



Department of Energy
 Yucca Mountain Project Office
 P. O. Box 88608
 Las Vegas, NV 89193-8808
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 QA.

Leslie J. Jardine, LLNL, Livermore, CA
 Larry R. Hayes, USGS, Las Vegas, NV
 Richard J. Herbut, LLNL, Los Alamos, NM
 Thomas O. Hunter, SNL, 6310, Albuquerque, NM

QUALITY ASSURANCE (QA) WORKSHOP

Please distribute a copy of the enclosure to those individuals selected to participate in the QA Workshop which begins on October 10, 1990.

Since lodging accommodations in Las Vegas, Nevada, may be complicated by other events, it is suggested you make your reservations as soon as possible.

Donald G. Horton
 Donald G. Horton, Director
 Quality Assurance
 Yucca Mountain Project Office

QA:NMV-143

Enclosure:
 Agenda and Logistic Information

cc:
 D. E. Shelor, HQ (RW-30) FORS
 Corinna Macaluso, HQ (RW-30) FORS
 Sharon Skuchko, HQ (RW-10) FORS
 D. W. Short, LLNL, Livermore, CA
 H. P. Nimes, LLNL, Los Alamos, NM
 R. R. Richards, SNL, 6319, Albuquerque, NM
 D. H. Appel, USGS, Denver, CO
 E. V. Tiesenhansen, Clark County, NV
 Steve Bradhurst, Nye County, NV

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ENCLOSURE A**AGENDA AND LOGISTICS INFORMATION**

For Participants in the

**U.S. DEPARTMENT OF ENERGY (DOE) QUALITY ASSURANCE WORKSHOP -
SECOND PHASE - October 10-12, 1990.**

DOE held a QA workshop on August 7, 1990, in Lakewood, CO which resulted in the following list of issues:

1. Lack of flexibility in the application of the QA Program
2. Computer software QA program problems
3. Data handling and definition
4. Interparticipant/project communications

You have been designated to participate in a 2 & 1/2 day workshop to address the first issue. Items 2 - 4 will be addressed in some other manner and another time. This workshop includes participation by a representative group of senior scientists from each of the national laboratories participating in the Yucca Mountain Project, the USGS, and the DOE. QA managers will participate in the workshop. TPOs have been invited to participate.

The Nuclear Regulatory Commission (NRC) will attend the workshop and be available to provide clarifications and offer both recommendations and assistance to DOE.

The workshop will be held in Las Vegas in Ballroom C at the Howard Johnson Plaza Suites Hotel, 4255 E. Paradise Road, Las Vegas, NV, beginning on Wednesday, October 10, 1990 at 8:00AM and ending at 12:00PM on Friday, October 12, 1990. The agenda will be devoted to specific issue identification and resolution. A preliminary copy of the agenda is attached. The goals for this workshop will be:

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

Don Horton has asked that participants be able to speak for their organization in regard to specific issues.

Facilitators for the workshop are Joe Caldwell and Herb Worsham. You can contact them at FTS 544-7240 (702-794-7240)

The hotel currently has rooms at the Government rate of \$69.00 including tax. The telephone number is 702-369-4400.

We have high hopes that we will reach a solution satisfactory to all Program participants. It is essential that the eventual results of the program stand up to both the decision making process to determine the applicability of Yucca Mountain for a waste site; and, if yes, to the licensing process and any possible challenges in the future.

AGENDA

1 INTRODUCTION

The workshop participants will introduce themselves. The background for the workshop will be presented. The agenda will be discussed. Management will discuss the overall goals for the project and for this workshop.

2 WORKSHOP PROCESSE

The facilitators and the participants will work out details of:

The long term goals for the program as it relates to the participants

The workshop goals

Acceptance criteria for Workshop results.

The do's and don'ts for the workshop.

Throughout the workshop the participants will work both in a single group and in smaller focus groups. Liberal use will be made of "flip charts" to capture and display the results.

3 THE CURRENT STATE OF THE SCIENTIFIC QA PROGRAM

The Denver results will be used as the starting point to determine the "Current State" of the scientific QA program. The participants will be expected to arrive at a consensus that meets the acceptance criteria set earlier.

4 THE DESIRED STATE OF THE SCIENTIFIC QA PROGRAM

The participants will agree on the necessary and desired state of those issues which need improvement.

5 "INSTANT SOLUTIONS"

The workshop participants will identify those issues that may be settled at this workshop by those people present. These issues will then be worked on until solved or until it is agreed that they will not be solved - and a transition plan and recommended actions have been agreed on by consensus.

6 TRANSITION PLANS

The workshop participants will work on those issues which cannot be solved "instantly". The result should be a plan of action to solve the issue. This plan should only call for actions that are to be controlled by the workshop participants or their management. If outside resources or actions are required, the plan should identify how the workshop participants are going to "make it happen".

7 INTEGRATED TEST

The total of the proposed solutions and transition plans will have an examination period to see if they meet the acceptance criteria as an integrated whole. A careful examination will be made of any anticipated issues that will result from the proposed solutions.

8 ACTION RECOMMENDATIONS

The workshop participants will formulate and agree on the recommendations that will result from the workshop. Responsibilities will be assigned. Followup and control will be specified. Unresolved items will be stated and actions toward their resolution should be agreed on.

Action recommendations should include any need for future workshops, meetings, or any other followup.

9 WORKSHOP REPORT

The workshop staff will capture the results of the sessions and distribute them promptly.

RESULTS OF THE DENVER WORKSHOP
AUGUST 7, 1990

The DOE QA workshop that was held on August 7, 1990, in Lakewood, CO (Denver) resulted in the following list of issues:

1. Lack of flexibility in the application of the QA Program
2. Computer software QA program problems
3. Data handling and definition
4. Interparticipant/project communications

Item one is to be covered in a workshop in Las Vegas, from October 10 through October 12, 1990. Specific points relative to item one are listed below. It is apparent that there is duplication and that some of these issues stem from the same root causes. This is simply a list of those issues. In the workshop the first step will be to agree on the real set of issues. That set may not look like this list. However, to meet the goals of this workshop it must be inclusive of all of the issues of this list - or rationalize the exclusion.

"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."

LIST OF ISSUES

1. Excessive level of detail.
2. Excessive rigidity
3. Excessive time for review and approval of scientific investigation planning documents, reports, articles, etc.
4. There are too many organizational levels of review and approval.
5. Clarification of the YNPO intention for review/acceptance/-approval of documents, if any, is needed.
6. QA controls imposed appear to be inappropriate for the early stage (maturity) of scientific/technical program activities.

7. There are apparently irrational or unreasonable requests for extensive justification about decisions made during early screening and scoping efforts.
8. There should be several people or groups of people pursuing the same research.
9. The QA program set out to define how a scientist should work, not to institute appropriate controls within the scientific process.
10. 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.
11. Requirements do not allow flexibility to customize process for different types of records and record sources.
12. The EMF system requires redundant documentation for samples.
13. APs focus on standardizing "sample documentation" rather than receiving samples or notification of sample collection.
14. Imposition of Project Office requirements and procedures on Participant subcontractors is often impractical.
15. The rate of change in project-level requirements and document hierarchy must be slowed. The role and applicability of APQs must be decided unequivocally.
16. Disconnect between AP authors and procedure users. (Authors' unfamiliarity with subject results in unworkable procedures.)
17. Project plans and procedures are too broadly drafted, have too much detail, and in many cases contain conflicting requirements.
18. QA grading system is misapplied and excessively conservative.
19. The authority for selection and application of quality controls should be given to the manager of the activities so that there is no "micro management" by people external to the manager's organization.
20. Current auditing practice is compliance based. This emphasis in auditing often fails to identify the root causes of problems.
21. Auditors should be trained and directed to shift to performance based auditing to ensure program improvement.

22. Different interpretations of requirements by different auditors makes compliance demonstration nearly impossible.
23. Auditor training including workshops around specific issues should be intensified to assure the consistent interpretation of requirements by auditors.
24. There is not a viable appeal process. There is no current process to arbitrate legitimate differences between auditors and participants in the interpretation of requirements.
25. A streamline, fast track, to binding interpretation is suggested.
26. QA auditors often appear as antagonists during audits and surveillances.
27. There is a wide variance in interpretation of requirements and operating modes of QA personnel.
28. Professional standards for auditor-auditee interaction should be emphasized.
29. The role of the auditor should be clarified so that everyone understands that he exists to support management.
30. The size of audit/surveillance teams detracts from usefulness of the activities
31. The focus of surveillance detracts from usefulness of the activities

DOE F 1325.7 (10-89)

(Exception to SF 14, Approved by NARS, June 1978)

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Mr. Ken Hooks NRC

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For your information are details relative to next week's DOE QA Workshop. This includes meeting location, telephone number, and agenda.

BE BRIEF - ELIMINATE UNNECESSARY WORDS

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