

# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## CORRECTIVE ACTION REQUEST

CAR No: 2005-5

Associated AR, SR, NCR No: AR 2005-1

**PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY**

Contrary to the requirements of QAP-005, Rev. 3, Chg. 0, the following discrepancies were identified:

1. Training requirements review for one consultant exceeded the due date of 3/18/05. (Ref. Form QAP-11-1)
2. Training in TOP-018 for two IMS personnel performing software installations has not been completed. (Para. 3.2.1)
3. CQAM program training was not documented for one SwRI auditor. (Para. 3.1.1 and related QAP-012, Para. 3.2)
4. Audit Observer Training for one staff member who has been involved in observation audits was not documented or could not be located. (Ref. TOP-025, Rev. 0, Chg. 0, Para. 4.2.1)
5. Previous findings related to training issues: See NCR 2004-09 and NCR 2004-14.

Initiated by: R. Weber

Responsible Individual: B. Brient

Date: May 18, 2005

Response Due: June 15, 2005

**PART B: PROPOSED ACTION****Discussion:**

Observation 1. QAP-005, 3.3.1 requires that "Training needs shall be reassessed when work assignments are changed, at a minimum, after Operations Planning activities." Consistent with this requirement, the QAP-11-1 form indicates the review will be completed "each year." In practice, consultants are reviewed when their consulting agreements are renewed annually, which is typically 12-14 months after the previous agreement.

In the case identified during the audit, the consulting agreement had not been renewed and no work had been assigned after 3/15/2005. Renewal of the consulting agreement was in progress. If an agreement is executed, training needs will be reassessed before work is started. The condition observed during the audit was not unusual and does not violate QAP-005. This condition is not a nonconformance, and no additional analysis is necessary.

Observation 2. TOP-018 was changed recently to specify that IMS personnel will install acquired software and perform installation testing in most circumstances. The need for training to TOP-018 for these individuals was not recognized when TOP-018 was revised.

Observation 3. The SwRI auditor has been performing services for Division 20 since 1990. This is <sup>QAP 5/31/05</sup> solely a case of missing documentation.

Observation 4. R. Fedors' qualification file included evidence of observation audit training dated 1/18/2000. The record was overlooked during the audit because it was a memo rather than a certificate. No additional analysis is necessary.

Observation 5. NCR 2004-09 pertained to SwRI Publications staff not receiving indoctrination when their work assignments changed to quality affecting activities. NCR 2004-14 was in regard to a missed annual review of Professional Personnel Qualifications for one person. These previous findings are very weakly related to the audit observations, so do not suggest recurring conditions.

**1) Extent of Condition:**

Observation 2: No other recent procedure changes involved changing or adding responsibilities that would affect procedure assignments or training. No other occurrences were identified.

Observation 3: All active Division, SwRI, and consultant/subcontractor qualification files were reviewed to confirm evidence of indoctrination, QAP-11 and QAP-11-1 forms, and yearly reviews. Aside from the individual identified in the audit (R. Weber), no other discrepancies were identified.

**2) Root Cause:**

Observation 2: The need for additional procedure assignment was not recognized when the responsibilities of IMS personnel were identified in TOP-018.

Observation 3: Since only one occurrence was identified during the audit and in the subsequent extent of condition analysis, remedial action is adequate and a root cause analysis is not necessary.

**3) Remedial Action:**

Proposed Completion Date:

6/15/2005  
LOS

Observation 2: Assign TOP-018 to affected IMS personnel and provide appropriate training.

Observation 3: Prepare an explanatory memorandum to the qualification file of the affected individual to substitute for the missing documentation.

**4) Corrective Action to Preclude Recurrence:**

Proposed Completion Date:

7/30/2005  
LOS

Observation 2: Revise QAP-002, 3.5, Quality Assurance Review, to include review of training needs associated with new or revised procedures.

Manager/Director:



Date:

5/31/2005

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PART C: APPROVAL  
Comments/Instructions

Director of QA:

Date:

## PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

TOP-018 is now assigned to INS personnel.  
An explanatory memo has been added to the  
personnel file for the individual missing the documentation.  
QAP-002 para 3.5 has been changed to include review of  
training needs associated with new or revised procedures.

Verified By:

Date: 8/8/05

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ORIGINATOR

GED MANAGEMENT