



Department of Energy
Washington, DC 20585
SEP 17 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:

This letter responds to the U.S. Nuclear Regulatory Commission (NRC) letter dated April 6, 1993 (Holonich to Shelor), which enclosed NRC Observation Audit Report No. 93-07 of the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. YMP-93-07 of the Civilian Radioactive Waste Management Systems (CRWMS) Management and Operating Contractor (M&O) QA Program in Nevada.

As requested in the NRC letter of April 6, 1993, this letter provides responses to weaknesses identified in the NRC Observation Audit Report No. 93-07, Section 5.9.2, concerning:

1. Personnel knowingly not following implementing procedures without documenting the authority or justification to do so;
2. The number of deficiencies combined into a single Corrective Action Request (CAR), and how the corrective actions would be accurately tracked; and
3. The questionable effectiveness of the Readiness Review process in view of the number of audit team findings.

Responses (Keyed to above-listed weaknesses)

1. On November 19, 1991, the Director, Office of Quality Assurance (OQA), issued a memorandum to members of his office (Enclosure 1) to reaffirm policy regarding documentation of departure from procedure requirements. As a result of the recent audits of the CRWMS M&O Contractor, the CRWMS M&O General Manager issued a memorandum to all M&O employees (Enclosure 2) to also reaffirm policy regarding this subject. Although there may be some isolated instances of misunderstanding and misinformation, no personnel are intentionally not following procedures.

240019

9309280212 930917
PDR WASTE
WM-11

PDR

102-7
WM-11
N403

The recent audits of the CRWMS M&O were the first OCRWM audits of this contractor. Similar situations existed the first time OCRWM audited other affected organizations and, during subsequent audits of those affected organizations, OCRWM found that the situation did not recur. The next time OCRWM audits the M&O, all personnel will have a better understanding of the QA program requirements regarding documentation of departure from procedure requirements and this situation should not recur.

NOTE: This response does not address similar NRC concerns identified in its previous observation audit reports relative to OCRWM audits 91-003 (DOE Office of Environmental Restoration and Waste Management--EM-343) and Headquarters (HQ) HQ-92-001, which were performed by HQ personnel.

2. OCRWM OQA audits are performed by qualified personnel who have been properly trained regarding the process of documenting conditions adverse to quality. During the audit of the CRWMS M&O in Las Vegas (Audit No. YMP-93-07), six examples of failure to properly implement CRWMS M&O Quality Assurance Procedure (QAP)-5-1 were identified and documented as a single CAR (YM-93-036). There was no value added to separating the deficiencies into six separate CARs. Root cause determination is based on the overall adverse condition described in the CAR, not the specific examples. Follow-up verification on CAR YM-93-036 will assure that the examples and any similar conditions adverse to quality identified by the M&O during its investigative action are corrected. In addition, follow-up verification will assure that proper root cause is determined and appropriate actions are taken to prevent recurrence.

Another CAR (YM-93-037) documented three examples of inadequate Implementing Line Procedures (ILPs). ILPs are CRWMS M&O procedures governing specific work locations such as CRWMS M&O Nevada operations. Again, there was no value added to separate the deficiencies into three separate CARs and follow-up verification will assure appropriate corrective action is accomplished.

There were also examples of deficiencies identified during this Las Vegas audit that dealt with inadequate QAPs and failure to verify education. There were similar deficiencies identified during the OCRWM audit of the M&O Vienna operations. Since the M&O QAPs are controlled out of their Vienna operations, and the process of verification of education requires interfacing with the Vienna operations, there was no value added by issuing separate CARs to the CRWMS M&O Nevada Operations organization. Effective

corrective action will be obtained via the CARs issued from OQA HQ. In conclusion, qualified audit personnel have a clear understanding of the CAR process and effective corrective action, that addresses root cause, will be accomplished.

3. Readiness Reviews are a systematic assessment of preparedness of an organization to start or continue a process or project phase and, as such, do not necessarily verify adequacy of all applicable procedures. Readiness Reviews do address whether or not there are approved procedures in place to control the activities that are to be accomplished. Each affected organization has an independent QA organization that reviews procedures for adequacy regarding QA program requirements.

Adequacy of procedures is addressed during an audit on a sampling basis; i.e., an audit does not necessarily verify adequacy of all procedures being implemented. The number of deficiencies found during an audit is not a direct indication of effectiveness of Readiness Reviews. For example, Readiness Reviews do not verify implementation of procedures; however, some audit findings document failure to implement procedures.

OCRWM appreciates the support of the NRC in identifying these weaknesses and will work with the M&O to ensure that the actions taken to resolve these weaknesses are effective.

If you have any questions, please contact Mr. Donald G. Horton of the OQA at (702) 794-7675.

Sincerely,



Dwight E. Shelor
Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

2 Enclosures:

1. Memorandum dated November 19, 1991 (Horton to Distribution); Subject: Generic Issues Identified During the OCRWM Audit
2. Memorandum dated April 22, 1993 (Robertson to All M&O Employees); Subject: Compliance with QA Program Requirements

cc w/Enclosures:

C. Gertz, YMPO
T. J. Hickey, Nevada Legislative Committee
R. Loux, State of Nevada
D. Bechtel, Las Vegas, NV
Eureka County, NV
Lander County, Battle Mountain, NV
P. Niedzielski-Eichner, Nye County, NV
W. Offutt, Nye County, NV
L. Bradshaw, Nye County, NV
C. Schank, Churchill County, NV
F. Mariani, White Pine County, NV
V. Poe, Mineral County, NV
J. Pitts, Lincoln County, NV
J. Hayes, Esmeralda County, NV
B. Mettam, Inyo County, CA
K. Hooks, NRC

memorandum

DATE: NOV 19 1991
REPLY TO:
ATTN OF: RW-3
SUBJECT: Generic Issues Identified During the OCRWM Audit
TO: Distribution

Two generic issues were identified during the OCRWM QA Audit that we should be sensitive to in the future.

The first issue involves a presentation by management during the Audit Entrance Meeting. Often times, the observers (NRC, State of Nevada, etc.) have no concept of the scope of work or the work activities performed since the last audit of the audited organization. Therefore, appropriate management of the audited organization should provide a brief overview of work activities during the entrance meetings of future audits.

The second issue involves documentation of departure from procedure requirements. Several instances of procedural noncompliance were identified during the audit. There are only two methods of not complying with requirements of a procedure. The activity can stop until a change to the applicable procedure can be processed, or document the departure from the procedure on a CAR and proceed until the procedure is changed. One must understand that by documenting the departure on a CAR and proceeding, there is a risk involved in that the procedure change may not be approved and the activity would have to be redone.

Audit personnel will be instructed to assure future audits address these issues. Your continued support is appreciated. If you have any questions, please contact me at (202) 586-8858.


Donald G. Horton, Director
Office of Quality Assurance

Interoffice Correspondence

Civilian Radioactive Waste Management System
Management & Operating Contractor



TRW Environmental
Safety Systems Inc.

Subject
Compliance with QA Program
Requirements

Date
April 22, 1993
VA.GM.RLR.4/93.024

WBS: 9.3.07
QA: N/A
From 
R.L. Robertson

To
All M&O Employees

cc

Location/Phone
TES1/8588
204-8600

M&O compliance with QAW procedures has been less than satisfactory as indicated by the recent QA audits.

In case there is any misunderstanding concerning the responsibilities of M&O personnel performing Quality Affecting Work (QAW) under both the M&O and DOE QA Programs, I want to make the following perfectly clear:

1. If you find that following a QA procedure will not allow you to perform your work as required, you will stop work and notify your supervisor immediately. You and your supervisor will immediately:
 - a. Identify consequences of following the procedure precisely as written.
 - b. Identify changes required to make the procedure proper for the work to be performed.
 - c. Notify M&O QA of your recommendations.
 - d. Not proceed with QAW until a revision to the procedure is approved under the QA Program.
2. If a QA procedure is not "user friendly", but will allow you to continue work, you will perform this work using that QA procedure as written, in parallel, notify your supervisor and taken actions as described in 1a, 1b, and 1c above.
3. If you are to perform work that is Quality Affecting (QAW) and find that approved QA procedures do not exist, you will not undertake this work until the required QA procedures are approved and available to you. You will immediately notify your supervisor and M&O QA of the need for new procedures.

The integrity of the OCRWM and M&O Quality Assurance programs depends on individual compliance, identification of needs, recommendations for improvements and priorities regarding procedures for QAW.

Each and every M&O employee performing QAW on this program, who knowingly does not conform to the requirements of the QA Program and, in particular, items 1, 2, & 3 above, will be subject to disciplinary action, which may include dismissal from this program.