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TO: Ken Hooks, HLPD, Division of High-Level Waste Management, M/S 4 H 3

FROM: Paul T. Prestholt, Sr. On-Site Licensing Representative

DATE: December 7, 1990

SUBJECT: REPORT - DOE QUALITY ASSURANCE WORKSHOPS
Denver and Las Vegas, 8/7, 10/10-12, 10/25/90

Please find enclosed the above-referenced document.

PTP:nan
cc: John J. Linehan, Director, HLPD, M/S 4 H 3

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WM-11
NH03

REPORT

DOE QUALITY ASSURANCE WORKSHOPS

DENVER AND LAS VEGAS

AUGUST 7, OCTOBER 10-12 AND 25, 1990

"BRING SCIENTIFIC RESEARCH AND THE QUALITY ASSURANCE PROGRAM TOGETHER AND PROVIDE WORKABLE RECOMMENDATIONS FOR MANAGEMENT ACTION."

(WORKSHOP CHARTER)

PARTICIPANTS

- SENIOR SCIENTIST
- QA MANAGERS
- TPOs

- LANL
- LLNL
- SNL
- USGS
- DOE

OBSERVERS

- NRC
- EEI
- NYE COUNTY (PARTIAL)

TABLE OF CONTENTS

1. INTRODUCTION

DOE Management and Quality Assurance have been listening to the scientific community and have embarked upon a series of workshops designed to bring forth the scientist concerns and provide acceptable solutions.

This report describes the participants, the process and the results of the workshops to date.

2. ISSUE IDENTIFICATION - DENVER - AUGUST 7

An initial workshop was held in Lakewood, Colorado (Denver) on August 7, 1990. This workshop was an open forum wherein the respective personnel from each participant discussed perceived concerns associated with the implementation of a Quality Assurance Program (10 CFR 50 Appendix B & NQA-1) in the scientific community.

There were four main areas of concern that resulted from that workshop:

A. **Lack of flexibility in the application of the QA Program during scientific research, acceptability of peer review, application of dual research, required restrictive predictions without consideration for unknowns, further definition of requirements, and procedures commensurate with acceptable (good) scientific practices.**

B. Computer Software QA program (too complex, does not allow freedom to develop conceptual/prototype design/analysis) is based upon obsolete model concepts, not updated to present state-of-the-art, excessive documentation during development, lack of flexibility/lengthy change process, and needs in-depth review.

C. Data - its definition, what form, when it is complete and most importantly, time limitation for transfer to the appropriate participants data archive within 45 days of completion of data acquisition or development.

> Note: This is not considered a QA problem per se, rather a management (project) problem.

D. Communications - it was apparent that interparticipant/project communications are limited and need improvement.

3. ISSUE PROCESSING - LAS VEGAS - OCTOBER 10-12

A significant start has been made on Issue A above. The introduction by Don Horton charged:

> **"Bring scientific research and the quality assurance program together and provide workable recommendations for management action"**

A two and one half day workshop was held October 10-12 in Las Vegas, Nevada. The subject was the concern: "Application of the Quality Assurance Program to scientific research." **Participants included a Geologist and a QA Consultant from DOE; seven scientists, five QA Managers, and four TPOs from LANL, LLNL, SNL, and USGS; one Quality Consultant from EEI; and two Facilitators from MACTEC. There were two observers from the USNRC.** A list of the attendees is included as Appendix A.

3.1 PROCESS

The agenda for the workshop was:

* Introduction
* Workshop Process
* Current State (statement of the problem)
* Desired State (goal)
* Problem Solving (specific issues addressed)
* Transition Plans (strategy for remaining issues)
* Integration
* Action recommendations

Participants stated their Expectations for the workshop. They are listed in Appendix B.

The basic process included working in two or three groups and then coming back together to process the results.

Workshop guidelines were developed and participants took an inventory to determine their Individual Work Styles. These were shared and were used throughout the workshop to improve communication.

3.2 PROBLEM STATEMENT

Participants developed the following Problem Statement.

> **The problem is:**

* **Current YMP QA program is not well suited for use by R&D programs.**
* **Current QA program does not adequately utilize decades of non-formal QA/QC scientific practices.**
* **Overly conservative interpretation of baseline requirements leads to overly rigorous, inappropriate and ineffective implementation.**

3.3 DESIRED STATE

The participants defined the Desired State of the YMP QA program in this goal statement.

The goal is to develop and implement a QA program that:

- **Documents the R&D products for use in legal and regulatory arenas**
- **Would be consistently written and interpreted, and stable**
- **Is NRC acceptable**
- **Is compatible with scientific method**
- **Facilitates R&D activities within a regulated environment**
- **Keeps initiative at working level**
- **Does not manage line activities**
- **Managers do not use for purposes other than assuring QA implementation**

3.4 ISSUES REVIEW

The participants reviewed the Denver issues list and modified it to include 33 QA program issues. These were prioritized. This list is given in Appendix C.

3.5 ISSUE STUDY

The participants identified two issues to be studied (and solved) during the workshop. Groups were formed to study those two and to study what to do with the rest.

GROUP 1: The QA program set out to define how a scientist should work, not to institute appropriate controls within the scientific process.

GROUP 2: Intermixing of QA implementation and other policy implementation in procedures, which then subjects the entire procedure content to QA audit (spreading auditability cancer)

The Problem Solving Process used for addressing these two issues was:

1. Identify problem
2. Collect Data
3. Identify cause
4. Generate solutions
5. Evaluate solutions/decide
6. Create action plan

3.6 WORKSHOP RESULTS

The initial results of this phase consisted of working notes issued to participants only for use in preparation for the next phase. They are not repeated here. They are represented in the recommendations from the next phase.

The results of work on the remaining unresolved issues included identification of where the issue could be solved. Many of these are beyond the direct control of Don Horton and the QA organization. Plans for obtaining solutions were proposed. The conclusions of this group included:

Given:

- **High level of interest of workshop participants**
- **We sense high level of interest by DOE management in solving problems**
- **The workshop participants understand the problems and process**
- **The workshop participants have a good cohesive and supportive relationship**

Recommendation:

* **Maintain work group in order to:**
  - **Maintain team momentum generated in the workshop**
  - **Pursue the progress toward effective solutions**

Action recommendations are included below.

3.7 WORKSHOP CLOSE

Don Horton thanked the participants for their hard work and successful efforts. He requested that workshop recommendations be presented to him in October.

The workshop participants felt that they needed more time to present a more complete action recommendation. They agreed to meet again to complete plans and to proceed beyond the original goals to also plan a presentation to Don Horton.

4. RECOMMENDATIONS - LAS VEGAS - OCTOBER 25

A one day workshop was held with most of the same people participating and with only one additional part-time observer (see Appendix A).

4.1 PROCESS

The agenda for this session was:

* INTRODUCTION
* ACTION PLANS
* PREPARE PRESENTATION
* NEXT STEP...
    - Larry - Presentation
    - Group Presentation to Don
    - Report of Today's Activities/Results

Participants stated their (revised) expectations which are given in Appendix B.

4.2 RECOMMENDATION REVIEW/PROCESSING

Participants were issued the following instructions for their first break-out period:

1. REVIEW ALL 3 ACTION PLANS:
   Discuss: What is similar, different?
   Decide: How to integrate 3 plans.
2. REVIEW OWN ACTION PLAN:
   Discuss: Is it related to root causes?
   Does it solve problem?
   Is it what you want?
   Restate all recommendations - short & clear
   Decide sequence: 0-6, 6-12, 12+ months
   Discuss priority of recommendations
3. RETURN READY TO:
   - Write all short, clear recommendations on chart
   - Integrate 3 Action Plans
   - Sequence, prioritize recommendations

After the results of this were discussed in the large group, they were instructed to:

1. Create simple flow chart for each recommendation.
2. Create Action Plan for each recommendation.

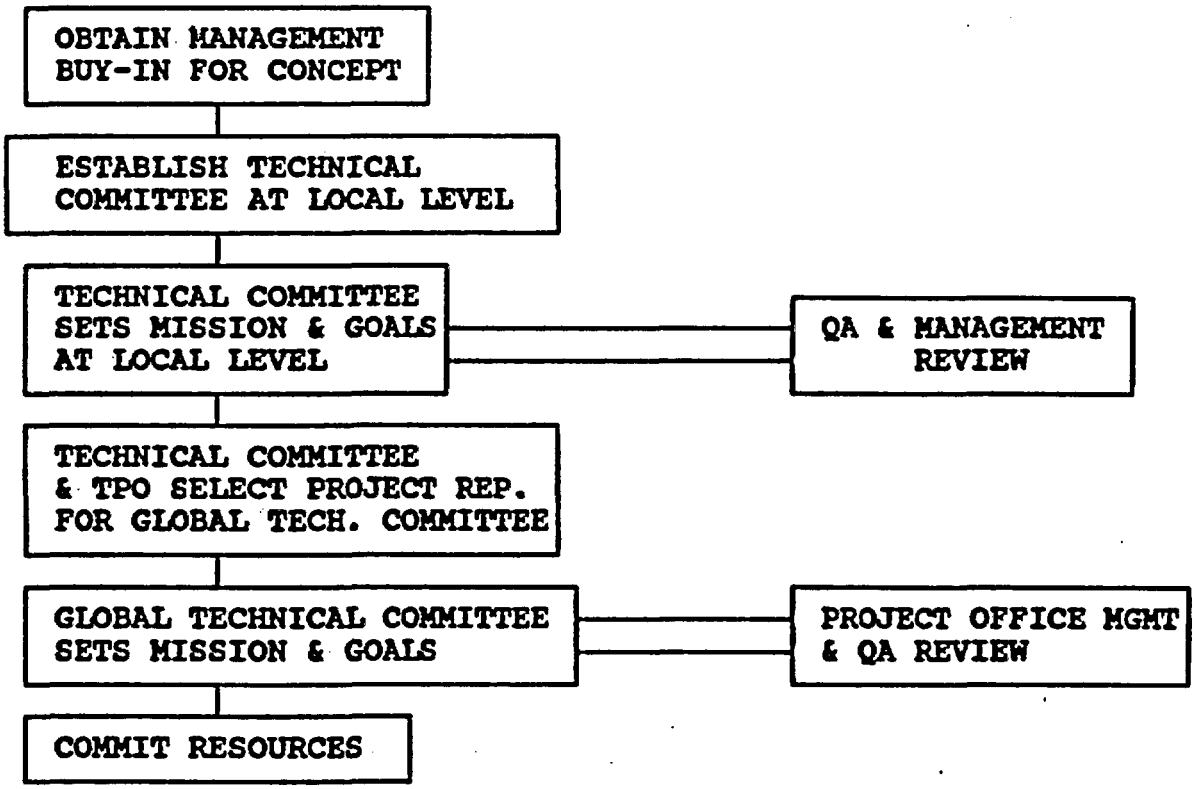
4.3 GROUP 1 RESULTS

RECOMMENDATIONS - GROUP 1

		MONTHS		
		0 - 6	6 - 12	12 +
1.	Establish committee of technical personnel to participate in QA decision making with QA personnel and management.	X		
2.	Establish forum for technical QA/Management exchange	X		
3.	Schedule licensing workshops		X	
4.	Formulate QA program that makes maximum use of scientific process			X

Group 1 Recommendation Flow Charts

Recommendation 1. ESTABLISH A COMMITTEE OF TECHNICAL PERSONNEL TO PARTICIPATE IN QA DECISIONS WITH QA PERSONNEL AND MANAGEMENT



Group 1 Responsibilities

Recommendation 1. TECHNICAL PERSONNEL INVOLVED IN QA DECISIONS WITH QA & MANAGEMENT

TASK	(Facilitator-Stuckless)	PERSON RESPONS.	TARGET DATE
1.	Obtain approval to establish Technical Committees	Gertz/TPO	
2.	Establish Technical Committee at local level	TPO	
3.	Define Mission & Goals	Tech. Comm. Chairman	
4.	QA & Management review	TPO & QAM	
5.	Select Project Rep. to global YMP Committee	TPO & TC Chair	
6.	Establish global YMP mission & goals	YMP Tech Comm. Chair	
7.	Review & approval YMP mission & goals	Gertz/ Horton	6 mos.
8.	Commit resources & priorities	Gertz/ Horton	

Group 1 Recommendation 2. - Establish forum for technical QA/Management exchange - Responsibilities

TASK		PERSON RESPONS.	TARGET DATE
1.	Develop charter	Hayes	02/91
2.	Formal charter review and acceptance	Hayes	04/91
3.	Member selection	Schelling*	06/91
4.	Organize/chair	members	07/91
5.	Initial report	members	08/91

Group 1 Recommendation 3. - Schedule licensing workshops

DOE/NRC/PARTICIPANTS INTERACTIONS

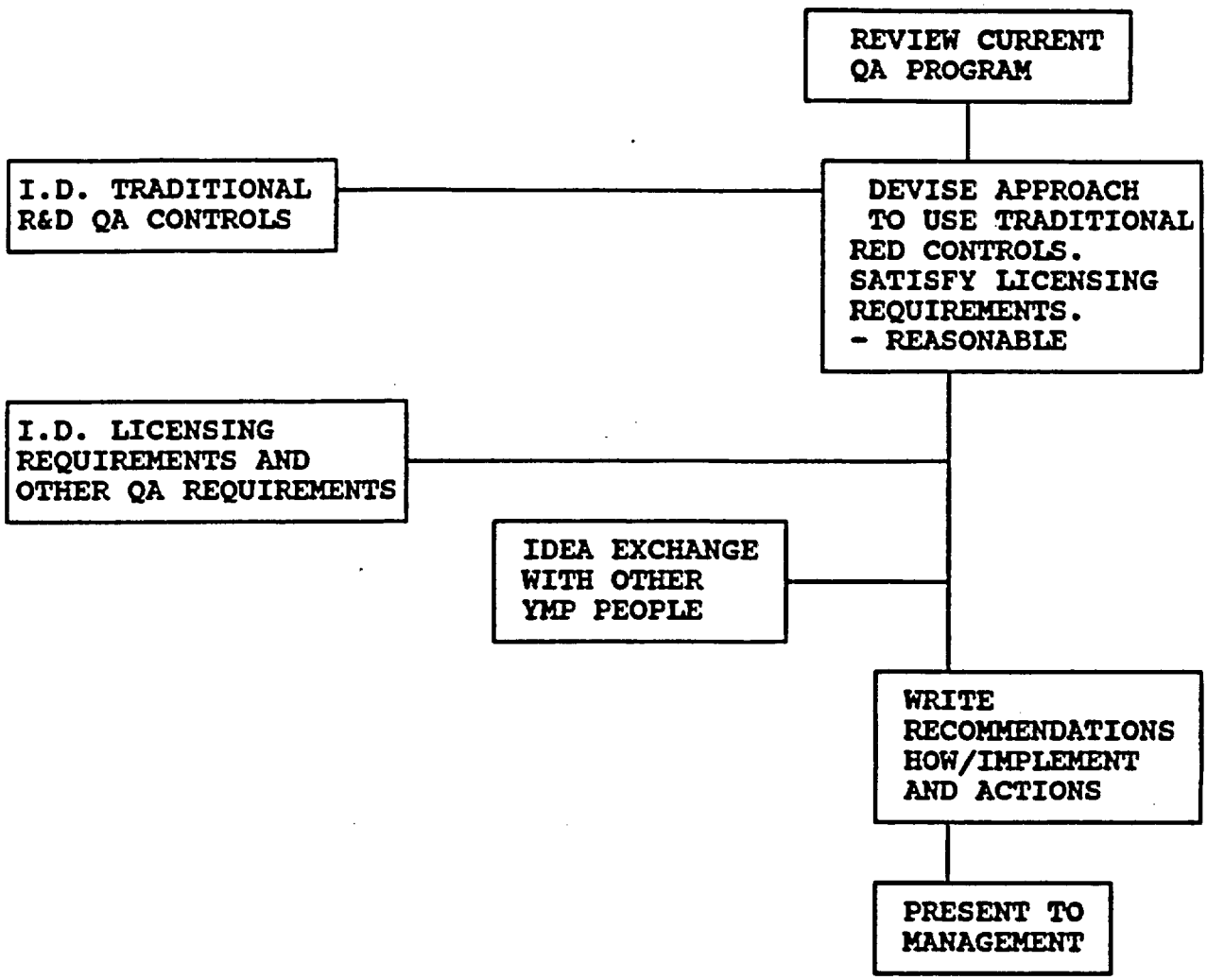
TASK		PERSON RESPONS.	TARGET DATE
1.	Initiate request from YMP to NRC for open interactions	Horton	12/90
2.	Obtain DOE/NRC agreement	Horton/ NRC	12/90

OR

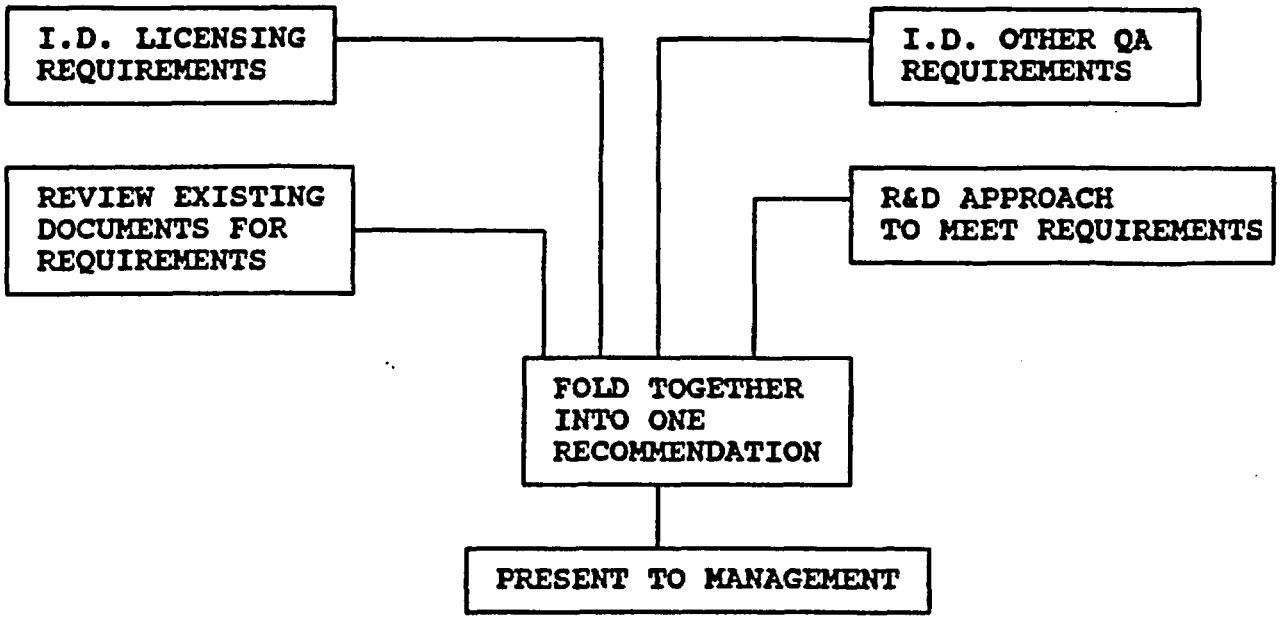
TASK		PERSON RESPONS.	TARGET DATE
1.	Define objective(s)	Chaney *	12/90
2.	Draft request to DOE	Chaney	01/91
3.	Initiate DOE request to NRC	Gertz/ Shelor	02/91
4.	Obtain NRC concurrence	Gertz/ Shelor	03/91
5.	Organize and conduct workshop (Define licensing requirements and process)	NRC/DOE	06/91
6.	Establish hearing roadshow	NRC/DOE	08/91

* Coordinate

Group 1 - Recommendation 4 - Formulate QA program that makes maximum use of scientific process



ALTERNATE Recommendation 4



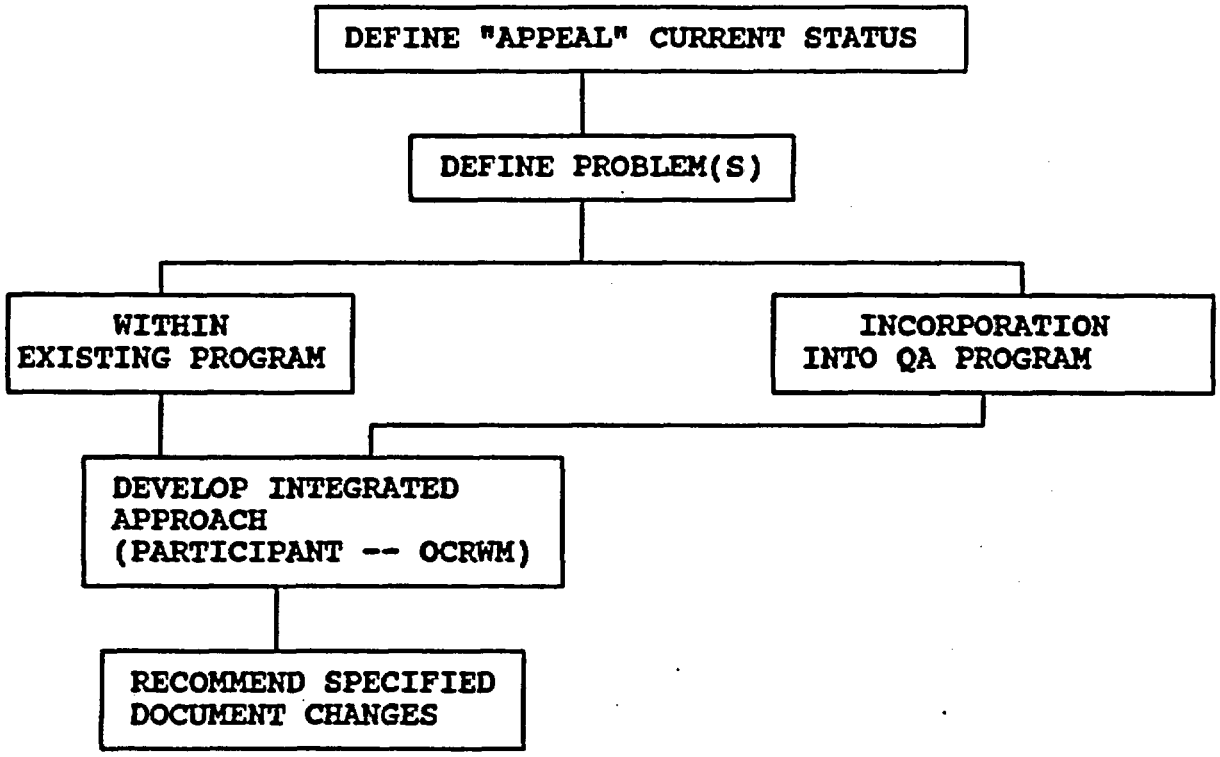
4.4 GROUP 2 RESULTS

RECOMMENDATIONS - GROUP 2

		MONTHS		
		0 - 6	6 - 12	12 +
1.	Document Review			X
2.	Document hierarchy			X
3.	APQ/AP Review			X
4.	Appeals Process	X		
5.	QA Records Definition *	X		
6.	Sufficient time to test procedures *	X		
7.	Develop NRC/DOE interaction	X		
8.	Workshops		X	

* For ongoing work and at end

Group 2 - Recommendation 4 - APPEALS PROCESS - Flow Chart



4.5 GROUP 3 RESULTS

RECOMMENDATIONS - GROUP 3

	MONTHS		
	0 - 6	6 - 12	12 +
Focus on practical solutions for short-term accomplishments.	X		
For each of the selected issues:			
• participant and DOE evaluate own program	X		
• discuss findings with other groups	X		
• develop Action Plan	X		
• revise your program	X		
• meet and evaluate accomplishments	X		
Selected Issues			
1. Training-effectiveness, need (Hayes)	X		
2. Procedures - flexibility, simplify, need, train (Price)	X		
3. Technical publications - revision requirements, streamline, train (Price)	X		
4. Document hierarchy - traceability, clarify, simplify, train	X		

5. INTEGRATED RECOMMENDATIONS

5.1 RECOMMENDATION - Short Term

The work shop participants felt strongly that some short term successes for selected issues are very important. Their initial recommendation was:

1. Focus on practical solutions for short term accomplishments

   Areas selected were:

   a. Technical Publications: revise requirements, streamline and train
   b. Effectiveness of training
   c. Simplification and flexibility of procedures
   d. Clarify, simplify and add traceability to the document hierarchy

5.2 OTHER RECOMMENDATIONS

2. Establish a technical advisory group on QA to participate with QA personnel and management in QA decision making.

3. Establish a forum for technical/QA/management exchange

4. Develop DOE/NRC interactions, including licensing workshops.

5. Ensure that the QA program makes maximum use of the scientific method.

6. Establish an appeals process

6. RECOMMENDED FULL PRESENTATION TO HORTON

The following was selected as the plan for a presentation to Don Horton, with the idea that it might be presented to others after a critique by Don.

6.1 OUTLINE

1. INTRODUCTION:
   - Agenda
   - What you want from him
   - Problem statement, Goal

2. 3 GROUP PRESENTATIONS:
   - The Problem : the need, the cost
   - The process used
   - The recommendations

3. INTEGRATED ACTION PLAN:
   - Description of each recommendation

4. CRITIQUE:
   - Questions
   - Suggestions for further presentations
   - Decisions on recommendations (yes, modify, defer)

5. AGREE ON NEXT STEP(S)

6.2 PRESENTATION ROLES

It was agreed by the participants that the presentation should be made by a team of participants to demonstrate the team spirit that has been created.

6.3 KEY POINTS FOR PRESENTATION

The participants listed their key points that they felt were important for Don Horton (and others) to hear.

- Need for scientific involvement
- Agreement on problem, goal
- Many problems are global problems

What we want Don to do for us

- Review problems and recommendations
- We are committed to following through on these recommendations (long term commitment), but we need Don's support
- Scientists, all of us, must see progress, and then we'll become very involved
- Don needs to ensure communication back to group
- Initiate same process for software

6.4 RECOMMENDED CLOSE - BY DON HORTON

The following statement is a message from Don Horton.

* In conclusion, I would like to tell you how optimistic I am. We now have an enthusiastic core group of scientists, QA people and TPOs willing to work together to resolve our differences.

* They have given us six workable solutions and their overwhelming support for continuing the problem solving process.

* I am very pleased with their results; not only their solutions, but more important, their cohesive team spirit.

* I believe we have a momentum now that will bring us continuing good news in the future.

APPENDIX A: WORKSHOP PARTICIPANTS

PARTICIPANT LIST

DOE

1. Susan Jones, Geologist
2. Joe Caldwell, QA Consultant (MACTEC) Workshop Leader/Organizer

LANL

3. Ned Patera, Tech. Coordinator
4. Steve Bolivar, QA Manager
5. Henry Nunes, QA Liaison
6. Dick Herbst, TPO

LLNL

7. Dale Wilder, Tech. Area Leader
8. Richard Van Konynenburg, Principal Investigator
9. David Short, QA Manager
10. Leslie Jardine, TPO

SNL

11. Ron Price, Sr. Mbr. Tech. Staff
12. Bob Richards, QA Manager
13. Tom Blejwas, TPO
14. Joe Schelling, Sr. Mbr. Tech Staff

USGS

15. John Stuckless, Geologist
16. Bill Steinkampf, Hydrologist
17. Dave Appel, Manager, QA Office
18. Tom Chaney, Assoc. Ch., QA Office
19. Larry Hayes, TPO

EEI

20. Tom Calandrea, Quality Consultant

Chris Hinkle - Short time

FACILITATORS

21. Herb Worsham
22. Cathie Martin

OBSERVERS

USNRC

23. John Gilray, Sr. Site Rep.
24. Paul Prestholt, Sr. Site Rep.

Nye County

25. Phillip A. Niedzielski-Eichner, Technical Advisor - Short time, 10/25 only,

DOE MANAGEMENT VISITS

26. Don Horton
27. Carl Gertz

APPENDIX B: EXPECTATIONS OF PARTICIPANTS

The workshop participants were asked to brainstorm their expectations for each session of the Workshop. These are reported here, both to aid their memory and to assist a non-participant reader in better understanding the issues and the need for resolution of the issues.

TUESDAY, OCTOBER 10, 1990

NOTE THAT THESE WERE DEVELOPED DIRECTLY AFTER THE INTRODUCTION AND BEFORE ANY WORK SESSIONS BY THE GROUP.

- Discover issues (without bounds)
- Discuss problems
- Find meaningful solutions
- Unravel complex mess
- Come out with QA program that works
- Take recommendations back
- Take information back about QA
- Develop outline for workable QA program, find way to limit restrictions
- Ways to communicate reinterpretation of requirements
- System for determining proper role of professionals
- Develop greater respect for team members
- Delegation of authority to implement (after approval)
- Understand why it is hard to publish
- Understand why raw data is needed
- Way to make system more useful to science
- Identification of root causes to use as a model
- Define adequate confidence
- We accept reality
- Improve communication so we're pulling together
- Remove emphasis of adding constraints
- Feedback/communication between procedure writers and users
- Create list of "management constraints" (remove from QA)
- Develop specific quality standard for R&D (not derived from previous standards) to include 10 CFR-50, appendix
- Hear concerns of scientists
- accomplish objectives of workshop letter
- Learn from experience in nuclear QA utilities
- Help create replacements for current program
- Better understanding of problems between groups
- Exorcise obsession

THURSDAY, OCTOBER 25, 1990

- Complete Workshop with good recommendations
- Wrap up action plans
- Get technical people involved in QA decisions
- Action plans get carried out
- Help put QA in it's proper role
- Observe work being done
- See closer interface: QA/Scientist
- Action plan for QA program we can believe in
- Give Don Horton something he can take to meeting
- Set in motion - have this ongoing group
- Come up with a plan (chance of getting implemented) for getting concrete work done
- Opens up better lines of communication between groups
- Action plan that is feasible, realistic
- Simple QA plan founded on scientific principles

APPENDIX C: MODIFIED AND PRIORITIZED DENVER ISSUE LIST

LIST OF ISSUES AS MODIFIED BY THE LAS VEGAS PARTICIPANTS

The QA program set out to define how a scientist should work, not to institute appropriate controls within the scientific process.

Intermixing of QA implementation and other policy implementation in procedures, which then subjects the entire procedure content to QA audit (spreading auditability cancer)

The SMF system requires redundant documentation for samples.

Micro management prevents line management from exercising the authority to select and apply QA controls to its own activities.

Excessive time for review and approval of scientific investigation planning documents, reports, articles, etc.

QA controls imposed appear to be inappropriate for the early stage (maturity) of scientific/technical program activities.

Disconnect between AP authors and procedure users. (Authors' unfamiliarity with subject results in unworkable procedures.)

Reactor QA mentality is misapplied to scientific investigation

Participants need to be able to raise concerns about questionable requirements without being accused of being "argumentative" and uncooperative.

No viable appeals process for audit differences

"Ex-post facto" application of changes in QA rules.

The rate of change in project-level requirements and document hierarchy must be slowed. The role and applicability of APQs must be decided unequivocally.

Excessive level of detail

Excessive rigidity

Lack of input/review for QA documents hierarchy

Auditors set policy, are antagonists, have no clear cut interpretations, subjective.

Imposition of Project Office requirements and procedures on Participant subcontractors is often impractical.

Clarification of the YMPO intention for review/acceptance/-approval of documents, if any, is needed.

There are apparently irrational or unreasonable requests for extensive justification about decisions made during early screening and scoping efforts.

There should be several people or groups of people pursuing the same research.

QA grading system is misapplied and excessively conservative.

Over planning

Licensing requirements unclear

There are too many organizational levels of review and approval.

Records requirements are designed to capture such a broad range of documents and are so detailed in the requirements that 100 percent implementation is not humanly feasible.

Requirements do not allow flexibility to customize process for different types of records and record sources.

The size of audit/surveillance teams detracts from usefulness of the activities

Lack of traceability of requirements to documents hierarchy

Fear causes excessive requirements.

QA training is excessive and ineffective.

Too many external surveillances.

Audit process is ineffective (compliance based vs. performance based).

APPENDIX D: PARTICIPANT CRITIQUE OF WORKSHOP

The participants were asked to provide feedback regarding any feature of the workshops. The following data was generated by strict brainstorming rules. As such an individual comment is therefore possibly not representative and may be in opposition to some other comment. The collection is useful and will be studied by any future workshop planners.

1. Would have felt better with DOE management observers (quiet).
2. Next step - needs more DOE involvement than just QA. (or at least soon).
3. Would like to have evening sessions - more work for time.
4. Move sessions around geographically.
5. Good team building.
6. Continue using this process to maintain focus.
7. Outstanding that TPOs came.
8. Nice interaction between TPOs/Scientists/QA
9. Keep number of observers balanced (and low).
10. Offsite location important.
11. Facility good for the purpose.
12. Facilitators should stay in role.
13. Good process.
14. Facilitators kept in focus.
15. More time should have been spent on solutions (better balance with problems).
16. Glad did style survey.
17. Liked knowing where going.
18. Liked fact that Don Horton introduced.
19. Liked fact that Carl Gertz visited.
20. Size about right, more would be unwieldy, less would be poorer representation.
21. Liked brainstorming.