

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No. 94-04 Associated AR,SR,NCR NO. N/A

PART 1: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

See attached.

Initiated by: Rodney M. Weber  Date: 4-29-94

PART 2: PROPOSED ACTION

Responsible Element Manager: McKague

a) Root Cause:

b) Corrective Action to Preclude Recurrence:

SEE ATTACHED. Target Date for Completion: _____

Response provided by: _____ Date: _____

PART 3: APPROVAL

Comments/Instructions:

Director of QA:  Date: 5/30/94

PART 4: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

memorandum, dated 6/2/94, sent from B. Sogon to Element managers to emphasize the procurement control requirements, especially as they apply to analytical services.

Verified by:  Date: 6/3/94

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

**Attachment to
CORRECTIVE ACTION REQUEST
No. 94-04**

Part 1: During the assessment of CQAM Section 7, "Procurement Control," the following discrepancy was noted:

The procurement of analytical services from Florida International and Arizona State University are not controlled in a manner that verifies the accuracy of the results.

Initiated by: Rodney M. Weber

Date: 4-29-94

Attachment to CAR 94-04

a) Root Cause: The Principal Investigator was not aware of the requirement to either send blind standard samples or to qualify the supplier prior to issuing a purchase order. Blind samples may be used for work by Florida International University, and it may be a candidate for qualification since it is an EPA accepted laboratory. The work at Arizona State University was a trial to determine if the procedure could be used for the specific application of the CNWRA. This should have not been considered a quality affecting activity because of its developmental status.

b) Corrective Action to Preclude Recurrence: By virtue of this CAR, the P.I. is now aware of procurement control requirements. In addition, the Technical Director shall issue a memorandum to P.I.s reminding them of procurement control requirements, particularly as they apply to analytical services.

The next procurement from Florida International University shall include blind standards and duplicate samples to verify the accuracy and precision of their analysis. If development of the technique at Arizona State University proves successful, means to qualify that laboratory will be explored.

Response provided by: A. Lawrence McKeay Date: 5/26/94

Target date for completion: 6/30/94

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

MEMORANDUM

To: CNWRA Principal Investigators June 2, 1994

From: B. Sagar, Technical Director *B. Sagar*

Subject: Requirements for Procurement of Analytical Services

The internal QA program audit conducted in early May, 1994, identified several situations in which analytical services had been obtained from outside the CNWRA without proper procurement controls. This memo is being provided to remind you of the applicable requirements, and to direct you to the QA staff for any questions that you may have. The following requirements are based on QAP-016, Procurement Control.

For services obtained from other Divisions of Southwest Research Institute, a work order or similar document must be used to specify the technical and quality requirements that apply to the work to be done. The work order shall identify the samples to be analyzed by identification number, the specific method to be used (or reference a standard method), and any other instructions. The work order must also indicate that the work must be performed in accordance with the CNWRA QA program or under the SwRI Nuclear QA Program. Most importantly, personnel performing the activities must be qualified and instruments calibrated under one or the other of the QA programs.

For analytical services obtained from outside suppliers, two methods may be used.

(1) The services can be obtained from a supplier that has been qualified by the CNWRA QA staff or under the SwRI Nuclear QA Program. Such a supplier will have a QA program, and the purchase order shall specify that the work be performed under that QA program. The CNWRA QA staff is also required to approve these purchase orders. The CNWRA has qualified only one supplier, the University of Arizona, for rock mechanics testing. I am not aware of any SwRI qualified suppliers that we have used for analytical services.

(2) Alternatively, services may be obtained from a supplier that has not been qualified by CNWRA QA if the burden of quality proof is carried by the CNWRA (instead of by the qualified supplier). This is done by sending blind (to the supplier) known samples and blind duplicate samples, in all, at least 10% of the total samples sent for analysis. Acceptable tolerances for accuracy (the difference between the know value and its analysis result) and precision (the difference between duplicate results) will be determined before the results are provided by the supplier. Upon receipt of the results, the P.I. is required to determine the actual accuracy and precision, and compare them to the acceptable tolerances. If the tolerances are met, the results of the "lot" of samples is accepted, otherwise the results must be discarded. The Scientific Notebook shall be used to document this acceptance process.

If neither of these methods appears to be implementable, the Director of QA should be consulted to identify other acceptable procurement options.

cc: Directors, Element Managers

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