



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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John J.

Reply to:
1050 E. Flamingo Rd., #319
Las Vegas, NV 89119
Tel: (702) 388-6125
FTS: 598-6125

TO: John J. Linehan, Director, HLPD, Division of High-Level Waste Management
FROM: John W. Gilray and Paul T. Prestholt, Sr. On-Site Licensing Representatives
DATE: October 16, 1990
SUBJECT: SECOND YMP QA WORKSHOP

- * DOE held a QA workshop at Las Vegas from October 10, 1990, through October 12, 1990. Participating in the workshop were the TPOs, scientists and QA personnel from the National Labs and USGS which support the YMP. The two NRC On-Site Representatives (P. Prestholt and J. Gilray) attended this workshop as observers.
- * The goals for this workshop were:
 1. To identify specific issues associated with any real life problems experienced by the scientific community in implementing the QA Program; Reach a consensus on the issues.
 2. To propose resolutions to those issues that can be solved at the workshop.
 3. To develop recommendations for actions by upper management and others to resolve any remaining issues.
- * The workshop was successful in that major issues were identified and recommended solutions were proposed. Time did not allow for the participants to formulate and consolidate these issues and recommendations into a workshop report and recommended action plan. The workshop will reconvene in the near future to complete these activities. Workshop attendees believe this workshop was very productive and worthwhile.
- * In general the major recommendations will probably be keyed to: (1)

Simplifying the complex hierarchy of requirement documents that are imposed on the participants particularly in the scientific research field;

- (2) Involving the scientist in the preparation and concurrence of implementing procedures; a &
- (3) Providing an educational seminar to the participants regarding the NRC licensing process and the rationale for the need for the Appendix B requirements for scientific and research activities.

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DOE QUALITY ASSURANCE WORKSHOP

OCTOBER 10-12 AND 25, 1990

"Bring scientific research and the quality assurance program together and provide workable recommendations for management action." (Don Horton)

MEMBERS

SENIOR SCIENTISTS

QA MANAGERS

TPOs

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

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

CONSENSUS PROBLEM STATEMENTS

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

Thirty-three issues were identified related to the above Problem Statements. The two highest priority issues were worked, leading to recommendations for resolution.

PROBLEM I

Inadequate understanding and "meeting of the minds" between the QA people, the managers, and the technical staff, with concurrence by the NRC regarding:

- building on existing scientific pract.**
- what will satisfy licensing require.**
- relevance of req. to work to be done**
- balance between prof. judgement & prescriptive procedures**
- benefits of controls on process and its inputs in assuring results**

Root Causes

- maximal approach to ensure compliance**
- lack of understanding of what is needed for success in licensing**
- poor communication**

RECOMMENDATIONS (PROBLEM I)

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/mgt. exchange | X | | |
| 3. Schedule licensing workshop | | X | |
| 4. Formulate QA program that makes maximum use of scientific process | | | X |

PROBLEM II

Intermixing of QA requirements and management policy in procedures that obstruct processes. Subsequent impact on productivity and verification/audit scope.

Root Causes

- multiple, ambiguous sources**
- overly conservative approach**
- no participant input**
- inexperienced personnel**

RECOMMENDATIONS (PROBLEM II)

	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 proced.	X		
7. Develop NRC/DOE <i>INTERACTIONS</i>	X		
8. Workshops		X	

SHORT TERM ACTIONS TO RESOLVE SELECTED REMAINING ISSUES

0-6 6-12 12+

Focus on practical solutions for short term accomplishments

X

For each of the selected issues:

X

- o Partic. & DOE evaluate own program**
- o Discuss findings with other groups**
- o Develop action plan**
- o Revise your program**
- o Meet and evaluate accomplishments**

SHORT-TERMS ACTIONS (cont.)

0-6

6-12

12+

Selected issues

- | | | | |
|---|---|--|--|
| 1. Training-
effectiveness,
need (<u>Hayes</u>) | X | | |
| 2. Procedures-
flexibility,
simplify, need, train
(<u>Price</u>) | X | | |
| 3. Technical
publications-
rev. reqmts, streamline,
train (<u>Jones</u>) | X | | |
| 4. Document
hierarchy -
traceability, clarify,
simplify, train (<u>Sastry</u>) | X | | |

Recommendations:

- 1. Process for solving short term issues:**
 - a. Technical publications**
 - b. Explain document hierarchy**
 - c. Procedures: (records definition, time to test)**
 - d. Training effectiveness**

- 2. Technical Advisory Group on QA (Senior Scientists)**

- 3. Forum for mgt/tech./QA exchange**

- 4. DOE/NRC/Participant interaction, e.g.**
 - o Informal technical interactions**
 - o Licensing workshops**

- 5. Ensure that the QA Program makes maximum use of the Scientific Method (Maximize quality of Science not control of QA)**

- 6. Appeals process**

KEY ISSUES FOR DON TO CONSIDER

- o Need for scientific involvement**
- o Agreement on problem, goal**
- o Many problems are system issues**
- o WHAT WE WANT DON TO DO FOR US**
- o Review problems and recommendations**
- o We are committed to following through on these recommendations (long term commitment), but need Don's commitment and support**
- o Scientists (& all of us) are desperate to see progress, and then we'll become very involved**
- o Communications back to group**
- o Initiate same process for software**