITH THE QA PROGRAM. GUIDANCE FOR THE CONTENT OF DOCUMENTATION OF COMPUTER CODES IS PROVIDED BY NUREG-0856, "FINAL TECHNICAL POSITION ON DOCUMENTATION OF COMPUTER CODES FOR HIGH-LEVEL WASTE MANAGEMENT."

NQA-1 REQUIREMENT:

"QA REQUIREMENTS OF COMPUTER SOFTWARE FOR NUCLEAR FACILITY APPLICATIONS" ARE DESCRIBED IN PART 2.7.

CONCLUSION

- NRC QA REQUIREMENTS
- GENERIC ISSUES

PRESENTATION AT NRC/DOE

QA WORKSHOPS

EXAMPLES IN EARTH SCIENCE

JOHN S. TRAPP, NRC
DIVISION OF HIGH-LEVEL WASTE MANAGEMENT
MAY 22, 1990

BACKGROUND

EXPERIENCE WITH SUBTIER CONTRACTORS:

APPROXIMATE EQUIVALENT TO NATIONAL LABORATORIES

UTILITY/AE APPROVED FIRM QA PLAN AND WOULD AUDIT

IN AREAS OF RESPONSIBILITY CONTROLLED PLANS,
PROCEDURES, REVIEWS, DOCUMENTATION, ETC.

NORMAL APPROVAL REQUIRED SIGNATURES OF PRINCIPLE
INVESTIGATOR, REVIEWER, QUALITY CONTROL AND
PROJECT MANAGER

CONTROL DOCUMENTS

FIRM QA PLAN

FIRM STANDARD PROCEDURES

PRODUCT IMPLEMENTATION DOCUMENT

INCORPORATE BY REFERENCE APPLICABLE

STANDARD PROCEDURES, ASTM'S,

NON-STANDARD PROCEDURES

PERSONAL ORGANIZATION

FILE PLAN

DEVIATIONS

ACCEPTANCE CRITERIA

OTHER PRODUCT SPECIFIC CRITERIA

CONTROL/DELEGATION

CRITERIA WITH AUTHORITY LIMITS FOR INDIVIDUAL INVESTIGATOR
(GENERALLY PROCEDURAL CRITERIA)

CRITERIA WITH AUTHORITY LIMITS FOR PRINCIPLE INVESTIGATOR
(GENERALLY TECHNICAL CRITERIA)

CRITERIA WITH AUTHORITY LIMITS FOR PROJECT MANAGER
(GENERALLY PROJECT CRITERIA)

CARROLL COUNTY ESR

SLOPE

CORE 20 - 40 FEET INTO ST. PETER

HYDROLOGIC TESTING

GEOPHYSICAL TESTING

INSTALL PIEZOMETER

FILTER SAND

PROBLEM

HIT "RE-PETE"

COULD NOT CORE WITHOUT ADDITIVES
WHICH COULD EFFECT HYDROLOGY

NCR

SOLUTION

CORE TO ST. PETER

DRILL TO DEPTH

LOG AND TEST AS DEEP AS POSSIBLE

INSTALL PIEZOMETER

LOG AND TEST

BYRON STATION

CRITERIA:

- PROCEDURES FOR MAXIMIZING CORE RECOVERY AND RQD

PROBLEMS:

- KARST FEATURES
- 20 FOOT BIT DROPS
- LOST CIRCULATION
- TOTALLY DISINTEGRATED CORE WITH MUD

SOLUTIONS:

- HOLE-BY-HOLE DECISIONS WITH AUTHORITY DELEGATED TO PI ON RIG
- COMPLETE DOCUMENTATION
- ULTIMATE SOLUTION = GROUTING OF FOUNDATION

E

IRAN

CRITERIA:

- MEET US NRC STANDARDS

DATA:

- FRENCH GEOLOGIC MAP, ABOUT 1940
- OUT-OF-FOCUS, MISMATCHED AIRPHOTOS, FLOWN DURING DUST STORMS
- SOME REGIONAL DATA, 99% IN ERROR

SOLUTION:

- STAGED APPROACH

BECKER DRILLING

PROBLEM:

- DETERMINE SUBSURFACE PROPERTIES IN AREA MINED BY WORLDS LARGEST SHOVEL
- ALL PREVIOUS ATTEMPTS USING CONVENTIONAL DRILLING HAD FAILED

SOLUTION:

- USE UNTESTED DRILLING PROCEDURES
- TO EXTENT POSSIBLE, DETERMINE WHAT COULD HAPPEN
- DEVELOP HOLD POINTS WHEN WHAT IFS HAPPENED
- DOCUMENT EVERYTHING

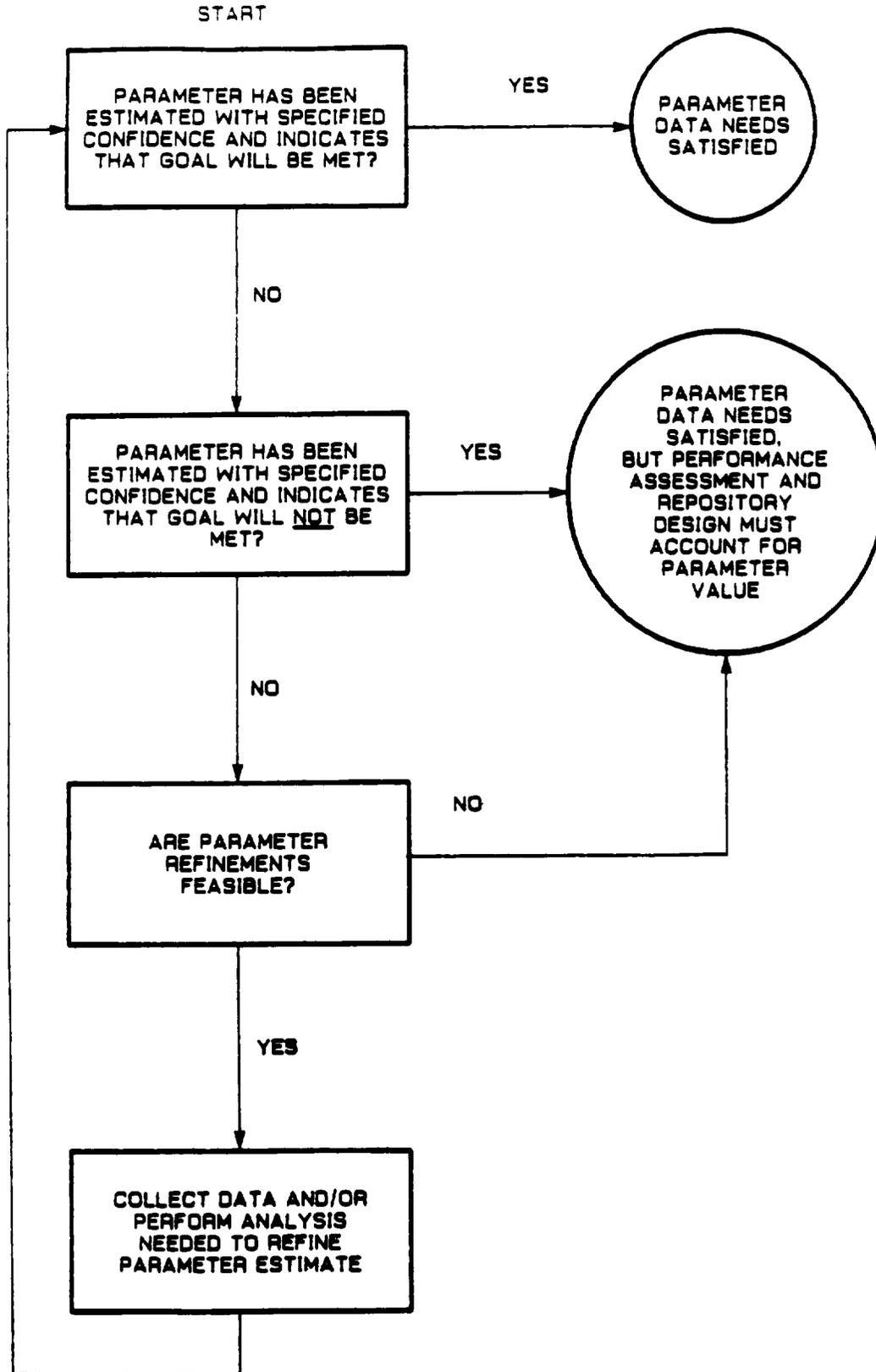


Figure 8.3.1.8-2. Parameter analysis

THE NUMBER OF SAMPLES ANALYZED FOR THE GEOCHEMISTRY STUDIES OF ERUPTIVE SEQUENCES CANNOT BE SPECIFIED WITH CERTAINTY. IT IS DEPENDENT PRIMARILY ON THE NUMBER OF RECOGNIZED ERUPTIVE UNITS AT VOLCANIC CENTERS, AND SECONDARILY ON THE RESULTS OF GEOCHEMICAL MODELING. OUR CURRENT GOAL IS TO COLLECT REPLICATE SAMPLES FOR EACH UNIT SO THAT THE NUMBER OF SAMPLES PER UNIT EQUALS OR EXCEEDS THE NUMBER OF MAPPED GEOLOGIC UNITS (DETERMINED DATA MATRIX).

MAKING QA WORK IN EARTH SCIENCE

- ° STANDARDIZE - DON'T REINVENT THE WHEEL
- ° DELEGATE CONTROL/AUTHORITY
- ° HAVE EXPERIENCED PERSONNEL WRITE PROCEDURES
- ° MAXIMIZE FLEXIBILITY - MINIMIZE UNNEEDED SPECIFICITY
- ° PLAN FOR THINGS TO GO WRONG (MURPHY'S LAW)
- ° DON'T OVER PLAN
- ° DOCUMENT, DOCUMENT, DOCUMENT