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Title

QAP-018 PROCEDURE FOR CONFIRMATORY ANALYSES

EFFECTIVITY AND APPROVAL

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Approvals

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CNWRA Form QAP 1-1 (12/92)

QAP–018 PROCEDURE FOR CONFIRMATORY ANALYSES

1. PURPOSE

The purpose of this procedure is to describe and establish the process used by the CNWRA to ensure procured chemical standards and materials that are quality-affecting meet the specifications and critical characteristics required for their use in analyses and experimental activities. This procedure also describes the method used to identify items that require confirmatory analyses (CA).

2. RESPONSIBILITY

The Director of Quality Assurance (QA) and the cognizant principal investigator (PI) are responsible for implementing this procedure and for complying with its provisions. The PI or Element Manager (EM) is also responsible for determining the specifications and critical characteristics of chemical standards verified through CA when different from the manufacturers' specifications. QA shall approve the CA specifications determined by the PI and shall maintain and store the Confirmatory Analyses Log Book.

3. PROCEDURE

3.1 Procurement Document Review

3.1.1 When the purchase of quality-affecting chemical standards or materials is required, it should be documented on a purchase requisition and shall follow the normal requisition process as outlined in QA Procedure 16, Procurement. In addition, the purchase requisition shall be stamped to indicate if the order is being placed with a vendor on the Southwest Research Institute Approved Suppliers List (ASL) and if CA is required. The QA representative stamps the purchase requisition.

3.1.2 If the chemical standards or materials are to be purchased from a supplier listed on the ASL, the requisition shall reference the need to supply a certificate of conformance/analysis (COC/COA). This requirement shall be placed on the requisition by the reference of the SwRI Q-Note Numbers 3, 4, and/or 51 (specifically for chemical analyses).

3.1.3 When the chemical standards or material(s) are to be purchased from a supplier that is not listed on the ASL, the cognizant PI and QA shall assure that the CA process described in Paragraph 3.2 or 3.3 is implemented.

NOTE:

Suppliers listed on the ASL shall initially only be required to provide a COC/COA for acceptance of chemical standards and materials. Taking into consideration past performance of the suppler, quality trends, availability of methods/sources for CA, and related factors, CA may also be required for purchases from suppliers listed on the ASL. Not all chemicals, chemical standards, and materials can be readily analyzed. A memorandum from the PI or EM that describes the acceptance method to be used for the items shall be sent to the Director of QA and retained in the Confirmatory Analyses Log Book.

3.2 Confirmatory Analyses Sample Acquisition

When chemical standards and materials that are quality-affecting are purchased from a supplier not on the ASL, the supplier's product shall undergo confirmatory analysis. This process will document the acceptability of the product being used, verify that the product procured meets the specifications required for its use, and confirm that the supplier consistently delivers an acceptable product.

CA shall be required for chemical standards and materials obtained from a supplier not on the ASL until at least three consecutive satisfactory CA results have been obtained.

3.2.1 Three consecutive CA results may be obtained from a single order of multiple items from a given supplier. These items may be representative of potential future purchases by the CNWRA from that supplier, but need not be exactly the same. Catalogs or other company literature shall be reviewed to identify items that may be purchased from the supplier.

3.2.2 To verify specifications on the purchase order through the CA program, the cognizant PI/EM should contact a testing laboratory on the ASL or an appropriate SwRI testing laboratory to ensure that the product(s) to be purchased can be satisfactorily tested and to determine appropriate testing methodology and specifications.

3.2.3 The purchase requisition shall reference Q-note Numbers 3, 4, and/or 51 (specifically for chemical analyses) that will require the supplier to provide a certificate of conformance/analysis for the procured items. The purchase requisition will be stamped to indicate if the order is being placed with an ASL vendor and also if CA is required.

3.2.4 Direction shall be provided in the instruction area of the purchase requisition to hold the item until a satisfactory CA has been performed. The chemical standard or material can be used prior to receipt of the CA with the risk that the work may be invalidated by an unsatisfactory CA result. If CA identifies an inconsistency, a nonconformance report will be initiated to document the actions taken to either accept or reject the chemical standard or material and what impact the use of that material had on any tests performed.

3.2.5 The requisition number, purchase requisition date, supplier, type of product being requested, and acceptance or rejection of the material, as based on CA, shall be documented in the Confirmatory Analyses Log Book data record (see sample).

3.3 Alternative Method for Placement on ASL

The Director of QA shall collect pertinent information necessary to compile a list of prospective suppliers of chemical reagents used in routine tests, chemical standards, and materials important to licensing as well as a list of typical products that are purchased or anticipated to be purchased from the proposed suppliers. This information may be collected through input from the PI, CNWRA or SwRI staff, or a review of previous purchase requisitions. Typical products from the prospective suppliers will be purchased and analyzed. The status of the prospective suppliers will be determined from the results of the CA. Suppliers that satisfactorily meet the criteria established by the CA procedure, will become approved suppliers quality-affecting of chemical reagents, chemical standards and materials. The list of approved suppliers will be placed on the SwRI ASL. Follow-up CA of suppliers of these products will be conducted as needed.

4. RECEIVING INSPECTION

4.1 The receiving inspection process will be performed in two steps. The first receiving inspection occurs when the chemical standard or material is received at the CNWRA from the supplier. Receiving inspection at this time will assure that the appropriate chemical standard or material has been sent (i.e., the identification of the standard or material) and the shipment contains the required documentation. The second receiving inspection step is described below.

4.1.1 When a chemical standard or material that was previously identified as requiring CA is received at the CNWRA, the PI will notify the Director of QA.

4.1.2 An appropriate amount of the chemical standard or material shall be sent to an ASL test laboratory or SwRI test facility capable of performing the CA to verify product specifications cited on purchase order.

4.1.3 Acceptance of the chemical standard or material shall be performed by the appropriate PI and shall be based on a review of product specification received from the original supplier and the test results received on the CA of the chemical or material. When both sets of information are within satisfactory limits, the chemical or material can be accepted for use.

4.1.4 The PI shall inform the Director of QA of the results of the CA. The Director of QA shall annotate the results of the analyses in the Confirmatory Analyses Log Book.

4.1.5 If the CA identifies unsatisfactory results, the material/chemicals shall be removed and segregated to prevent future use, and a nonconformance report shall be initiated to document the discrepancy. The NCR shall also determine whether the chemical standard or material can be used for the intended purpose.

4.2 Establishment of Satisfactory History

Once a supplier not previously listed on the ASL has obtained three satisfactory CAs, that supplier shall be placed on the SwRI ASL. In addition to requirements SwRI places on suppliers listed on the ASL, the CNWRA will require that a product sample be processed through CA every 18 months after initial qualification or on the first purchase after that period. Satisfactory results will qualify that supplier for another 18 months without additional CA.

5. RECORDS

The original analyses and the corresponding CA documentation shall be placed in the Confirmatory Analyses Log Book. Copies of these documents may be placed in the appropriate scientific notebook. The Confirmatory Analyses Log Book shall be maintained as a QA record in accordance with CQAM Section 17.

CONFIRMATORY ANALYSES LOG

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Requisition No.	Date	Item Tested	Supplier	PI/EM	Test Requirements	Test Performed By	Accept/Reject

Sample