



Department of Energy
Washington, DC 20585

FEB 5 1993

Mr. Joseph J. Holonich, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Holonich:

In a continuing effort to evaluate and improve the U.S. Department of Energy Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Program, the OCRWM Director, Office of Quality Assurance (OQA), observed several audits conducted by his support staff during 1992. By observing the audits, he was able to evaluate the auditors' performance, evaluate how the QA program is being implemented, evaluate the QA program effectiveness, and propose recommendations to management on improving certain areas. In addition, it provided valuable input on improving the documented QA program.

The enclosed audit observation reports identify the recommendations made to management. Though this is not a QA program requirement, the Director, OQA, will continue to periodically observe the audits and issue reports to management. Any recommendations made to management are tracked by the Director, OQA, to assure adequate closure and overall program improvement. Future audit observation reports will be transmitted to you for information as they are issued.

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Should you have questions in this regard, please contact Mr. Donald Horton, Director, Office of Quality Assurance, at (202) 586-8858.

Sincerely,



John P. Roberts
Acting Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

4 Enclosures:

1. Memorandum dated September 1, 1992
(Horton to Distribution); Subject:
Results of Observing Sandia National
Laboratories Audit
2. Memorandum dated October 6, 1992
(Horton to Distribution); Subject:
Results of Observing Yucca Mountain
Site Characterization Project Office
Program Audit 92-94 on September 28-
October 2, 1992
3. Memorandum dated October 30, 1992
(Horton to Distribution); Subject:
Results of Observing OCRWM Audit
No. YMP-93-01 of U.S. Geological
Survey on October 19-23, 1992
4. Memorandum dated November 13, 1992
(Horton to Distribution); Subject:
Observation of OCRWM Audit
No. YMP-93-02 at Los Alamos National
Laboratory on November 2-5, 1992

cc w/Enclosures:

C. Gertz, YMPO
T. J. Hickey, Nevada Legislative Committee
R. Loux, State of Nevada
S. Zimmerman, State of Nevada
M. Baughman, Lincoln County, NV
J. Bingham, Clark County, NV
B. Raper, Nye County, NV
P. Niedzielski-Eichner, Nye County, NV
G. Derby, Lander County, NV
P. Goicoechea, Eureka, NV
C. Schank, Churchill County, NV
F. Mariani, White Pine County, NV
V. Poe, Mineral County, NV
E. Wright, Lincoln County, NV
J. Pitts, Lincoln County, NV
R. Williams, Lander County, NV
J. Hayes, Esmeralda County, NV
B. Mettam, Inyo County, CA
K. Hooks, NRC

memorandum

DATE: SEP 1 1992

REPLY TO
ATTN OF: RW-3

SUBJECT: Results of Observing SNL Audit

TO: Distribution

During August 24-28, 1992, I observed the OQA Audit of Sandia National Laboratory. Three Corrective Action Requests (CARs) were issued and four issues were resolved during the audit. There were no significant issues identified and they are satisfactorily implementing their QA program. The following are observations and comments from my perspective during the audit. If you have any questions please contact me.

- 1) Do you have any problems with performing scientific tasks and implementing the QA program requirements?
 - o J.Jun/L.Costin - Feel that QA requirements frequently overwhelm the scientific work. It increases the cost of the work. Though it can be and frequently is useful, it is also usually overwhelming in a scientific investigation. There are no attempts to short cut the system, but it is sometimes very frustrating, i.e. given a choice between using an outdated code and going through the trials and tribulations of getting it updated within the QA system, there is a real temptation to use the inferior code. There are customer needs and the scientist's needs. The scientists are willing to cooperate with the customer's needs. Such things as the QA documentation is clearly beneficial, but the totality is cumbersome.
 - o M.E. Fewell/S.R. Sobolik - QA controls are a major expense, however it improves the overall process. Management controls are costly for planning and revising these plans. Technical personnel are now more involved in modifying QA procedures.
 - o Overall feeling is that there has been significant improvement in the last two years and the scientific and QA groups continue to discuss, resolve and improve the program.

- 2) There is confusion on what information is, should be, and how it's identified in the RIB. A memo of explanation should be issued by the Project Office to all personnel on the program. The SEPDB should also be included in the memo.
- 3) OQA needs to issue a "Lessons Learned" notice on requirements for maintenance and control of QA Program Procedures and Technical Document Review comment resolution sheets.
- 4) One of the technical auditors had a disagreement with an SNL technical person on specifying design requirements in Design Investigation Memos (DIM). The SNL person stated that they don't perform design input work. Recommend the technical auditor discuss this with the project office personnel for resolution and issue a memo to affected participants.
- 5) There appears to be some conflicts between QARD requirements and directions being given by the records management people (YMP) to the participants records management people i.e. what records are to be submitted; the statement for packages with blanks, changes, illegible records; and microfilm vs. hardcopies.
- 6) There is still a question as to what, if any, the responsibility is for the M&O in site characterization. If they have any, their QAPD needs to describe it.
- 7) Due to SAIC losing several technical specialists to the M&O, the number of technical specialists available to YMQAD is limited. OQA needs to determine if we can train and utilize some of the technical specialists from the M&O in future DOE audits.
- 8) Technical products that are quality affecting being prepared by SNL and their contractors are not being appropriately reviewed by the SNL QA organization. It's recognized that the line managers are responsible for quality of their work, however QA should perform some type of review to verify quality of the product. SNL is not overseeing their subcontractors adequately to assure quality products. There are too many errors slipping thorough the present system. In addition, several months ago, YMQAD agreed to remove themselves from project office review of participants reports provided the participants' QA organization was involved in the preparation and review. I don't think this is being implemented at SNL.

- 9) SNL is currently not funded beyond September 30, 1992 for work on the SEPDB & RIB. The current status of EG&G's QA program and implementing procedures is in question for being ready by that date. YMP may want to provide some transition funding to SNL. In addition, the SNL employee who has worked on these data bases will be unemployed as of September 30, 1992. She has worked on this for more than four years and we will be losing a very knowledgeable person. EG&G has no plans to hire this employee.
- 10) SNL has a concern about transferring P.A. responsibilities to the M&O. The M&O proposed to take over the responsibilities and centralize the controls in one place. However, the M&O is going to have the effort performed in three or four places. Therefore, there is less centralization and less control.
- 11) Many of the SNL implementing procedures are undergoing revision. This should continue as a priority item. The current procedures have many conflicting requirements with each other.
- 12) The proposed offer by the M&O to consolidate document control functions in FY 93 for controlled document (CD) management services for all participants with no additional resources should be thoroughly reviewed. The logistics is going to be a problem and I don't see how the M&O can do this with no additional resources.



Donald G. Horton, Director
Office of Quality Assurance

memorandum

DATE: OCT 06 1992

REPLY TO: RW-3
ATTN OF:

SUBJECT: Results of Observing YMPO Program Audit 92-94 on September 28 -
October 2, 1992

TO: Distribution

During the week of September 28, 1992, I participated as an observer in YMPO Program Audit 92-94. The overall results of the audit indicated that YMPO is satisfactorily implementing the Quality Assurance (QA) program in the areas audited with the exception of configuration management (CM) which was judged to be marginal. A total of four Corrective Action Requests (CARs) were issued. Personal observations from the audit are included. If you have any questions, please contact me at (202) 586-8858.

- 1) The results of the audit in the area of CM indicated concerns with the CM process itself. First of all, there are too many procedures with too many self imposed administrative requirements to effectively implement the process. In addition, the procedures are not well integrated with one another, nor are they user friendly. The most important observation is that the CM process currently is structured to manage the configuration of documentation and not the configuration of items.

The initial recommendation is to review the entire CM process and eliminate the restrictive administrative requirements. In addition, it is suggested that the CM procedures be consolidated, where feasible, to address how configured items, their documentation, and changes thereto are identified, reviewed, approved, implemented, tracked and closed. This suggestion would necessitate the consolidation of YMPO procedures QMP-03-09, AP-3.3Q and AP-3.5Q. It is also recommended that a review of any CM procedures at DOE-HQ be performed to determine if they can be integrated at the Program level.

An overall philosophical recommendation is that the CM process be examined with the focus of using items that are to be configured as the basis of CM. This would require the up front identification of items (engineered and natural) to be included in CM. As items are identified, the associated documentation that affect the items would be identified and placed in CM. In essence, the configured items should be the basis for and drive the CM process with associated documentation (drawings, specifications, plans, etc.) being a product of and an essential part of the CM process.

It is essential that the Program including YMPO have an organized, structured and efficient process to manage configured items as the Program moves into ESF design and construction.

- 2) The procedures at YMPO currently do not contain a revision history. A procedure could be changed to address a regulatory requirement or CAR and it could later be changed and drop the requirement without knowing why it was originally included. This is also applicable at DOE-HQ. The proposed Quality Assurance Requirements and Description Document (QARD) will include requirements for revision history. It is recommended that all procedures include a revision history page and log that identify date, type of change, reason for change, etc. This recommendation could be implemented as procedures are revised and issued.
- 3) The real time training process at YMPO needs to be examined. In reviewing several document packages during the audit, I noticed several discrepancies on procedure revision and ICN numbers that were documented by the reviewers. It appears that many people are not completing the correct training/reading assignments prior to performing the work activity. YMPO management should evaluate the current methods of documenting real time training to determine if it is achieving the objectives.
- 4) The perception still exists that a CAR is bad and an indication of less than satisfactory performance on an individual basis. YMPO management should continue stressing that a CAR is only a device to identify deficiencies in the program and to obtain recommended solutions. They are not used in performance appraisals.

- 5) Several ICNs on procedures were issued during the audit to revise or delete requirements. The ICNs were issued to eliminate potential CARs. Though I don't endorse issuing insignificant CARs, I do have a concern about the number of ICNs issued. It appears that personnel are either not reading the procedures or they are knowingly violating the procedural requirements. YMPO management, as well as DOE-HQ management, should be sensitive to this perception and assure changes are made to procedures if the requirements are inappropriate prior to audits/surveillances identifying the need for change.



Donald G. Horton, Director
Office of Quality Assurance

Distribution

J. Bartlett, RW-1
F. Peters, RW-2
R. Clark, RW-3
T. Isaacs, RW-4
J. Saltzman, RW-5
S. Rousso, RW-10
C. Gertz, RW-20
S. Brocoum, RW-22
J. Roberts, RW-30
R. Milner, RW-40
R. Rousso, RW-50
R. Spence, YMPO
W. Booth, Weston
M. Meyer, CER
OQA Personnel

memorandum

DATE: OCT 30 1992

REPLY TO
ATTN OF: RW-3

SUBJECT: Results of Observing OCRWM Audit Number YMP-93-01 of U.S. Geological Survey (USGS) on October 19-23, 1992

TO: Distribution

During the week of October 19, 1992, I participated as an observer in OCRWM Audit No. YMP 93-01 of USGS. The overall results of the audit indicated that USGS is satisfactorily implementing the Quality Assurance (QA) program in the areas audited. A total of four Corrective Action Requests (CARs) were issued. It should be noted that there has been significant improvement during the past two years at USGS by the line organizations in acceptance and implementation of the QA program. Personal observations from the audit are included. If you have any questions, please contact me at (202) 586-8858.

- 1) The problem exists at USGS in the records area that has been identified at the other participants and at YMPO. Poor quality records packages are being submitted by the technical staff and accepted by the records center. A CAR written during the YMPO audit should identify corrective action to be implemented by all participants to address the records issue. In addition AP1.18Q should be revised to address specific concerns in the CAR.
- 2) The technical staff stated that the QA requirements for computer software was too restrictive. After further discussion with the staff, it was determined that it was not QA requirements. The internal procedure requirements may be too restrictive. I recommend that USGS review the current software control procedures to determine if they are consistent with the required controls.
- 3) During the audit, the State of Nevada representative was denied access to USGS personnel qualification files. Apparently the Federal Register notice filed by the Department of Interior was slightly different than the one filed by the Department of Energy and it does not allow access by representatives of State and local governments. I recommend that USGS verify that this is the true interpretation to eliminate potential concerns raised by State representative on future audits/surveillances.

- 4) USGS QMP-8.03 governs the submittal of data into the data bases in conjunction with AP5.1Q. The USGS submittals fall into two categories; acquired data and developed data. Until October 1, 1992, Sandia National Laboratory was the custodian for entering the data into the Technical Data Base. USGS has a large backlog of submittals for which there has been no feedback as to the status of the data.

When data has been accepted, USGS has received feedback that the data has been "accepted". USGS receives no information as to what has actually been incorporated into the data base - tables, charts, or any limitations and caveats associated with the data. Likewise, there seems to be an importance in submitting the data, but the emphasis does not seem to extend to entering the data into the technical data base (TDB). It would be appropriate to have the submitting organization review the information incorporated into the TDB and required the custodian to act on the data submittals in a defined time interval.

There does not appear to be adequate guidance from the Project Office for the form, format and quality of data that are submitted to the Project Data Bases. There also does not appear to be adequate provisions to review data that is in these data bases for technical content.

A finding at the SNL audit was that the Reference Information Base contains two separate sources for stratigraphy for borehole G-4. These sources do not agree.

Discussions with Pat McKinley, and other USGS personnel, indicate that they have not been given enough guidance for what should be submitted. Currently he sends a report to the data base administrator who decides what part of the report will be included in the data base. Often this is just a figure or a table from the report without all of the qualifying assumptions and conditions.

The Project Office should examine the need for these data bases. If they are valuable, adequate funding should be provided to process input and review data quality. If not, they should be eliminated.

In addition, I recommend that YMP conduct a workshop for all participants to discuss the data issues. There is much confusion at all the participants and within the OCRWM organization pertaining to data.



Donald G. Horton, Director
Office of Quality Assurance

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R. Spence, YMPO
W. Booth, Weston
M. Meyer, CER
L. Hayes, USGS
T. Cheney, USGS
OQA Personnel

memorandum

DATE: NOV 13 1992

REPLY TO
ATTN OF: RW-3

SUBJECT: Observation of OCRWM Audit Number YMP-93-02 at Los Alamos National Laboratory (LANL) on November 2-5, 1992

TO: Distribution

During the week of November 2, 1992, I participated as an observer in OCRWM Audit No. YMP-93-02 of LANL. The overall results of the audit indicated that LANL is satisfactorily implementing the Quality Assurance (QA) program in the areas audited. A total of two Corrective Action Requests (CARs) were issued. There has been significant improvement at LANL during the past two years. The technical personnel responsible for the areas reviewed during the technical portion of the audit should be commended for the excellent manner in which they are performing and documenting their work. Personal observations from the audit are included. If you have any questions, please contact me at (202) 586-8858.

- 1) The same records problem identified at other participants and YMPO exists at LANL. A records package was reviewed and some of the pages were not legible, but had been accepted by the Central Records Facility (CRF) with the "statement" on the cover page about blanks, legibility, etc. The microfilm was also not legible. YMPO was called and an individual went to CRF and checked the original records package which was not legible. YMP QAD should perform a surveillance of CRF for all the deficient records packages identified at the participants during the audits. In addition, CAR YM-93-04 should be expanded to include records at LANL.
- 2) Several of the participants are going to start utilizing electronic media for scientific notebooks. To maintain Program consistency, YMPO should establish and publish rules to all participants about how often hard copies of the media should be printed and sent to records, how to document corrections and changes, backup requirements for entries, etc.
- 3) Several technical staff members of some participants have expressed concerns about Configuration Control Board's (CCB) involvement in the software quality assurance (SQA) process. They feel that there are too many reviewers and reviews resulting in a long complicated process. The participants should review the SQA procedures and determine if the process can be improved.



Donald G. Horton, Director
Office of Quality Assurance

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S. Rousso, RW-50
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