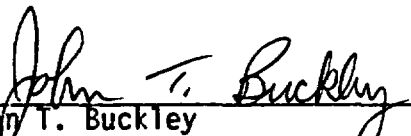
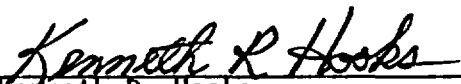


U.S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT NO. 91-4  
FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
AUDIT NO. OCRWM HQ-91-001 OF KOH SYSTEMS, INC.

 3/5/91  
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## 1.0 INTRODUCTION

From January 7 through 11, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. OCRWM HQ-91-001 of Koh Systems, Inc. (KOH), conducted in Washington, D.C.

KOH is responsible for operation of the OCRWM Headquarters (HQ) Central Records Facility (CRF). This report addresses the effectiveness of the OCRWM audit, and to a lesser extent, the adequacy of the KOH QA program.

## 2.0 OBJECTIVES

The objectives of the OCRWM audit were to evaluate portions of the KOH QA Program Plan (QAPP) Revision 4, and to determine the effectiveness of implementation of the KOH QA program. The NRC staff's objective was to gain confidence that OCRWM and KOH are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE audit and determining whether the KOH QA program is in accordance with the requirements of the OCRWM Quality Assurance Requirements Document (QARD), Revision 4.

## 3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the OCRWM audit process and the KOH QA program on direct observation of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., the audit plan, checklists, and KOH documents). The NRC staff has determined that, overall, Audit No. OCRWM HQ-91-001 of KOH achieved its purpose of determining the adequacy of the KOH QA program implementation. The audit was conducted in a professional manner. The audit team was well prepared and their checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary OCRWM audit team findings that KOH generally has an adequate QA program; however, the NRC staff is concerned about the lack of OCRWM and KOH management attention given to identified training deficiencies and filling the KOH QA Manager position.

OCRWM should monitor the KOH program to ensure that deficiencies identified during this audit are corrected and 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 independent audit at a later date to assess the adequacy and effectiveness of the KOH QA program.

## 4.0 AUDIT PARTICIPANTS

### 4.1 NRC

John T. Buckley      Observer

#### 4.2 OCRWM

John Marchand	Audit Team Leader	WESTON
Norman Frank	Auditor	CER
Samuel Smith	Auditor	WESTON
Victor Montenyohl	Auditor-in-Training	WESTON

#### 5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2 Revision 2, "Audit Program." The audited requirements include KOH OCRWM/Quality Implementing Procedures and Glossary, and KOH Quality Assurance Plan, Revision 4. The NRC staff observation of the audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989.

NRC staff observations are classified in accordance with the procedure guidelines. The NRC staff findings may also include weaknesses (actions or items which are not deficiencies, but could be improved), good practices (actions or items which enhance the QA program) and requests for information required to determine if an action or item is deficient. Written responses to weaknesses identified by the NRC staff will be requested when appropriate.

In general, weaknesses and items related to requests for information will be examined by the NRC staff in future audits or surveillances.

#### 5.1 SCOPE OF AUDIT

The audit scope was to verify that the KOH QA program meets the requirements of the QARD, Revision 4 and to verify that the necessary managerial control systems are in place.

##### (a) Programmatic Elements

The audit utilized checklists developed from requirements in the KOH Quality Implementing Procedures (QIP's) and Quality Assurance Plan (QAP), Revision 4. The checklists covered QA program controls for 9 of the 18 10 CFR Part 50 Appendix B Criteria. The nine Criteria evaluated were 1, 2, 4, 5, 6, 7, 16, 17, and 18.

##### (b) Technical Areas

No technical areas were evaluated during this audit.

#### 5.2 TIMING OF THE AUDIT

The NRC staff believes that the timing of the QA audit was appropriate. Since a review of the KOH program was not included within the scope of the OCRWM HQ audit conducted during October 15-19, 1990 a timely audit of the KOH program was necessary in order to complete the evaluation of the OCRWM QA program.

In addition, the timing of this audit allowed OCRWM and KOH to assess the adequacy of improvements made in the KOH program since the KOH internal audit conducted on May 21-24, 1990.

### 5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

The programmatic checklists covered the QA program controls for the nine elements listed below.

#### Programmatic Elements

- 1.0 Organization
- 2.0 Quality Assurance Program
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

The NRC staff observed the OCRWM audit team's evaluation of selected programmatic elements of the KOH QAP. Only portions of some elements were observed. Therefore some programmatic deficiencies identified by the audit team were not observed by NRC staff. Such deficiencies will not be discussed in detail in this report.

#### (a) Corrective Action (Criterion 16)

The auditors interviewed the KOH QA Manager in an effort to understand the QA program and corrective action process. The auditors' interview questions were based on the published audit checklists. KOH staff responses were pursued by evaluating the objective evidence. The first evidence reviewed by the auditors consisted of three Corrective Action Reports (CARs) prepared under QIP 16.1 Revision 0. The auditors determined that all CARs processed under QIP 16.1 have been closed out and QIP 16.1 Revision 0 was recalled. QIP 16.1, Revision 0 was superseded by QIP 16.2 which in turn was superseded by QIP 16.3 on June 8, 1990. All deficiencies identified during the KOH internal audit are being processed under QIP 16.3.

Since all CARs processed under QIP 16.1 have been closed, the audit team reviewed open CAR No. CSK-89-01-02 issued on May 19, 1989 and processed under QIP 16.2. The auditors were satisfied that this CAR was being adequately tracked, but were concerned about the numerous extension requests granted which have delayed closure of this CAR. Interview responses by the KOH QA Manager indicated that it may well be some time before CAR No. CSK-89-01-02 can be closed. An observation regarding untimely closeouts of CARs may be added to the OCRWM audit report.

While addressing the checklist questions related to QIP 16.3 it was discovered that the KOH QA Manager position was vacant from July 19 through December 1, 1990. Objective evidence reviewed indicated that the KOH Project Manager (PM)

was designated acting QA Manager from August 20 through September 21, 1990. It appears that the QA Manager's position was left unattended between July 19 through August 20, 1990 and again from September 21 through December 1, 1990. The auditors identified several deficiencies resulting from the absence of a QA Manager. First, the acting QA Manager, the PM, signed a deficiency report written against the QA Manager. According to QIP 16.3, deficiencies written against the QA Manager should be signed and analyzed by the PM. Second, it appears that QIP 16.5 has not been implemented resulting in the issuance of no trending reports. Finally, full implementation of QIP 16.4 (Stop Work Action) requires the availability of trending reports. Since no trending reports have been issued, QIP 16.4 has not been implemented.

(b) Quality Assurance Records (Criterion 17)

Due to the complexity of the KOH records processing system, the audit team evaluated QIP Sections 17.1, 17.2, and 17.3 separately. For the review of QIP 17.1, the auditors evaluated the KOH program for processing mail records, package records, and one-of-a-kind and special process records. The auditors effectively used the prepared checklists and obtained additional insight into the KOH program by interviewing the Document Processing Supervisor.

According to QIP 17.1, the KOH Information Specialist is to screen all incoming mail records against criteria outlined in Records Management Policies and Requirements, Revision 1 (RMPPR) and QA Glossary to determine which mail records are of "limited value" and thus discardable. The NRC observer pointed out that the review criteria are sufficiently complex to warrant additional training for the Information Specialist regarding the review criteria. The OCRWM audit report will contain a recommendation that additional training be provided in this area.

The auditors identified a concern regarding the maintenance of a KOH Accession Number Log. Paragraph 5.1.2 of QIP 17.1 requires that the KOH Accession Number Log reflect the date of CFR receipt beside each document log entry. A KOH management directive memo states that KOH no longer must keep an Accession Number Log. However, no interim change notice (ICN) was issued, thus this memo is inconsistent with the QIP. This deficiency will be addressed by the auditors as an observation since QIP 17.1 is currently being revised and the requirement will be removed in the revision.

In order to evaluate the system for processing package records (quality records) the auditors reviewed the only available package record. The review indicated that the KOH Technical Assistant did not issue the required checklist, Attachment 7.5 of QIP 17.1, in the preparation of the package record. Since the processing of this package record was not yet completed, the auditor allowed this deficiency to be corrected during the audit and thus no CAR was issued.

The evaluation of QIP 17.2 consisted of reviewing microfilming program records and interviewing the KOH Microfilm Supervisor. The auditor noted a vast improvement in this area since the KOH internal audit conducted in May 1990. No deficiencies were uncovered.

QIP 17.3 addresses the receipt and batching of OCRWM mail for indexing. In order to evaluate this area of the KOH program, the auditor effectively utilized the checklist prepared from Section 5.1 of QIP 17.3 and interviewed the KOH Document Processing Supervisor. The objective evidence reviewed to verify compliance with QIP 17.3 included batch record packages, KOH Indexing Manual, various indexing forms, Document Analysis Batch Log, and the only available quality record package.

A deficiency was identified by the auditors in the area of technical indexing. Section 5.2 of the QIP identifies several duties of the Technical Abstractor. The current KOH organization has no Technical Abstractor. The Abstractor's duties are currently being done by the Document Processing Supervisor and staff. The NRC staff raised the concern that the Document Processing Supervisor and staff may not be qualified to prepare new or modify existing abstracts. This concern will be addressed in the CAR prepared by the auditors on this topic.

#### 5.4 EXAMINATION OF TECHNICAL PRODUCTS

Due to the scope of the audit, there were no technical documents reviewed during the audit.

#### 5.5 CONDUCT OF AUDIT

The OCRWM audit was productive and performed in a professional manner. The audit checklists were comprehensive and included the QA controls addressed in the KOH QAP and QIPs. The audit team used the checklists effectively during interviews with KOH staff members. When necessary the auditors probed beyond the checklist questions to determine the operational aspects of the KOH program.

One area in which the audit could have been improved was the exit meeting. Due to the limited presence of the KOH upper management at the audit team/KOH management briefings, it would have been beneficial to hold a more formal and comprehensive exit meeting than was conducted. The NRC observer believes the following items would have significantly improved the exit meeting and enhanced the KOH management's understanding of the audit process and conclusions:

- (1) an overview of the audit scope and criteria evaluated,
- (2) a clear and concise summary chart (viewgraph or handout) showing the number of deficiencies and recommendations associated with each criteria, and
- (3) effectiveness conclusions for each criteria evaluated and the program overall.

#### 5.6 QUALIFICATION OF AUDITORS

The qualifications of the DOE auditors on the team are acceptable based on certification in accordance with procedure OCRWM Quality Assurance Administrative Procedure (QAAP) 18.1.

### 5.7 AUDIT TEAM PREPARATION

The QA auditors were well prepared in their areas of assigned responsibility and knowledgeable of the KOH QAP and QIPs. Audit Plan OCRWM HQ-91-001 was generally complete and included: (1) audit scope, (2) a list of audit team personnel, (3) a list of audit activities, (4) the KOH QIPs and QAP, and (5) audit checklists. However, it would have been beneficial to also include a copy of the KOH Internal Audit Report from the May 21-24, 1990 internal audit.

### 5.8 AUDIT TEAM INDEPENDENCE

The audit team members did not have prior responsibility for performing the activities they investigated and thus audit team independence was preserved.

### 5.9 SUMMARY OF NRC STAFF FINDINGS

#### (a) Observations

The NRC observer did not identify any observations relating to deficiencies in either the OCRWM audit process or the KOH QA Program.

#### (b) Weaknesses

- (1) The NRC staff believes it is important for the senior management of the audited organization to be present during the daily audit team briefing for the audited organizations' management. It is particularly important for the senior management to attend the entrance and exit meetings, even if it requires rescheduling the audit. The KOH Project Manager was absent from the entire audit with the exception of the exit meeting. Further, although the KOH Division Director was available he did not attend the entrance meeting and one of the audit team/KOH management briefings. The OCRWM Technical Project Officer (TPO) was not present at any of the audit team/KOH management briefings.
- (2) During the audit it was determined that from July 19 through August 20, 1990 and September 20 through December 1, 1990 KOH had no QA Manager nor acting QA Manager (see Section 5.3(a)). The NRC staff understands that KOH was actively trying to fill the QA Manager's position during this time period. However, the staff is concerned that KOH upper management did not recognize the need to appoint an acting QA Manager to oversee the QA program.
- (3) The inability of KOH upper management to complete required QA reading assignments in a timely manner was recognized and documented in at least three Training and Indoctrination Status Reports, and yet management took no action to resolve the

deficiency (see Section 5.10, CAR HQ-91-014). This deficiency was not acted upon by the OCRWM TPO in charge of the KOH contract.

- (4) The exit meeting presentations could have been improved. A summary of the audit scope, visual presentation of criteria evaluated and associated findings, and effectiveness summaries for each criteria would have enhanced the level of understanding between the audit team and KOH management (see Section 5.5).

#### 5.10 SUMMARY - DOE/YMPO AUDIT FINDINGS

The audit team identified a total of eight deficiencies requiring corrective action. The following CARs were generated:

<u>Programmatic Element</u>	<u>CAR #</u>	<u>Adverse Condition (Summary)</u>
1	HQ-91-013	KOH organizational chart does not reflect current organization.
1	HQ-91-018	KOH had no QA Manager from 7/19/90 - 8/20/90 and 9/21/90 - 12/1/90
2	HQ-91-014	Training documentation does not indicate that KOH Project Manager and Division Director have completed required training within established timeframe.
2	HQ-91-017	No evidence exists to demonstrate that KOH has a documented method for tracking the resolution of deficiencies identified during management assessment conducted by KOH in April 1990.
6	HQ-91-019	The CRF is not always listed as receiving an uncontrolled copy.
7	HQ-91-016	No evidence to justify sole source procurement of items or services.
16	HQ-91-015	Trend analysis program has not been developed.
17	HQ-91-020	"Technical Abstractor" position has been eliminated and responsibilities are carried out by untrained Document Analysts.



In addition to the CARs identified above, the audit team generated 13 recommendations. One recommendation each was generated for programmatic elements 5, 6, 7, and 16, while elements 17 and 18 had six and three recommendations respectively.