

MINUTES OF THE APRIL 30, 1992, QUALITY ASSURANCE MEETING

A meeting of the staff of the U.S. Nuclear Regulatory Commission and representatives of the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), to discuss items of mutual interest with regard to quality assurance (QA), was held at the NRC Headquarters, Rockville, MD on April 30, 1992. An attendance list is included as Attachment 1. The State of Nevada was represented at this meeting. Nye County, NV was the only affected unit of local government in attendance.

At this meeting, DOE presented information on the following topics: (1) update of the Management and Operating (M&O) Contractor's QA program and transition plans; (2) status of qualifying past core samples; (3) status of efforts to qualify data produced prior to QA programs being accepted; (4) update of the Quality Concerns Program; (5) status of the new OCRWM Quality Assurance Requirements Document (QARD); and (6) update on recent drilling activities. DOE and other participants also discussed the status of the mini-audit process and the role of technical specialists in audits. The NRC staff presented observation summaries of Yucca Mountain Site Characterization Project Office audit (YMP-92-07), Oak Ridge National Laboratory audit (HQ 92-02), and Sandia National Laboratories audit (YMP-92-09). The NRC also gave a presentation on the status of QA Open Items.

The meeting began with introductory remarks followed by introduction of the attendees. Following the introductions, DOE presented an update on the M&O's QA program and transition plan. There are two aspects to the M&O's start-up: transition of work to the M&O from other participants and new work. The M&O is required to develop a transition plan for all work taken from other participants. A QA review of the transition plan is required. Technical Direction Letters authorizing the start of work under transition plans will not be signed until all hold points and open items in the transition plan are satisfied. Prior to the start of new work, the M&O was required to hold readiness reviews. New work cannot begin until M&O hold points are closed and results are in from the readiness review. Further, new work cannot begin until a Technical Direction Letter is signed by the Director of the Office of QA for OCRWM, with review and concurrence by the Yucca Mountain Project Office QA Division (YMQAD). DOE provided a list of the work which has undergone transition to the M&O as of mid-April (see the second page of Attachment 2).

The NRC noted that the NRC has asked for, but has not yet received, copies of any M&O transition plans. The NRC asked that DOE provide copies of all transition plans to the NRC. The State also asked for copies. The NRC asked that transition plans be placed in the public document room (PDR). The NRC also asked for copies of the technical direction letters that initiate new or transitioned work by the M&O. The DOE agreed to provide transition plans and technical direction letters if there were no proprietary restrictions. The NRC then requested that if transition plans are not available for public release, that they be made available at audits of the M&O.

Next, DOE presented information on efforts to qualify past core samples. DOE stated that it currently has no plans to qualify past core samples, but instead the samples will be used only as corroborating data.

The third presentation by DOE was about the status of its efforts to define, evaluate, or qualify data that were not produced under an accepted QA program. At present, DOE has no plans to qualify any data produced before QA programs were accepted. An internal DOE letter of September 12, 1991, so states. Data being generated now will be collected in accordance with a qualified program. NRC asked DOE whether the basis for determining when data is qualified is the date of DOE program approval or the date of NRC program acceptance. DOE agreed to state the basis for determining when data is qualified. The State asked whether Administrative Procedure AP 5.9Q precludes the possibility of bad data being accepted because it was collected under an approved QA program. DOE responded that bad data would be recorded as deficient and would have to go through a QA corrective action program. Later in the meeting, USGS stated that the M&O is preparing a package on qualifying past data on soil samples by peer review. This topic will be discussed at the May 27, 1992, technical exchange on erosion.

Next on the agenda was DOE's presentation on the Quality Concerns Program (see Attachment 3). In response to an NRC question, DOE said that neither employee quality concerns or their resolution would be put into the PDR. The NRC asked DOE to provide a breakdown of the origin of the concerns raised to date, if it does not violate the confidentiality of the contributors. In response to a question from Edison Electric Institute, DOE stated that no concerns have been raised that would cause them to take major action, and that a number of concerns had been identified earlier and were being corrected. Nye County asked about the process for closure of concerns. DOE explained the process of investigation and closure of concerns and indicated that there had been some appeals, but generally closure was satisfactory.

DOE, NRC and the State then discussed the mini-audit (limited-scope audit) process. The NRC stated that preparation for mini-audits was more difficult for the technical staff when technical checklists and technical procedures are not available before the entrance meeting. The State added that early receipt of programmatic checklists would also be helpful. DOE stated that the purpose of the audits is not to satisfy the NRC or the State but to determine the effectiveness of the QA programs. However, DOE will try to assist the NRC and the State at the same time. DOE stated that it is not satisfied with either the mini-audit process or the annual programmatic audits with respect to the information being provided to DOE managers. DOE is considering treating the participants as vendors and doing a programmatic (compliance) audit triennially with annual evaluations and technical performance (vertical slice) audits whenever work dictates. A decision has not yet been made. The NRC stated its likely preference for at least an annual evaluation of any program doing significant amounts of work. The State asked that "annual evaluation" be defined. DOE stated that it may be any approach available, such as a desk

audit. The NRC asked that it be kept informed at an early date in the audit process. DOE stated that if a new audit approach is selected, it will be reflected in OCRWM's new QARD. A change may be made in the next fiscal year. After discussion, DOE stated that when a change in audit style is near, DOE will call a meeting to discuss the proposed new system. The NRC noted that the proposed audit changes may or may not be acceptable to NRC management.

Next, NRC and DOE discussed the role of the technical specialist. The NRC stated that the role of technical specialists in audit plans and the actual work being done by technical specialists is inconsistent. The NRC also stated that what is being done is productive, but it is not consistent with what has been agreed upon. Attachment 4, a quality management procedure, QMP-18-01, shows what was agreed on regarding the role of the technical specialist. DOE stated that the role of technical specialists will be reconsidered and possibly revised when the audit style changes.

Next on the agenda was NRC's presentation of its observations for the QA audits of the Yucca Mountain Project Office (YMP-92-07), Sandia National Laboratories (YMP-92-09), and Oak Ridge National Laboratories (HQ-92-02). Discussions of these audits are included as Attachment 5.

The NRC then gave a presentation on the status of QA Open Items (see Attachment 6). The NRC stated that it has not yet received a list identifying all DOE approved changes since NRC staff accepted the Lawrence Livermore National Laboratories' QA Program Plan (Item 10.e in Attachment 6). The NRC also identified some QA programs that seem to have lessened the QA commitments in their QA Program Plans/Descriptions. Attachment 7 shows the discrepancies in the programs as identified by the NRC. The NRC stated that it had received the M&O QA Program Description in the week before this meeting. The NRC requested that DOE send to NRC the M&O matrices showing conformance to the OCRWM QARD and to the NRC review plan. DOE agreed to send the matrices to the NRC and the State. The State asked about the status of OCRWM's new QARD. DOE is currently going over comments on the QARD. Release is expected by July. OCRWM will issue a transition plan for implementation of the new QARD. It is expected that there are a few items in the QARD which will require NRC acceptance because they might be considered a degradation of requirements. DOE will send the QARD to NRC and the State for review. NRC and the State asked to be included in a DOE briefing about new requirements in the QARD. DOE will plan a briefing for some time in mid-May.

The last agenda item was DOE's presentation on recent drilling activities. The last page of Attachment 2 is a map showing recent drill holes and their depth in feet. The NRC requested copies of audit and surveillance reports dealing with drilling holes. DOE agreed to send to NRC and the State QA reports regarding oversight of site field activities.

After completing discussions of the planned topics, the NRC staff brought forth some additional topics for discussion. The NRC stated that it had not received

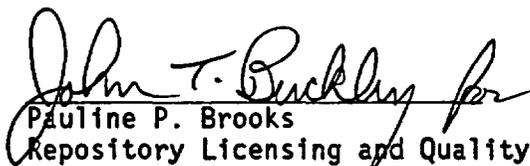
the Trend Report. DOE stated that the report has been issued. The NRC stated that it still plans to visit CER Corporation to look at the trend report process. The NRC requested copies of M&O Surveillance Reports and stated that it had two reports. DOE stated that it had done only two surveillances. NRC then asked for copies of surveillance reports written by DOE as observers of M&O internal surveillances. The NRC also asked for a copy of the DOE Office of Environmental Restoration and Waste Management's Office of Quality Assurance and Quality Control (EM-20) audit report of its audit of the Vitrification Projects Branch (EM-343). DOE noted that the report has not yet been issued.

The NRC stated that, based on the last USGS audit, it believes that the USGS QA program is greatly improved.

The NRC then invited the State and the affected units of local government to express any items of concern. The State and the Nye County, NV representative did not express any concerns at this time.

The floor was then open for closing remarks. The State of Nevada had no closing remarks. The Nye County representative stated that the county still intends to appoint onsite representatives. DOE has not yet agreed with Nye County that onsite duties may include certain off-site functions. The EEI representative asked whether the NRC intended to apply the revised reactor Standard Review Plan (SRP 17.3) to the high-level waste program. NRC stated that it had reviewed the SRP and found no benefit in applying it to the high-level waste program at this time.

The meeting was adjourned after tentatively selecting July 16, 1992, as the next NRC/DOE QA meeting date.


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Repository Licensing and Quality
Assurance Project Directorate
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Sharon L. Skuchko
Regulatory Integration Branch
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

4/30/92

NRC/DOE QA MEETING

<u>ORGANIZATION/NAME</u>	<u>PHONE NUMBER</u>
<u>NRC</u>	
John Buckley	301-504-2513
Bill Belke	301-504-2445
Kenneth R. Hooks	301-504-2447
Ken Kalman	301-504-2428
Pauline Brooks	301-504-3465
John Jankovich (Transportation)	301-504-2454
Phil Justus	301-504-3460
<u>DOE</u>	
Chris Einberg	202-586-8869
Bob Clark	202-586-1238
Donald G. Horton	202-586-7220
Richard E. Spence	702-794-7504
<u>State of Nevada</u>	
Susan Zimmerman	703-687-3744
<u>Nye County</u>	
Elgie Holstein	703-834-1173
<u>EEI</u>	
Tom Colandrea	619-487-7510
<u>TRW</u>	
Jim Tierney	703-204-8764
Marc Meyer	703-276-9300
<u>U.S. Geol. Survey</u>	
Ray Wallace	202-586-1244
Tom Chaney	303-236-1418

M&O QUALITY ASSURANCE PROGRAM

- Readiness Review - Nevada Operations - December '91
- Readiness Review - Charlotte, NC - MRS - March '92
- Readiness Review - Vienna, VA - April '92

Current Exceptions to M&O QA Program Acceptance

- OCRWM Approval of M&O Grading Procedure
- OCRWM Approval of M&O Computer Software QA Program

M&O WORKING CONDITIONS UNDER OCRWM'S QA PROGRAM

- QUALITY AFFECTING WORK - ACCOMPANIED BY A TRANSITION PLAN
- TRANSITION PLANS - ACTIVATED BY OCRWM LETTERS OF TECHNICAL DIRECTION
- EXAMPLES OF TRANSITION
 - Local Records Center Consolidation 3/1/92
 - Plans/Procedures 3/23/92
 - Configuration Management 5/92
 - * • Document Control (T&MSS) 8/1/92
 - * • Central Records Facility (T&MSS) 8/1/92
 - * • ESF Design (RSN) 10/1/92

* WORK WILL BE PERFORMED UNDER THE M&O QA PROGRAM. WORK CURRENTLY UNDER OTHER PARTICIPANTS' QA PROGRAMS

FIELD ACTIVITIES TO DATE

- **JF-3 non-quality Park Services monitoring well - Job Package No. 92-1**
- **Completed neutron holes - Job Package No. 91-9**
 - N11, N15, N16, N17, N36, N37, N38, N54, N55, N64
 - N27 in progress
- **UZ-16 (LM-300) - Job Package No. 92-4**
 - UZ-16 drill pad complete
 - Waiting for tracer permit
- **NRG-1 (north ramp hole) Exile Hill - Job Package No. 92-2**
 - Access road and drill pad complete
 - Waiting for tracer permit
 - Rock and soil properties - 30 of 33 pits excavated
- **Midway Valley trenching (pits) - Job Package No. 92-5**
 - Excavated 31 of 48 proposed pits
- **SRG-1 (south ramp borehole) - Job Package No. TBD**
 - Information for job package being collected

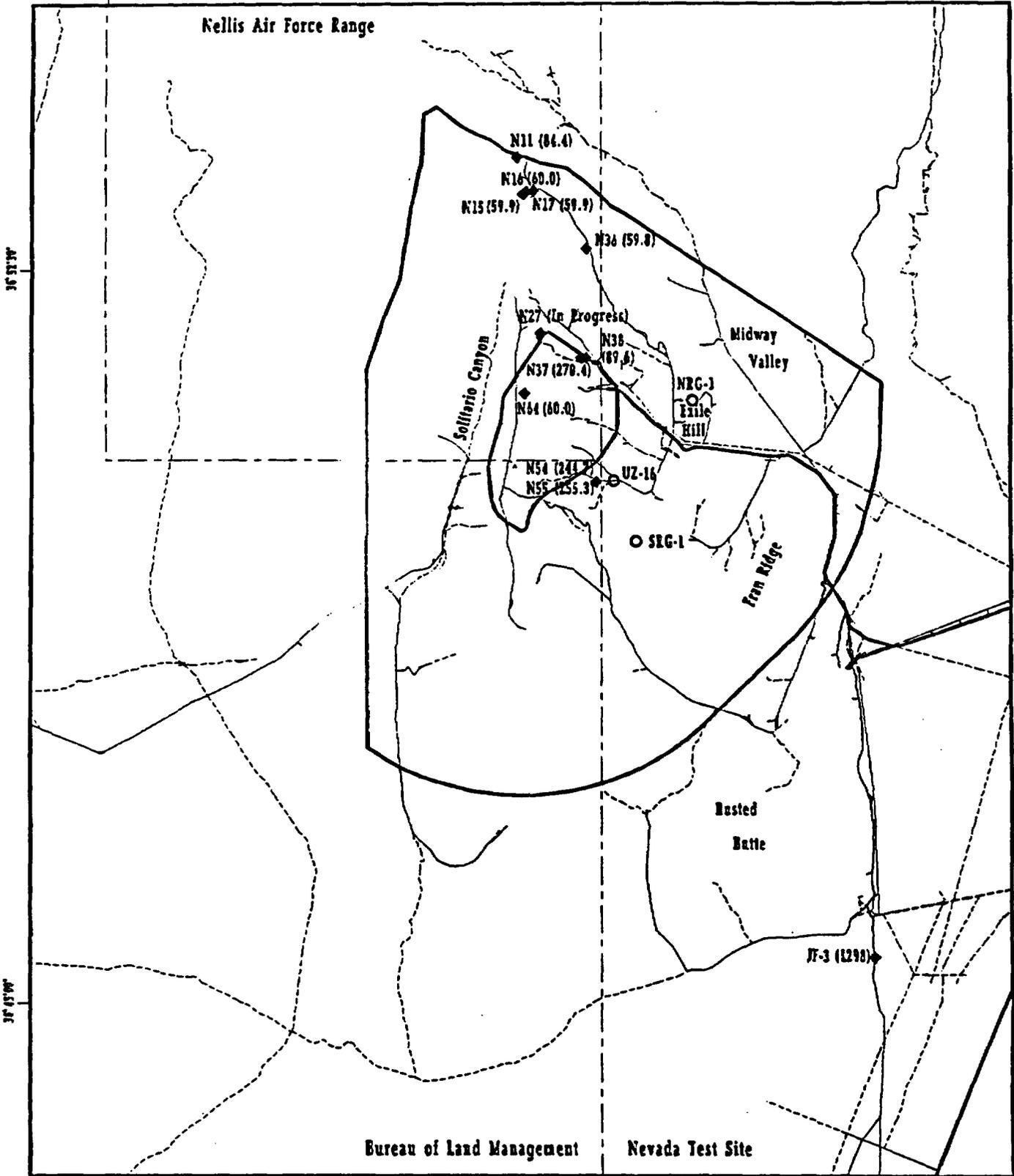
YMP DRILLHOLE SUMMARY

Depth in feet

ES39043H
ES40102z

ES6640H
ES9002m

Kellis Air Force Range

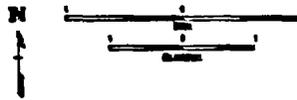


Bureau of Land Management

Nevada Test Site

116° 30' 00"

116° 22' 30"



QUALITY CONCERNS PROGRAM TOPICS

1991

PUBLIC SAFETY •
NUCLEAR WASTE SITES •
M&O METRIF. STUDY •
PNL REPORT/HYDROCHEMISTRY **
EMPLOYEE DISCRIMINATION •
NUCLEAR WEAPONS TESTING •
PUBLIC SAFETY •
RECORD TRACEABILITY **
YMP TRAINING PROGRAM **
DOC. REVIEW TRACEABILITY **
DEVELOPMENT OF CASK **
DOE PERSONNEL CONDUCT •
DOCUMENT CONTROL PROCESS **
DISTRIBUTION DELAYS •

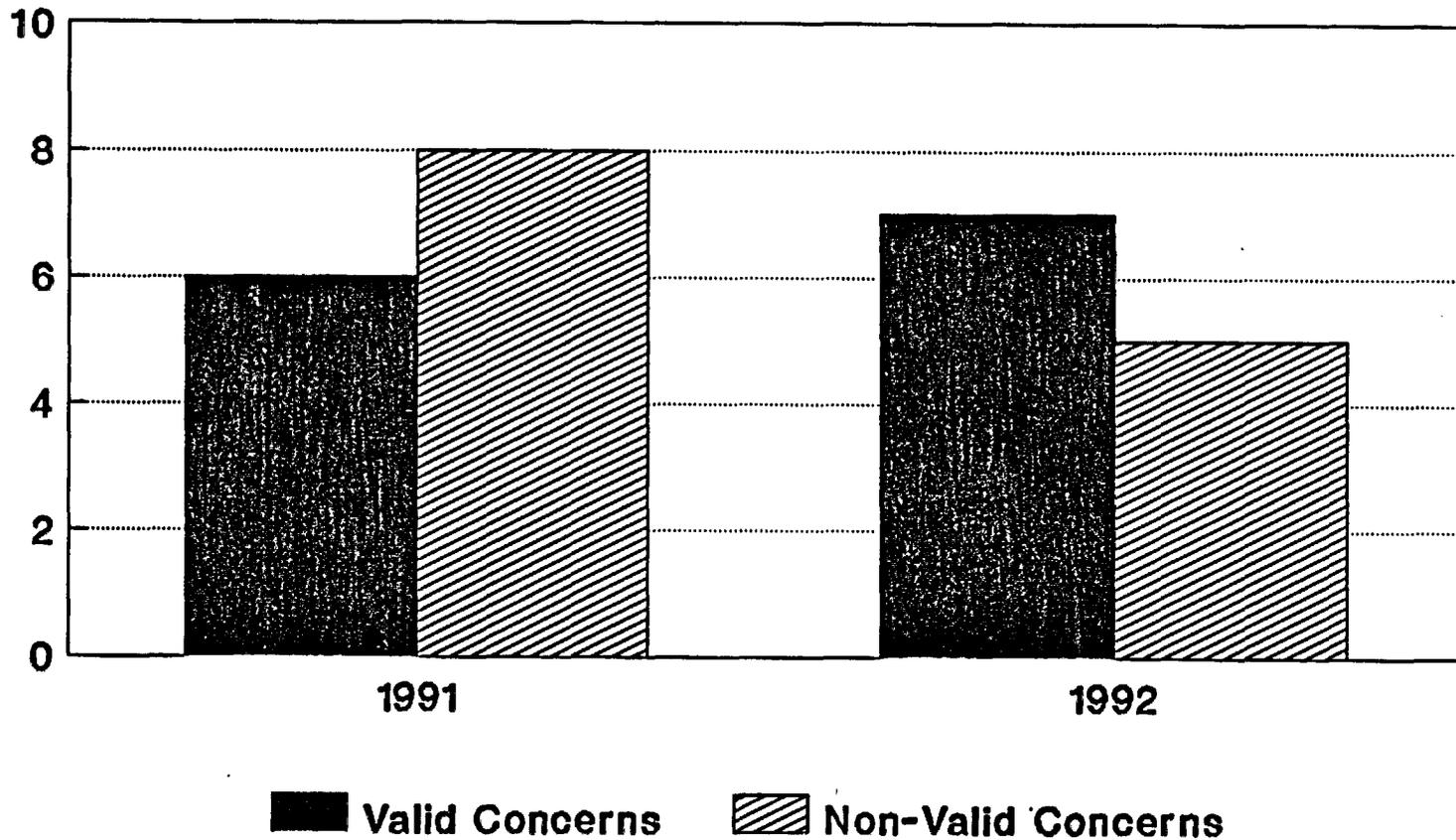
1992

ISSUANCE OF LETTERS **
DOE STAFFING •
LRC CONSOLIDATION **
QA PROGRAM **
COMPUTER CODES **
STUDY PLANS **
PROCEDURE REVIEW PROCESS **
TECHNICAL REVIEWS **
CONTRACTOR TIME-CHARGES •
SRP MANAGEMENT ISSUES •
SRP MANAGEMENT ISSUES •
EMPLOYEE LAYOFFS •

•Non-Quality Concerns **Quality Concerns

QUALITY CONCERNS PROGRAM

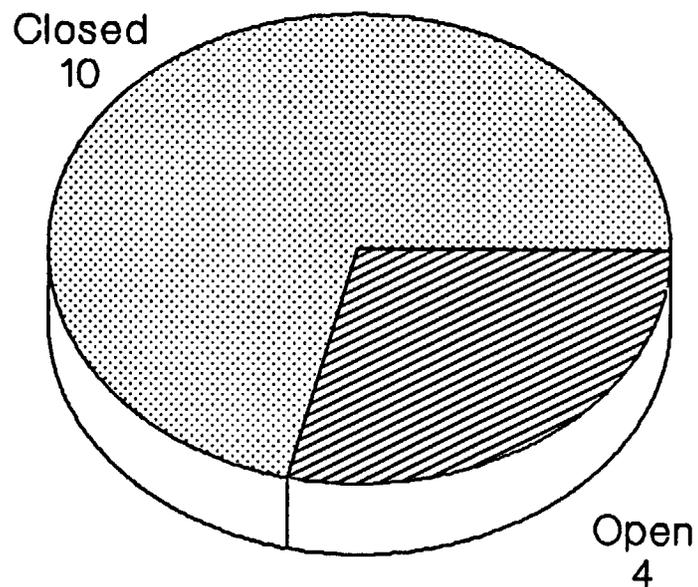
Valid vs. Non-valid Concerns



1991 - Total 14 Concerns
1992 - Total 12 Concerns

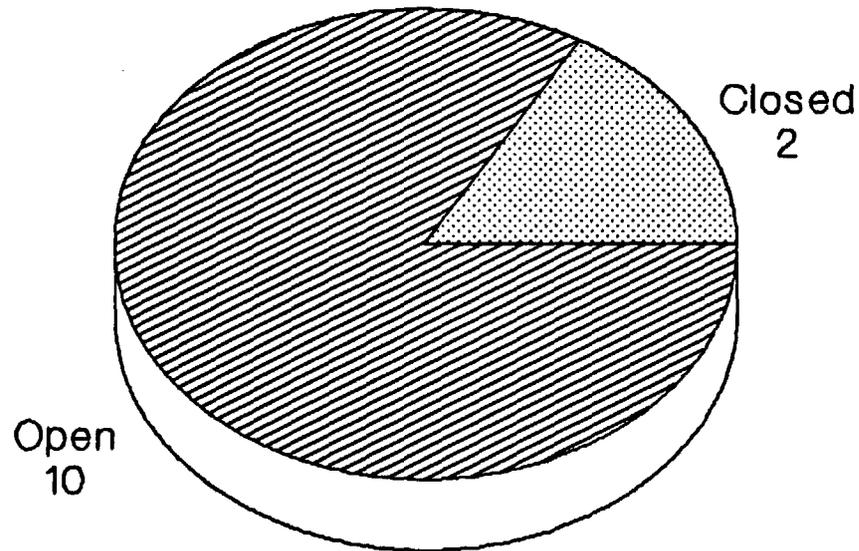
QUALITY CONCERNS PROGRAM

1991 Results



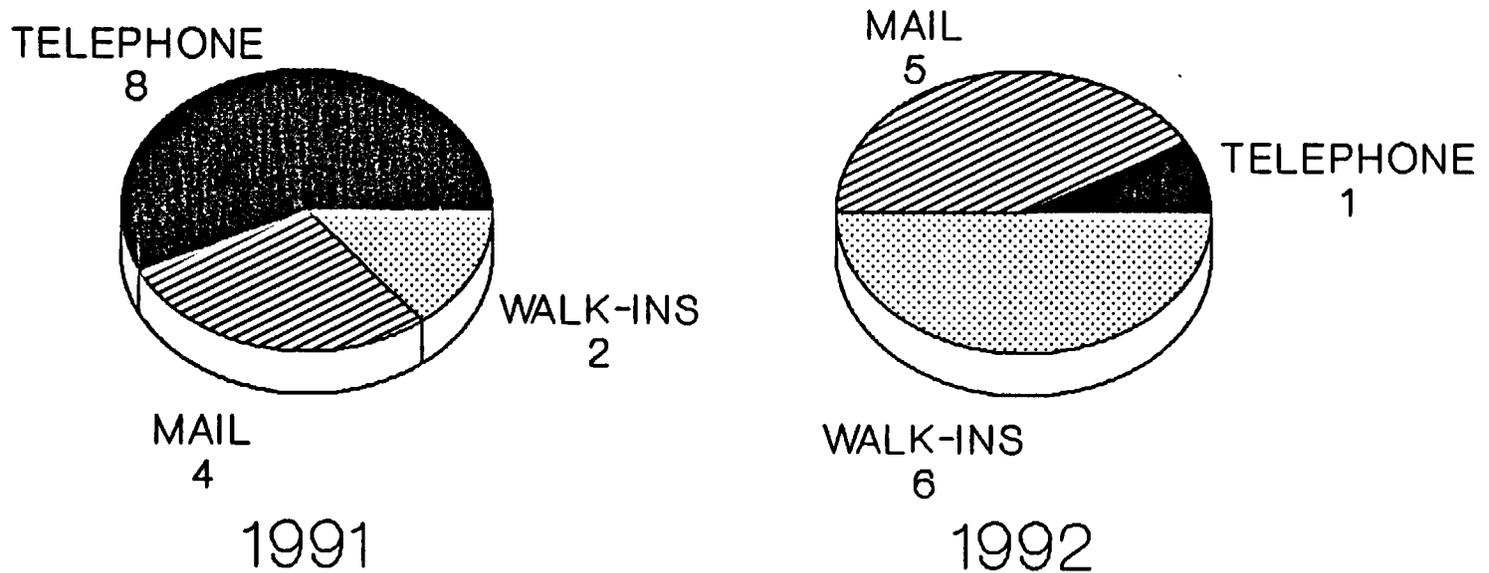
Total = 14 Concerns
6 were Quality related, 4 are still open
8 were Non-Quality related, all closed

QUALITY CONCERNS PROGRAM 1992 Results



Total = 12 Concerns
7 were Quality related, 1 closed
5 were Non-Quality related, 1 closed

QUALITY CONCERNS PROGRAM HOW REPORTS RECEIVED



Total Concerns = 26
14 In 1991
12 In 1992 (to 4/92)



WASTE MANAGEMENT PROJECT OFFICE

QUALITY MANAGEMENT PROCEDURE

N-QA-016
6/88

Title
AUDIT SYSTEM FOR THE WASTE
MANAGEMENT PROJECT OFFICE

No. QMF-16-01 Rev. 3
Effective Date 10/3/88
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OBJECTIVES FOR THE TECHNICAL PHASE OF THE QA AUDIT

In order to provide a unified approach to the conduct of the technical phase of a Quality Assurance audit the following questions are provided. The intention is to have these questions serve as the basis for the questions developed in the technical checklist (XX-2).

- o Were there sufficient technical procedures for the activity under review?
- o Were the procedures in place technically adequate for the intended application?
- o Did the prime or critical methodologies employed consider existing/accepted approaches and technologies?
- o Where controversial methodologies were employed was an adequate peer review performed?
- o Was the background/credentials of those individuals engaged in the task/activity appropriate to the desired/intended outcome of the activity?
- o Was the level of effort/rigor employed commensurate with the stated objectives of the task/activity?
- o Where concerns exist as to the efficacy of an activity is a further technical review indicated?
- o Where the interim analysis or interpretation of data supports reported results, is the analysis/interpretation appropriate for the proposed activity/task?
- o Were the design calculations, design methods, and design analyses employed for an activity appropriate to the maturity of the design?

Figure 5

Attachment 1

AUDIT PLAN 88 - 4

Rev.1,13May88

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ORNL 4/3/92

1.0 INTRODUCTION

From February 24-26, 1992, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) quality assurance (QA) Audit No. HQ-92-02 of Oak Ridge National Laboratory (ORNL) in Oak Ridge, Tennessee. A portion of this audit, which was not observed by NRC staff, was conducted at the offices of E. R. Johnson Associates, Inc., in Oakton, Virginia on February 27, 1992.

This report addresses the effectiveness of the DOE/OCRWM audit and the adequacy of the ORNL QA program.

2.0 OBJECTIVES

The objective of the DOE/OCRWM audit was to evaluate the implementation and effectiveness of the ORNL QA program in meeting the applicable requirements of DOE/RW-0214, "Quality Assurance Requirements Document" (QARD), Revision 4. The NRC staff's objective was to gain confidence that DOE/OCRWM and ORNL are properly implementing the requirements of their QA programs in accordance with the QARD and Title 10 Code of Federal Regulations (10 CFR) Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/OCRWM audit process and the ORNL QA program on direct observations of the auditors, discussions with the audit team and ORNL personnel, and reviews of the pertinent audit information (e.g., audit plan, checklists, and ORNL documents). The audit was well organized and conducted in a professional manner, with minimal logistic delays. The audit team was well qualified in the QA discipline, and its assignment and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team findings that the ORNL QA program has adequate procedural controls in place for the items that were audited, and program implementation is adequate for six of the ten criteria that were audited. The audit team found one criterion not being effectively implemented; one criterion indeterminate due to lack of significant quality affecting activities; and two criteria to be not applicable to the ORNL scope of activities.

DOE/OCRWM should monitor the ORNL QA program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own audits at a later date to assess the adequacy and effectiveness of the ORNL QA program.

5.9 Summary of NRC Staff Findings

(a) Observations

The NRC staff did not identify any observations relating to deficiencies in either the audit process or the other elements of ORNL QA program implementation.

(b) Weaknesses

The audit could have been enhanced by evaluating the ORNL procedures for adequacy as well as evaluating for implementation. The checklist would have benefitted from a more comprehensive set of requirements beyond those found in a limited group of procedures.

The observers received the audit notebook just one working day prior to the audit. It is recognized that NRC agreed with DOE that the audit notification letter would be furnished to NRC in advance, and the audit books (including the audit checklists, procedures etc.) at the audit. It appears that this method is not working in an effective manner, since it does not allow time for adequate preparation for the audit by the observers. Observers now need to ask questions that could have been answered or tracked down had the audit book been provided a week in advance and often interfere with the auditor's time during the audit. Therefore, it is recommended that DOE reconsider providing the observers the audit book at least a week prior to the audit to allow ample time for observers to prepare for the audit.

(c) Good Practices

At the audit entrance meeting, there was a presentation from ORNL personnel to explain their activities and the status of the work being accomplished. Since the audit observers are not part of the audit scoping process, this presentation was beneficial to the audit observers in order to determine whether the audit team has selected the proper sample and scope from which the audit is based on.

The NRC staff recognizes that this audit was not intended to be technical in nature. The DOE audit team was accompanied by two technical observers. When issues of a technical nature surfaced, the two technical observers were able to constructively contribute and assist in resolving questionable issues. The NRC staff recommends DOE continue to include at least one technical observer on future audits of this nature.

The ORNL staff demonstrated a positive attitude and knowledge of the ORNL QAPD and implementing procedures. The ORNL staff took immediate corrective action to correct any deficiencies identified by the auditors.