

# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## CORRECTIVE ACTION REQUEST

CAR No: 98-02

Associated AR,SR,NCR No: Audit Report 98-01

**PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY** Contrary to the requirements of QAP-006, Paragraphs 3.1.1 and 3.1.3, materials requiring controls under this procedure are not being inspected by Quality Assurance personnel. In addition, QAP-016, Paragraphs 4.1.1, 4.1.2 and 4.1.4, require that complete and appropriate information, as defined by this procedure, be included on purchase orders. Contrary to the procedure, quality requirements are not being included on purchase documents.

Initiated by: T. Trbovich

Date: 6/26/98

**PART B: PROPOSED ACTION**

Responsible EM: B. Mabrito  
Response Due: 07/27/98

1) Extent of Condition:

See attached page.

2) Root Cause:

See attached page.

3) Remedial Action:

Proposed Completion Date: N/A

See attached page.

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 12/11/98

See attached page

Element Manager: [Signature]

Date: 7/24/98

**PART C: APPROVAL**  
Comments/Instructions

*Starting in August, 1998, input was taken from CNWRA Technical staff and Financial support staff to determine a better system to ensure quality procurements. Several drafts were written and segments were discarded in the process of arriving at a new QAP-016 Rev 1.*

Director of QA: [Signature]

Date: 11/25/98

**PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION**

*On Nov. 19, 1998, Quality Assurance Procedure - 016, Titled Procurement Control, was issued as Revision 1 to key CNWRA staff. QAP-006, Rev 1, Acceptance and ID of Procured Items and Samples, was also superseded by this new procedure.*

Verified by: [Signature]

Date: 11/25/98

*J.C. [Signature]  
12/3/98*

*Distribution: Element Managers  
B. Sagar / H. Garcia  
W. Patrick  
T. Trbovich / 30*

July 24, 1998

CAR 98-02

PART B: PROPOSED ACTION

- 1) **Extent of Condition:** In 1993, the CNWRA QA staff made a conscious decision not to inspect chemical standards, reagents and chemical supplies upon receipt. At that time, the CNWRA put the following statement in the CNWRA QA Manual: "Note: Standard laboratory reagents and supplies are considered to have sufficient purity and accuracy such that procurement controls are not applicable." This statement was made after almost four years of performing QA receiving inspections on procured chemicals and finding no quality problems whatsoever. A couple of times the shelf life date on one bottle was only 4-6 months into the future and those chemicals were returned to the vendor with a request to provide the requested reagents with a longer shelf life. Since that change in the QA Manual, CNWRA technical staff have been accepting the ordered chemicals and no quality problems have been reported whatsoever. The controls on received materials appears to be adequate. Further, it should be noted that consulting agreements and subcontracts for technical staff services are based on the concept that the individual is qualified under the CNWRA QA Program and receives QA Indoctrination, and the work is fully conducted under the CNWRA QA Program. All CNWRA management staff work under this approach.
- 2) **Root Cause:** There has been reliance on CNWRA technical staff to receive procured items and they can better determine the acceptability of chemicals, reagents, standards and other procured materials. This is in concert with the general trends in QA today and maintains a smaller QA overhead in Division 20. The root cause of this CAR is, however, the fact that the QA Procedures were not updated in a timely manner.
- 3) **Remedial Action:** None anticipated. There has not been a specific materials/purchase order/consultancy problem identified, only the fact that QA staff have not been implementing the Quality Assurance Procedures -006 (Acceptance and Identification of Procured Items and Samples) and -016 (Procurement Control) adequately.
- 4) **Corrective Action to Preclude Recurrence:** Rewrite or eliminate one or both of the procedures listed in 3) above. In the corrective action process, procurement methods utilized at the SwRI level will be studied and, to the extent possible, they will be referenced in the revised procedures. This may mean greater reliance on SwRI systems to ensure the procured items or services meet the needs of the CNWRA in order to produce a quality product.



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**Title QAP-016 PROCUREMENT CONTROL**

EFFECTIVITY

Revision 1 of this procedure became effective on 11/16/98. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
All	0	11/16/98

*11/16/98*

Supersedes Procedure No. QAP-006 Rev 1 and QAP-016 Rev 0

Approvals			
Written by  Bruce Mabrito	Date 11/18/98	Technical Review  English Pearcy	Date 11/18/98
Quality Assurance  Mark Ehstrom	Date 11/18/98	Cognizant Director  Henry Garcia	Date 11/18/98

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**QUALITY ASSURANCE PROCEDURE**

QAP-016 PROCUREMENT CONTROL

1. PURPOSE

The purpose of this procedure is to describe the controls for the procurement of materials, items, equipment, and services important to licensing. This procedure implements the requirements of the CNWRA Quality Assurance Manual (CQAM), section 7.

2. RESPONSIBILITIES

- 2.1 Requestor of procurement action(s) is responsible for providing required technical and/or scope of work requirements for the procurement documents.
- 2.2 The Director of Quality Assurance (QA) is responsible for providing quality requirements in procurement documents, if required.
- 2.3 Element Managers and the cognizant Directors are responsible for approving purchase requisitions, if required.
- 2.4 The Southwest Research Institute (SwRI) Purchasing Department is responsible for preparing Purchase Orders.

3. DISCUSSION

In fulfilling its mission, the CNWRA utilizes highly-qualified internal staff, and SwRI and "outside" consultant scientists and engineers to perform work that is integrated into CNWRA reports and products. The consultants must meet strict conflict of interest (COI) criteria to ensure they have no COI. Such individuals are qualified through CNWRA QA Procedure, (QAP)-007, Professional Personnel Qualification, and receive QA indoctrination to work under the CQAM controls and methodology. Individuals employed by corporations (subcontractors) are individually qualified through the same above referenced process. It is important to recognize that the bulk of such quality-affecting procurement activities are associated with individuals identified as CNWRA consultants or subcontractors.

Other procurement activities potentially affecting quality include scientific investigations, experiments, tests, and analytical services. Those results are accepted or rejected by the CNWRA Principal Investigator (PI) who is in the best position to determine the true quality of the work. This activity is described in section 7.1.2 of this procedure.

Calibrations that need to be traceable to a national or international standard (e.g., National Institute for Standards and Technology) shall be purchased from organizations selling such services. In all calibration procurement activities, the CNWRA shall utilize the SwRI Approved Supplier List (ASL), maintained by the SwRI QA Department.

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Standard laboratory reagents, supplies, and glassware are considered by the CNWRA to have sufficient purity and accuracies that procurement controls are not applicable.

It should be noted that "Subcontract Submission and Approval" and "Consultant Agreement Submission and Approval" are controlled by CNWRA Administrative Procedures (AP)-005 and -006, respectively.

**4. PROCUREMENT PLANNING**

**4.1 Procurement Controls**

4.1.1 Controls for procurement documents shall be applied to the following:

- Scientific investigations, experiments and tests
- Chemical and laboratory analyses and tests
- Special processes, such as welding, heat treating, and nondestructive testing
- Calibration services
- Samples and test materials used in scientific investigations

**4.2 Procurement of Services**

4.2.1 The services of individuals performing activities affecting quality, which may include analyses, technical or peer reviews, or similar activities, are controlled in accordance with CQAM, section 2.6.

4.2.2 Experimental, test, analytical laboratory, and special process services may be purchased from approved suppliers listed on the SwRI ASL, commercial-grade suppliers, or universities or other sources determined to be qualified by the CNWRA PI. If the PI requests such work to be accomplished from a supplier not listed on the ASL, the PI has the responsibility to provide blind standards or duplicate samples to determine analytical accuracy and precision (see paragraph 7.1).

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4.3 Procurement of Materials, Items and Equipment

Materials, items and equipment (such as steel plate, welding wire, test instruments, etc.) may be accepted from approved sources on the SwRI ASL as specified in paragraph 7.2.1. Procurement of materials, items and equipment from commercial-grade suppliers shall be accepted as specified in paragraph 7.2.2 of this procedure.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When a purchase of affected material, equipment, or services is desired, the Requestor shall identify the following on the Purchase Requisition (or on an attachment to the requisition), depending on the type of procurement:

- Scope of work, or detailed description of materials, equipment, or services required
- Applicable codes, regulations, specifications, standards, or technical requirements
- Certification requirements for chemical and physical properties
- Requirements for certification of special processes
- Requirements for special documentation

5.1.2 If the Purchase Requisition references documents such as drawings, specifications, or requests for quotations and proposals, legible copies of these should be provided to the person developing the requisition.

5.2 Procurement Document Review

5.2.1 Specifically for procurement of services through subcontracts, the Director of QA shall include an appropriate Purchase Requisition Quality Requirements statement which reads (to the effect): "Work/activities performed by xxx xxx (company name or individual) shall be governed by the CNWRA QA system, which includes CNWRA QA indoctrination and CNWRA Professional Personnel Qualification. If there are any QA-related questions, please contact CNWRA QA immediately."

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- 5.2.2 Approved Purchase Requisitions shall be forwarded to the SwRI Purchasing Department, which shall transfer purchase requisition requirements verbatim and transmit the order.
- 5.2.3 Procurement document changes to the scope of work, quality, or technical requirements shall be approved in the same manner as originals.

**6. SUPPLIER SELECTION AND QUALIFICATION**

**6.1 Approved Suppliers of Materials, Items and Equipment**

- 6.1.1 The SwRI QA Department shall maintain the ASL. The ASL identifies suppliers of material, items and equipment determined by approved methods (e.g., audit and other methods) that are qualified to supply SwRI with acceptable products. The ASL also tracks suppliers who consistently provide products in accordance with specific technical requirements. Supplier qualification shall be based on meeting the requirements set by the PI or Project Manager demonstrating consistent conformance to technical requirements.
- 6.1.2 The SwRI ASL can be used to determine appropriate and competent suppliers of products based on the audits that are performed and the trending that is maintained by the SwRI QA Department.

**6.2 Commercial-Grade Procurement**

Commonly available materials, items or equipment which can be ordered based on the supplier's published descriptions are termed commercial grade. Commercial-grade materials, items and equipment shall be purchased from suppliers identified by the PI as meeting his or her requirements, however, the supplier shall provide appropriate supporting documentation on the supplied material, item or equipment.

**7. ACCEPTANCE OF SERVICES AND ITEMS**

**7.1 Acceptance of Services**

- 7.1.1 Acceptance of calibration, test, laboratory analysis, and special process services from qualified suppliers shall be based on the appropriate CNWRA technical staff review upon receipt of vendor-supplied documentation, such as calibration certificates, analysis reports, or heat treatment reports and logs to verify compliance with purchase order document requirements. Acceptance documentation shall include the identification of the supplier, reference to the purchase document, the items or services supplied, and the results.

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7.1.2 Analytical services procured from commercial-grade sources shall be accepted based on inspections and tests performed upon receipt to verify conformance to procurement document technical requirements. Blind standards and duplicate samples can be utilized to determine analytical accuracy and precision, which shall be evaluated against limits determined by the cognizant PI prior to issuance of the purchase document. Check samples composed of approximately 10 percent of the total number of the unknown samples can be utilized along with other methods, to "bracket" and verify the analysis to provide confidence in the results. In cases where blind standards are not possible, the testing shall be to nationally or internationally accepted test methods or a manufacturer's instrument instructions. Evidence of calibration and process control, along with identification of the test method, shall be recorded with the analysis data and provided to the CNWRA PI.

7.2 Acceptance of Materials, Items and Equipment

7.2.1 Items received from ASL-qualified suppliers shall be accepted based on review of the supplier's inspection and/or test reports by the PI. The review shall verify that both technical and documentation procurement requirements are satisfied. The PI or other receiving person shall show acceptance by initialing and dating the Material Received Report (MRR). The MRR will then be forwarded to the CNWRA Financial Clerk who maintains the MRRs.

7.2.2 Materials, items and equipment procured from commercial-grade sources shall be accepted based on inspections and/or tests performed by the CNWRA technical staff upon receipt to verify conformance to procurement document technical requirements. The technical staff person responsible for acceptance shall initial and date the MRR. The MRR will then be forwarded to the CNWRA Financial Clerk who maintains the MRRs.

7.3 Acceptance Documentation

Acceptance documentation shall either be recorded or placed in scientific notebooks or project record files. Acceptance documentation can include receiving inspections, test reports, copies of MRRs, reports from an analysis organization, and observations of the received item that can discern whether it meets the CNWRA requirements.

7.4 Control of Subcontractor or Consultant Nonconformances

7.4.1 Subcontractors and consultants shall be required to notify CNWRA of nonconformances to procurement document requirements. Notification shall include a description of the nonconformance, recommended disposition, and technical justification. The nonconformance shall be processed in accordance with QAP-009, Nonconformance Control (CNWRA Form QAP 9-1), to obtain the proper evaluation, disposition, and corrective action.

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- 7.4.2 Nonconformances identified during receiving acceptance activities from commercial-grade suppliers shall also be processed in accordance with CQAM section 15.
- 7.4.3 Copies of supplier Nonconformance Reports shall be included in the receiving acceptance files. Nonconformances can be considered in qualified supplier performance evaluations.
- 7.4.4 Supplier nonconformances shall be evaluated individually to determine if the product or service should not be utilized by the CNWRA.

**8. RECORDS**

- 8.1 ASL supplier files shall be maintained by the SwRI QA Department.
- 8.2 Purchase documentation shall be maintained by the SwRI Purchasing Department.
- 8.3 Acceptance documentation shall be maintained by the PI or CNWRA staff member in the appropriate scientific notebook or project files. The MRR shall be maintained by the CNWRA Financial Clerk for the period determined for administrative records.
- 8.4 Any quality records (i.e., surveillance reports, nonconformance reports, corrective action requests) generated as a result of the procurement process shall be maintained by CNWRA QA in the QA Records Room. CNWRA Scientific Notebooks which contain related procurement project information are turned in to QA following completion of the project work and maintained as QA Records.

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**Date:** 11/20/98  
**Sender:** Bruce Mabrito  
**To:** #DIRS-MGRS, #SA-WO\_TECH  
**bcc:** Mabrito, Bruce, Ehnstrom, M., awhiting@swri.edu, Castro, John, Maldonado, Paul,  
#SA-WO\_SUPPORT  
**Priority:** Normal  
**Subject:** Procurement Control Procedure QAP-016

The Procurement Control Procedure of the CNWRA has been revised and has been issued this week. QAP-016, Revision 1, Procurement Control, addresses the controls for the procurement of materials, items, equipment and services important to licensing. This QAP-016 is a revision of our earlier procedure, which was found lacking during our annual QA audit earlier this year, and also replaces QAP-006, Acceptance and Identification of Procured Items and Samples.

QAP-016 specifies that procurement controls are required for: (i) scientific investigations, experiments and tests; (ii) chemical and laboratory analyses and tests; (iii) special processes, such as welding, heat treating, and nondestructive testing; (iv) calibration services; and (v) samples and test materials used in scientific investigations. The procedure allows utilization of the SwRI Approved Supplier List (which I am putting on circulation today) and from other sources determined by the purchaser. Since we order the vast majority (if not all) of our chemicals for the CNWRA Labs from Fisher Scientific, and since they are on the ASL, no special requirements are placed on our staff (the ASL has about 200 firms that are periodically checked and QA verifies that they have been providing SwRI with acceptable products/services).

QAP-016 details the process that is to be used to order services, materials, items and equipment. CNWRA QA will work closely with John Castro and others in the procurement system to ensure compliance with this procedure. Each Element Manager has a copy of this procedure and I encourage you to review it prior to you next procurement. If you have questions, please call me at x 5149. Bruce Mabrito