CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-016 Revision 0 Chg. 0 Page 1 of 7

Title

QAP-016 PROCUREMENT CONTROL

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 10/5/93. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
A11	0	10/5/93

SUPERSEDED

Superseded by Rev 1 Chg 0 11/16/98

Supersedes Procedure No. N/A

Approvals

Written By	Date	Technical Review	Date
RD Brett	10/5/93	[signature]	10/5/93
Quality Assurance	**Date**	**Cognizant Director**	**Date**
[signature]	10/5/93	[signature]	10/5/93

CNWRA Form QAP-1

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 to be used in the conduct of activities affecting quality. This procedure implements the requirements of the CNWRA Quality Assurance Manual, Section 7.

2 RESPONSIBILITIES

2.1 Requestors of purchases are responsible for providing required technical and scope of work requirements for purchase documents.

2.2 The Director of QA is responsible for providing quality requirements in procurement documents, approving affected purchase requisitions and qualifying suppliers.

2.3 Element Managers and cognizant Directors are responsible for approving purchase requisitions.

2.4 The Institute Purchasing Department is responsible for preparing Purchase Orders.

3 PROCUREMENT PLANNING

3.1 Application of Procurement Controls

3.1.1 Controls for procurement documents, selection and evaluation of suppliers, and acceptance of procured items and services shall be applied to the following:

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

Note: Standard laboratory reagents and supplies are considered to have sufficient purity and accuracy such that procurement controls are not applicable.

3.1.2 Services obtained from SwRI departments outside the CNWRA shall be initiated through work orders or similar methods. These documents shall provide adequate description of the scope of work, technical requirements, and applicable QA program requirements.

3.2 Procurement of Services

3.2.1 The services of individuals performing activities affecting quality, which may include analyses, technical or peer reviews, or similar activities are controlled in accordance with the CQAM. The procurement controls of this procedure shall not be applied to consultant professionals, who shall be treated as staff and shall be qualified in accordance with CQAM Section 2.6.

3.2.2 Experimental, test and analytical laboratory, calibration, and special process services may be purchased from suppliers qualified in accordance with paragraph 5.2 of this procedure, or from commercial-grade suppliers (see paragraph 5.1).

3.3 Procurement of Items

Items may be purchased from qualified sources having a QA program meeting applicable portions of 10 CFR Part 50, Appendix B, or from commercial-grade suppliers, and shall be accepted as specified in section 6 of this procedure.

4 PROCUREMENT DOCUMENT CONTROL

4.1 Initiation of Purchases

4.1.1 When a purchase of affected material, equipment, or services is desired, the Requestor shall identify the following on the purchase requisitions, depending on 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 of chemical and physical properties.
- Requirements for certification of special processes.
- Requirements for special documentation.

4.1.2 If necessary, requirements may be specified by reference to other documents.

4.1.3 If the purchase requisition references other Institute documents such as drawings, specifications, or requests for quotations/proposals, legible copies of these should be provided to the Requisitioning Agent.

4.1.4 For purchases to be obtained from, or requiring qualified suppliers, the Director of QA shall include, on the purchase requisition, requirements for the following:

- Application of the supplier's qualified QA program to the order.
- A description of those nonconformances from the CNWRA procurement requirements dispositioned as "accept as is" or "repair."
- Provisions for access to an organization's facility.
- Any other pertinent information required to ensure receipt of a quality product suitable for the intended use.
- Requirements that a qualified supplier is used.

4.1.5 When a qualified supplier is required, and no qualified supplier exists, the Director of QA shall perform the necessary evaluations for qualification in accordance with Section 5 of this procedure, prior to the initiation of activities affecting quality.

4.2 Procurement Document Review

4.2.1 The Element Manager responsible for the purchase and the cognizant Director shall approve the purchase requisition. The Director of QA shall review purchase requisitions which require qualified suppliers.

4.2.2 Approved purchase requisitions shall be forwarded to the Institute Purchasing Department, which shall transfer purchase requisition requirements verbatim and transmit the order. When applicable, the order shall be placed with a qualified supplier.

4.2.3 Procurement document changes to the scope of work, quality, or technical requirements shall be approved in the same manner as originals.

5 SUPPLIER SELECTION AND QUALIFICATION

5.1 Commercial-Grade Procurement

Commonly available items or services which can be ordered based on the supplier's published descriptions are termed commercial-grade. Commercial grade items and services shall

be purchased from either suppliers qualified in accordance with paragraphs 5.2 and 5.3, and shall be accepted in accordance with paragraph 6.1.1 or 6.2.1, or, any (non-qualified) supplier and accepted in accordance with paragraph 6.1.2 or 6.2.2.

5.2 Qualified Suppliers

5.2.1 Supplier qualification shall be based on one or more of the following criteria:

(a) Documented history of providing identical or similar products meeting the technical requirements of the procurement documents. Non-qualified suppliers of commercial grade items may be upgraded to qualified suppliers by demonstrating consistent conformance to technical requirements.

(b) Evaluation of the supplier's technical and quality capability as determined by a survey (or audit) of the facilities, personnel, and implementation of the quality assurance program.

(c) Qualification in accordance with the SwRI NQAPM (inclusion on the SwRI Qualified Vendors List).

5.2.2 Satisfactory history shall be established through 100-percent verification of technical characteristics through receipt inspection, test, or validation of documentation.

5.2.3 Supplier capability determinations shall be determined through receipt and programmatic evaluation of a controlled copy of the supplier's quality program manual, and a source survey (audit) conducted in accordance with CQAM Section 18. The evaluation shall determine which criteria of 10 CFR Part 50, Appendix B are applicable to the service or items to be procured, and shall determine if the quality program and implementation satisfy the applicable criteria.

5.2.4 Initial qualification of suppliers shall be approved by the Director of QA, and shall be documented by objective evidence of compliance to this section.

5.3 Qualified Supplier Performance Evaluation

5.3.1 Qualified suppliers of services shall be periodically evaluated to verify continued satisfactory performance. Verification shall be by audits conducted in accordance with CQAM Section 18. Audits shall be scheduled every three years, or as determined by the Director of Quality Assurance, based on the criticality of the services procured, the level of work, and the supplier's performance history. Annual telephone surveys shall be conducted to determine

whether changes have been made in the Supplier's QA program or organization that may necessitate re-audit.

5.3.2 Qualified suppliers of materials, parts, and items shall be periodically evaluated based on performance and by audits or verification of quality conformance. Verification of quality conformance shall confirm that vendor-supplied inspection or test certifications are valid. Validation shall be performed by duplicate inspection or test, as applicable, of every fifth lot of items received, or once every six months, whichever occurs more frequently.

5.3.3 Qualified supplier records shall document the method of vendor performance verification.

6 ACCEPTANCE OF ITEMS AND SERVICES

6.1 Acceptance of Services

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

6.1.2 Services procured from commercial-grade sources shall be accepted based on inspections and/or tests performed upon receipt to verify conformance to procurement document technical requirements. Blind standards and duplicate samples shall be utilized to determine analytical accuracy and precision, which shall be evaluated against limits determined by the cognizant Principal Investigator prior to issuance of the purchase document. Check samples shall compose at least 10% of the total number of samples.

6.2 Acceptance of Materials, Parts and Items

6.2.1 Items received from qualified suppliers shall be accepted based on review of the supplier's inspection and/or test reports. The review shall verify that procurement document technical and documentation requirements are satisfied.

6.2.2 Materials, parts, and items procured from commercial-grade sources shall be accepted based on inspections and/or tests performed upon receipt to verify conformance to procurement document technical requirements.

6.3 Acceptance Documentation

Receiving files shall be maintained of supplier's documentation, receiving inspection and test reports, and other documentation associated with the acceptance of materials, equipment, items, and services.

6.4 Control of Supplier Nonconformances

6.4.1 Qualified suppliers shall be required to notify SwRI 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 CQAM Section 15 to obtain the proper evaluation, disposition, and corrective action.

6.4.2 Nonconformances identified during receiving acceptance activities shall be processed in accordance with CQAM Section 15.

6.4.3 Copies of supplier Nonconformance Reports (NCRs) shall be included in the applicable receiving acceptance files. Nonconformances shall be considered in qualified supplier performance evaluations.

6.4.4 Supplier nonconformances shall be evaluated individually to determine if disqualification is warranted.

6.5 Qualified Suppliers Documentation

Qualified supplier files shall be maintained containing documentation of initial qualification, performance evaluations, and other documentation and correspondence pertinent to qualification.

7 RECORDS

7.1 Procurement documents, receipt and acceptance document packages shall be maintained for each purchase, and retained as QA records in accordance with CQAM Section 17 for three years.

7.2 Qualified supplier files shall be maintained as QA records and retained for three years after the last use of the supplier.

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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.

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

SUPERSEDED

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 Ehnstrom	Date 11/18/98	Cognizant Director Henry Garcia	Date 11/12/98

CNWRA Form TOP-1 (8/93)

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.

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).

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."

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.

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.

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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Title QAP-016 PROCUREMENT

EFFECTIVITY

Revision 2 of this procedure became effective on 11/12/99 . This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
All	0	11/12/99

SUPERSEDED

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

Approvals			
Written by Bruce Mabrito	Date 11/12/99	Concurrence Review English Pearcy	Date 11/12/99
Quality Assurance Mark Ehnstrom	Date 11/12/99	Cognizant Director Henry Garcia	Date 11/12/99

CNWRA Form TOP-1 (8/93)

QAP-016 PROCUREMENT

1. PURPOSE

The purpose of this procedure is to describe the controls for the procurement of goods and services used in activities affecting quality. This procedure implements the requirements of the Center Nuclear Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM), sections 4 and 7.

2. RESPONSIBILITIES

2.1 Requestor of procurement action(s) is responsible for providing required technical specifications and/or scope of work requirements in the procurement documents.

2.2 The Director of Quality Assurance (QA) is responsible for assuring that quality requirements are provided in procurement documents.

2.3 Element Managers (EMs) and the cognizant Directors are responsible for approving purchase requisitions.

2.4 The Southwest Research Institute (SwRI) Human Resources Department (for consultants) and Purchasing Department (for goods and subcontractors) are responsible for preparing procurement documents.

3. DISCUSSION

In fulfilling its mission, the CNWRA utilizes qualified core staff and students, as well as qualified SwRI staff, consultants, and subcontractors to perform quality-affecting activities to be integrated into CNWRA reports and products. The consultants must satisfy 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 applicable portions of the CQAM. Individuals employed by subcontractors are individually qualified through the same process.

Activities potentially affecting quality include scientific investigations, experiments, tests, analytical services, reviews, code development, and numerical analyses. The results from these activities are accepted or rejected by appropriate and qualified CNWRA technical staff based on their case-by-case assessment of the quality of the work relative to project requirements. It should be noted that Administrative Procedures (AP)-005 and -006, "Obtaining Subcontractors" and "Obtaining Consultants," are an integral part of the CNWRA procurement selection process. The processes for obtaining such services are fully described in and controlled by those procedures. Procurement controls are not applicable to standard laboratory reagents, supplies, and glassware because these goods are considered by the CNWRA to have sufficient purity and accuracy.

4. PROCUREMENT PLANNING

4.1 Procurement Controls

Controls for procurements shall be applied to the following activities:

- Scientific investigations, experiments and tests
- Laboratory analyses and tests
- Analysis services, including reviews
- Code development and numerical analysis
- Calibration services
- Samples and test materials used in scientific investigations

Procurement documents for quality-affecting goods and services shall be reviewed by CNWRA QA and by the cognizant technical CNWRA staff member to verify that appropriate technical and quality provisions are included.

4.2 Procurement of Goods

Quality-affecting materials, items, and equipment (such as test materials, calibration standards, test instruments, etc.) may be procured from approved sources on the SwRI Approved Supplier List (ASL). Goods can also be procured from suppliers not listed on the SwRI ASL. In such cases, an independent analysis to confirm acceptability and to verify compliance with procurement documents shall be performed by an ASL-qualified laboratory. In situations where a method other than ASL independent analysis is used, the method shall receive prior approval from CNWRA QA. This method of approval shall be documented and kept in project files or in the applicable scientific notebook.

4.3 Procurement of Services

4.3.1 The services of individuals performing activities affecting quality, which may include scientific investigations, experiments, tests, analytical services, reviews, code development, numerical analysis, or similar activities, will be performed by individuals who have received indoctrination to the CNWRA QA Program, and whose education, experience, and freedom from conflict of interest have been verified by the CNWRA Source Evaluation Committee.

4.3.2 Experimental, test, analytical laboratory, and special process services may be purchased from approved suppliers listed on the SwRI ASL. Commercial-grade suppliers, universities, or other sources determined to be qualified by CNWRA QA and technical staff but not listed on the ASL can also be used. The method for determining qualification is based on the good or service being purchased and examples for these are shown below.

4.3.2.1 Calibration Services

Most calibration services are provided by the SwRI Calibration Laboratory. When SwRI Calibration Laboratory services are not used, the CNWRA will utilize the SwRI ASL for procurement of calibration services. Calibration services affecting quality shall be purchased from a laboratory that can provide traceability to a national or international standard. CNWRA QA shall determine acceptability of laboratories not appearing on the SwRI ASL. The method for determining acceptability of calibration services not listed on the ASL shall be documented and kept in the instrument or project files.

4.3.2.2 Procurement of Computer Codes, Software, and Databases

Prior to the procurement of services for the development of computer codes, software, and databases, the subcontractor shall have completed a SwRI Quality Questionnaire. This questionnaire shall be evaluated by CNWRA QA and technical staff to determine acceptability of their quality program. If no quality program is provided by the subcontractor, the subcontractor shall utilize the CNWRA QA program. A Software Requirements Description will be developed and provided to the subcontractor prior to start of work on computer codes, software, and databases. Upon completion of the computer code, software, or database, a receiving acceptance test will be performed by a member of the CNWRA technical staff to determine acceptability of the finished product.

4.3.2.3 Procurement of Research and Analysis

Research and analysis activities will be performed by individuals qualified in accordance with QAP-007 and subcontractors shall have completed a SwRI Quality Questionnaire (Reference Figure Sample 1 and Sample 2). This questionnaire shall be evaluated by CNWRA QA to determine acceptability of their quality program. If no quality program is provided by the subcontractor, the subcontractor shall utilize the CNWRA QA program. Completed research and analysis activities will be evaluated by CNWRA technical staff to determine acceptability of the finished product.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When quality-affecting goods or services are required, 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 the goods or services required
- Applicable codes, regulations, specifications, standards, CNWRA procedures or technical requirements
- Certification requirements
- 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.

5.1.3 When a purchase of quality-affecting material, equipment, or services is desired from a division within SwRI, a memorandum or a SwRI division-specific form addressing intra-SwRI services shall be used to document such activities.

5.2 Procurement Document Review

5.2.1 Approved procurement documents shall be forwarded to either the SwRI Human Resources or Purchasing Department, which shall transfer the requirements verbatim to a consulting services agreement or a purchase order for transmittal to the goods or services provider.

5.2.2 Procurement document changes to the scope of work, quality, or technical specification requirements shall be approved in the same manner as original procurement documents.

5.2.3 Specifically for procurement of services through consultants or subcontractors, 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."

6. SELECTION AND QUALIFICATION

6.1 Approved Suppliers of Goods and Services

6.1.1 The SwRI QA Department shall maintain the ASL. The ASL identifies suppliers of goods and services who consistently provide acceptable products in accordance with specific technical requirements. Supplier qualification shall be based on meeting the requirements that demonstrate consistent conformance to technical and quality specifications.

6.1.2 The SwRI ASL can be used to determine appropriate and competent suppliers of products and services based on audits and other methods that are performed.

6.2 Qualification of Non-ASL Goods and Services

A SwRI Quality Survey Questionnaire will be sent to all CNWRA subcontractors not on the ASL. CNWRA QA will review the completed questionnaire and determine whether the quality system of the subcontractor is acceptable. This evaluation will be based on references to nationally or internationally accepted quality systems.

7. ACCEPTANCE OF GOODS AND SERVICES

7.1 Acceptance of Goods

7.1.1 Acceptance of goods from suppliers on the ASL shall be based on the appropriate CNWRA staff review upon receipt of supplier-provided documentation, such as analysis reports, and logs to verify compliance with the purchase order document requirements. Acceptance documentation shall include identification of the supplier, reference to the purchase document, the goods supplied, and results of the review. The CNWRA staff person responsible for acceptance will initial and date the SwRI Receipt Traveler (Reference Figure Sample 3). The Traveler will then be forwarded to the CNWRA Financial Clerk who will make a copy and forward the original to QA Records.

7.1.2 Goods procured from non-ASL sources will be accepted based on inspections and/or tests performed by the CNWRA upon receipt to verify conformance to procurement document technical requirements. The technical staff person

responsible for acceptance will initial and date the SwRI Receipt Traveler. The Traveler will then be forwarded to the CNWRA Financial Clerk who will make a copy and forward the original to QA Records. When appropriate, entries into a project record folder or scientific notebook shall be made by the appropriate CNWRA technical staff member.

7.2 Acceptance of Services

7.2.1 Services received from ASL-qualified suppliers will be accepted based on review of the supplier's inspection and/or test reports by an appropriate member of the CNWRA technical staff. The review will verify that both technical and quality procurement requirements are satisfied. The technical staff member or other receiving person will show acceptance by noting acceptance and the basis for such in a scientific notebook or project record folder.

7.2.2 Analytical services procured from non ASL-approved sources shall be accepted based on inspections and tests performed upon receipt to verify conformance to the technical and quality 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 CNWRA technical staff member prior to issuance of the purchase order. Check samples composed of approximately 10 percent of the total number of the unknown samples can be utilized along with other methods, 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, will be recorded with the analysis data and provided to the CNWRA technical staff member by the supplier. Where independent analysis is required for acceptance, analysis results from the original purchase and from the duplicate analysis must be in agreement for acceptance.

7.2.3 Scientific investigations, experiments, tests, reviews, code development, numerical analysis, and similar activities will be accepted based on inspections and/or testing of the service provided. An appropriate, qualified CNWRA staff member will make the determination of acceptability or unacceptability of the procured service. If accepted, the objective evidence will be the approval of the consultant or subcontractor invoice for the service. A copy of the approved invoice will be sent to QA Records by the CNWRA Financial Clerk. If not acceptable, the objective evidence will be nonpayment of the invoice, notation in a scientific notebook or project record, or a memorandum to the file so stating.

7.2.4 When CNWRA activities require the expertise of other SwRI staff, that staff member shall be qualified and shall work under the direction of a CNWRA Principal Investigator (PI) or EM. Acceptance of SwRI staff work and/or products is shown by a signature of the EM on the AP-6 Form, Document Review Request and Transmittal Control.

7.2.5 Most service procurements result in written papers, reports, analyses, and the like, which are separately published or incorporated in CNWRA publications. Objective evidence of acceptance or rejection of these services will be the documentation resulting from review in accordance with QAP-002.

7.3 Acceptance Documentation

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

7.4 Control of Nonconformances

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

7.4.2 Nonconformances identified during receiving inspections of goods and services from non-ASL suppliers will also be processed in accordance with QAP-009.

7.4.3 Copies of supplier Nonconformance Reports will be included with the traveler, the project record folder, or in CNWRA QA records. Nonconformances can be considered in qualified supplier performance evaluations.

7.4.4 Supplier nonconformances will be evaluated individually to determine if the good or service should not be utilized by the CNWRA.

8. RECORDS

8.1 ASL supplier files will be maintained by the SwRI QA Department.

8.2 Procurement documentation will be maintained by the SwRI Purchasing Department.

8.3 Consultant services agreements will be maintained by the SwRI Human Resources Department.

8.4 Acceptance documentation for quality-affecting goods will be maintained by the cognizant CNWRA technical staff member in the appropriate scientific notebook or project record files. The Traveler will be maintained by the CNWRA Financial Clerk initially, but it will be forwarded to QA Records quarterly for permanent retention.

8.5 Any quality records (i.e., acceptance documentation, surveillance reports, nonconformance reports) generated as a result of the procurement process will be maintained by CNWRA QA in the QA Records Room. CNWRA scientific notebooks that can contain related procurement project information are turned in to QA following completion of the project work and maintained as permanent QA Records. CNWRA electronic scientific notebooks are periodically printed and provided to QA Records for safe keeping (QAP-001, Scientific Notebook Control).

SOUTHWEST RESEARCH INSTITUTE SUPPLIER QUESTIONNAIRE

Supplier Name: Address:

Phone: FAX:

Nature of Business/Product/Service:

Number of Employees: Number of QA/QC Personnel:

Part I QUALITY ASSURANCE

Does your business have a quality program? ☐ Yes ☐ No

Check the appropriate system in place at your facility:

☐ ISO 900__
☐ ANSI/NCSL Z540
☐ ISO Guide 25
☐ 10CFR50, App B or NQA-1
☐ ASME Section
☐ Other _____

Has your facility received certification or accreditation of your quality system? ☐ Yes ☐ No
If so, please provide a description of your certification/accreditation and include a copy with your response.

Will you please provide SwRI copies of your organization chart and quality manual? ☐ Yes ☐ No
If no, please explain: _____

Who (name and title) heads your quality department? _____

List a minimum of three major customers who have audited your quality system to the specifications listed above and, if possible, provide evidence of their acceptance:

Company	Type of Work	Spec.	Contact

For each of the questions below, please indicate "Yes" or "No". If "yes," please list procedure or document that describes how it is accomplished.

1. Does your company provide for a review of contracts for conflicts, capabilities, and clarity? ☐ Yes ☐ No
2. Does your company have a design control process that includes verification of design adequacy? ☐ Yes ☐ No
3. Does your company have a document control system that ensures that the appropriate revisions are available at the point of use and provides control of obsolete documents? ☐ Yes ☐ No
4. Does your company provide for assessment of suppliers and subcontractors? ☐ Yes ☐ No
5. Does your company provide for identification and traceability of items during all stages of production or fabrication? ☐ Yes ☐ No _____
6. Does your company provide for control of processes which affect quality by such methods as work instructions, monitoring and surveillance, and acceptable workmanship criteria? ☐ Yes ☐ No _____

SwRI Form QA-66-5 [q:\common\forms\qa-66.frm]

Sample 1

7. Does your company have a program to address verification of items at receipt, in-process, and in completed stages prior to delivery? ☐ Yes ☐ No _____
8. Does your company have a system for control and calibration of inspection, measuring, and test equipment traceable to national standards? ☐ Yes ☐ No _____
9. Is the inspection and/or test status of material clearly identified? ☐ Yes ☐ No _____
10. Does your company have a system for control, segregation, and disposition of nonconforming items? ☐ Yes ☐ No _____
11. Does your company have a system to ensure effective implementation of corrective action to prevent recurrence? ☐ Yes ☐ No _____
12. Does your company have a system that addresses handling, storage, packaging, and shipping of material? ☐ Yes ☐ No _____
13. Is there a documented program at your company for the storage and maintenance of quality records? ☐ Yes ☐ No _____
14. Does your company have a program for periodic audit to verify compliance with system requirements? ☐ Yes ☐ No _____
15. Does your company have a program to verify and provide training in quality-related activities? ☐ Yes ☐ No _____
16. Does your company system address servicing? ☐ Yes ☐ No _____
17. Does your company utilize statistical techniques for evaluating process capability and product characteristics? ☐ Yes ☐ No _____

Part II SPECIAL PROCESSES

Does your company perform special processes such as those listed (include associated specification):

☐ Welding _____ ☐ Heat Treatment _____ ☐ Soldering _____

☐ Surface treatment (plating, anodizing, etc.) _____

☐ Other _____

Part III SOFTWARE

Does your company develop software or modify available software either as a product or in support of production? ☐ Yes ☐ No

Is software development controlled through a documented program? ☐ Yes ☐ No

Does your company have a software configuration management plan? ☐ Yes ☐ No

Does your program comply with: ☐ DoD-STD-2167A/-2168 ☐ MIL-STD-498 ☐ ISO 9001 ☐ Other _____

Part IV QUESTIONNAIRE COMPLETED BY

Supplier Representative:

Signature*: _____ Date: _____

Printed Name: _____

Title: _____

* Duly authorized representative.

SwRI Evaluation By**:

Name: _____

Date: _____

** Addition requires completion of SwRI Form QA-167.

For SwRI Use Only:

Accept ☐ Reject ☐ _____

Questionnaire Response Acceptable? ☐ Yes ☐ No _____

Site Audit Required? ☐ Yes ☐ No _____

SwRI Form QA-66-5 (Cont')

Sample 2

SOUTHWEST RESEARCH INSTITUTE

10/21/1999 RECEIPT TRAVELER Page 1

Warehouse:10

Receipt ID: 10RC-00401 Packing Slip: 18670 Receiver: Dehoyos, Teresa T.

Receipt Date: 10/21/1999

PO X89614V Rel: 0 Change Ord: 0 Vendor: AMERICAN CONSORTIUM

Receipt Notes: p/w for 10/19/99.

Line: 1

Item: 6750-01-0027 FILM, TYPE 600 POLAROID TRANSFER FROM FRANK/68

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Y Hazmat: N

Deliver To: Frank Mesa/68 Order Ref: Requisition: 69656

Qty Rcv: 27.0000 Qty Accpt: 27.0000 Qty Rej:

Location: 68 Location: 68 Location:

Prime Contract	Priority	Project	Organization	Account
		INVEN.068	1.10	141-101

Notes:

Sample 3

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-016 Revision 3 Page 1 of 13

Title QAP–016 PROCUREMENT

EFFECTIVITY

Revision 3 of this procedure became effective on 8/29/2000. This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
All	0	8/29/2000

SUPERSEDED

Supersedes Procedure No. QAP-016 Rev 2, Chg. 1

Approvals			
Written by Mark R. Ehnstrom Mark Ehnstrom	Date 8/30/2000	Concurrence Review English Pearcy	Date 8/30/2000
Quality Assurance Bruce Mabrito	Date 8/30/2000	Cognizant Director Henry Garcia	Date 8/30/00

CNWRA Form TOP-1 (8/93)

QAP-016 PROCUREMENT

1. PURPOSE

The purpose of this procedure is to describe the controls used in the procurement of goods and services for activities affecting quality. Among the procurement activities affecting quality described in this procedure are qualifying suppliers, identifying purchasing data, and verifying receipt of purchased items and services. This procedure implements the requirements of the Center Nuclear Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM), sections 4 and 7.

2. RESPONSIBILITIES

2.1 Requestor of procurement action(s) is responsible for providing required technical specifications and/or scope of work requirements in the procurement documents.

2.2 The Director of Quality Assurance (QA) is responsible for assuring that quality requirements are included in procurement related documents.

2.3 Element Managers (EMs) and the cognizant Directors are responsible for approving purchase requisitions.

2.4 The Southwest Research Institute (SwRI) Human Resources Department (for consultants) and Purchasing Department (for goods and subcontractors) are responsible for preparing contract and purchase order documents. In addition, the SwRI Purchasing Department is responsible for selecting procurement sources; conducting bid evaluation and award; and determining supplier performance.

2.5 The SwRI Manager of Quality Systems Technology is responsible for qualifying suppliers, maintaining the Approved Suppliers List (ASL), and periodically evaluating and rating suppliers.

2.6 The CNWRA Director of QA is responsible for the control of nonconformances, corrective action, and quality assurance records.

2.7 The CNWRA staff member is formally qualified on a CNWRA Form Q-11 and is responsible for final acceptance of goods and services.

3. DISCUSSION

In fulfilling its mission, the CNWRA utilizes core staff and students, as well as SwRI staff, consultants, and subcontractors to perform quality-affecting activities to be integrated into CNWRA reports and products.

Activities potentially affecting quality include scientific investigations, experiments, tests, analytical services, reviews, code development, receiving inspections, and numerical analyses. The results from these activities are accepted or rejected by appropriate and qualified CNWRA technical staff based on their case-by-case assessment of the quality of the work relative to project requirements.

Procurement controls are not applicable to consumables (e.g., laboratory chemicals, reagents, supplies, and glassware) because standard commercial practices provide adequate assurance. Note: Commercial off-the-shelf (COTS) materials and items used by the CNWRA have no special design or "Nuclear" requirements. Based on CNWRA experience and procurement history, the majority of CNWRA-purchased goods fall into the COTS category. Items and materials routinely used at the CNWRA include standard commercial reagent-grade chemicals, standards for chemical and other analyses, standard fasteners, standards laboratory glassware, laboratory tools, geological standards, and standard microbial materials. These COTS items are not subject to design or specification requirements that are unique to nuclear facilities, but are commonly used in various industries, and are ordered from the manufacture/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog).

4. PROCUREMENT PLANNING

Procurement Planning activities are planned and documented on the Quality Requirements Application Matrices (QRAM) form. This QRAM form is initiated in the planning phase for each Key Technical Issue, Integrated Subissue, or project by the PI and/or EM, Technical Director, and the Director of Quality Assurance. This QRAM form shall identify if the Key Technical Issue, Integrated Subissue, or project will have procurement of products and services affecting quality.

4.1 Procurement Controls

Controls for procurement shall be applied to the following activities:

- Scientific investigations, experiments and tests
- Laboratory analyses and tests
- Analysis services, including reviews

- Code development and numerical analysis
- Calibration services
- Sample and test materials used in scientific investigations

"Obtaining Subcontract Service"are described in CNWRA Procedure AP-005. "Obtaining Consultant Service" are described in CNWRA Procedure AP-006.

Procurement documents for quality-affecting goods and services shall be reviewed by the CNWRA QA and by the cognizant technical CNWRA staff member to verify that appropriate technical and quality provisions are included.

4.2 Procurement of Goods

Quality-affecting materials, items, and equipment (e.g., as test materials, calibration standards, test instruments, etc.) may be procured from approved sources on the SwRI ASL. Goods can also be procured from COTS suppliers.

4.3 Procurement of Services

4.3.1 The services of individuals performing activities affecting quality, which may include scientific investigations, experiments, tests, analytical services, reviews, code development, numerical analysis, or similar activities, will be performed by qualified staff as defined in 2.7 and verified by the CNWRA Source Evaluation Committee.

4.3.2 Experimental, test, analytical laboratory, and special process services may be purchased from approved suppliers listed on the SwRI ASL, or from suppliers who are provided "blind samples" by the CNWRA to confirm precision and accuracy. Commercial-grade suppliers, universities, or other sources determined to be qualified by CNWRA QA and technical staff but not listed on the ASL also can be used.

4.3.2.1 Calibration Services

Most calibration services are provided by the SwRI Calibration Laboratory. When SwRI Calibration Laboratory services are not used,

the CNWRA will use the SwRI ASL to identify suppliers for the procurement of calibration services. Calibrations services affecting quality shall be purchased from a laboratory that can provide traceability to a national or international standard. The SwRI QA Calibration Lab shall determine acceptability of laboratories not appearing on the SwRI ASL.

4.3.2.2 Procurement of Computer Codes, Software, and Databases

Prior to the procurement of services for the development of computer codes, software, and databases, the subcontractor shall have completed a SwRI Quality Questionnaire. This questionnaire shall be evaluated by CNWRA QA to determine acceptability of their quality program. If no quality program is provided by the subcontractor, the subcontractor shall utilize the CNWRA QA program.

4.3.2.3 Procurement of Research and Analysis

Research and analysis activities shall be performed by individuals qualified in accordance with QAP-007 and subcontractors shall have completed a SwRI Quality Questionnaire (Reference Figure Sample 1 and Sample 2). This questionnaire shall be evaluated by CNWRA QA to determine acceptability of their quality program. If no quality program is provided by the subcontractor, the subcontractor shall use the CNWRA QA program. Completed research and analysis activities shall be evaluated by CNWRA technical staff to determine acceptability of the finished product.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When quality-affecting goods or services are required, 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 the goods or services required
- Applicable codes, regulations, specifications, standards, drawings, CNWRA procedures or technical requirements
- Quality requirements

- Requirements for certification of special processes
- Requirements for special documentation, certification requirements

5.1.2 The QA-related purchasing data shall be applied to the purchase requisition by reference to commonly used "QA-clauses" through written addenda to the requisition. When the existing QA clauses do not address specific requirements or when the QA clauses need to be supplemented, special written addenda may be used.

5.1.3 If the purchase requisition references documents such as drawings, specifications, or requests for quotation and proposals, legible copies of these should be provided to the person developing the requisition.

5.1.4 When a purchase of quality-affecting material, equipment, or services is desired from a Division within SwRI, a memorandum or a SwRI division-specific form addressing intra-SwRI services shall be used to document such activities.

5.1.5 Receiving inspection instructions may be identified on the procurement document. When receipt testing is necessary for acceptance, a brief statement describing that activity will be annotated directly on the procurement document.

5.2 Procurement Document Review

5.2.1 Procurement documents shall be initiated and/or reviewed by a technical staff person responsible for the purchase. This person shall review the document to assure that technical references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions including any revisions included that describe the items or service to be furnished. The procurement document shall be reviewed by CNWRA QA to assure that appropriate quality and technical requirements are included.

5.2.2 Approved procurement documents shall be forwarded to either the SwRI Human Resources or Purchasing Department, which shall transfer the requirements verbatim to a consulting services contract or a purchase order for transmittal to the goods or services provider.

5.2.3 Procurement document changes to the scope of work, quality, or technical specification requirements shall be approved in the same manner as original procurement documents.

5.2.4 Specifically for procurement of services from consultants or subcontractors, the Director of QA shall include an appropriate 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."

6. SELECTION AND QUALIFICATION

6.1 Approved Suppliers of Goods and Services

6.1.1 The SwRI QA Department shall maintain the ASL. The ASL identifies suppliers of goods and services who consistently provide acceptable products in accordance with specific technical requirements. Supplier qualification shall be based on meeting the requirements that demonstrate consistent conformance to technical and quality specifications.

6.1.2 The SwRI ASL can be used to determine appropriate and competent suppliers of products and services based on audits and other methods that are performed.

6.2 Qualification of Non-ASL Goods and Services

A SwRI Quality Survey Questionnaire will be sent to all CNWRA subcontractors not on the ASL. CNWRA QA will review the completed questionnaire and determine whether the quality system of the subcontractor is acceptable. This evaluation will be based on references to nationally or internationally accepted quality systems (e.g., 10 CFR 50 Appendix B, ISO 9000-Series, and other nationally or internationally recognized quality systems).

7. ACCEPTANCE OF GOODS AND SERVICES

7.1 Acceptance of Goods

7.1.1 Acceptance of goods from the ASL-qualified suppliers shall be based on the appropriate CNWRA staff review of supplier-provided documentation, (e.g., analysis reports, and logs to verify compliance with the purchase order document requirements) at the time of receipt. The CNWRA staff person responsible for acceptance will initial and date the SwRI Receipt Traveler (Reference Figure Sample 3). Completion of the Receipt Traveler constitutes acceptance of the goods and services listed on the traveler. The traveler, then, will be forwarded to the CNWRA Financial Clerk who will make a copy and forward the original to QA Records.

7.1.2 Goods procured from COTS sources will be accepted based on inspections and/or tests performed by the CNWRA upon receipt to verify conformance to procurement document technical requirements. The technical staff person responsible for acceptance will initial and date the SwRI Receipt Traveler. The traveler, then, will be forwarded to the CNWRA Financial Clerk who will make a copy and forward the original to QA Records. When appropriate, entries into a project record folder or scientific notebook shall be made by the appropriate CNWRA technical staff member.

7.2 Acceptance of Services

7.2.1 Services received from ASL-qualified suppliers will be accepted based on review of the supplier's inspection and/or test reports by an appropriate member of the CNWRA technical staff. This review will verify that both technical and quality procurement requirements are satisfied. The technical staff member or other receiving person will show acceptance of the service by approving the voucher/invoice for the service and providing entry into the scientific notebook or project folder, if appropriate.

7.2.2 Analytical services procured from non ASL-approved sources shall be accepted based on inspections and tests performed upon receipt to verify conformance to the technical and quality 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 CNWRA technical staff member prior to issuance of the purchase order. Check samples composed of approximately 10 percent of the total number of the unknown samples can be utilized along with other methods, to provide confidence in the results. In cases where blind standards are not possible, the testing shall be accomplished pursuant 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, will be recorded with the analysis data and provided to the CNWRA technical staff member by the supplier. Where independent analysis is required for acceptance, analysis results from the original purchase and from the duplicate analysis must be in agreement for acceptance.

7.2.3 Scientific investigations, experiments, tests, reviews, code development, numerical analysis, and similar activities will be accepted based on inspections and/or testing of the product provided. An appropriate, qualified CNWRA staff member will make the determination of acceptability or rejection of the procured service. If accepted, the objective evidence will be the approval of the consultant/subcontractor invoice for the service. A copy of the approved invoice will be sent to QA Records by the CNWRA Financial Clerk. If not acceptable,

the objective evidence will be nonpayment of the invoice, notation in a scientific notebook or project record, or a documenting memorandum to the file.

7.2.4 When CNWRA activities require the expertise of other SwRI staff, that staff member shall be qualified and shall work under the direction of a CNWRA Principal Investigator (PI) or EM. Acceptance of SwRI staff work and/or products is shown by a signature of the EM on the AP-6 Form, Document Review Request and Transmittal Control.

7.2.5 Most service procurements result in written papers, reports, analyses, and the like, that are separately published or incorporated in CNWRA publications. Objective evidence of acceptance or rejection of these services will be the documentation resulting from review in accordance with QAP-002.

7.3 COTS Suppliers

Goods and services purchased from COTS suppliers shall be verified upon receipt as meeting the specifications set forth in the product description by the appropriate CNWRA technical staff member as noted in the purchase order or contract.

7.4 Acceptance Documentation

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

7.5 Control of Nonconformances

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

7.5.2 Nonconformances identified during receiving inspections of goods and services from non-ASL suppliers will also be processed in accordance with QAP-009.

7.5.3 Copies of supplier Nonconformance Reports will be included with the traveler, the project record folder, or in CNWRA QA records. Nonconformances can be considered in qualified supplier performance evaluations.

7.5.4 Supplier nonconformances will be evaluated individually to determine if the good or service should not be utilized by the CNWRA.

8. RECORDS

8.1 ASL supplier files will be maintained by the SwRI QA Department.

8.2 Procurement documentation will be maintained by the SwRI Purchasing Department.

8.3 Consultant services contracts will be maintained by the SwRI Human Resources Department.

8.4 Acceptance documentation for quality-affecting goods will be maintained by the cognizant CNWRA technical staff member in the appropriate scientific notebook or project record files. The traveler will be maintained by the CNWRA Financial Clerk initially and will be forwarded to QA Records quarterly for permanent retention.

8.5 Any quality records (i.e., acceptance documentation, surveillance reports, nonconformance reports) generated as a result of the procurement process will be maintained by CNWRA QA in the QA Records Room. CNWRA scientific notebooks that can contain related procurement project information are sent to QA following completion of the project work and maintained as permanent QA Records. CNWRA electronic scientific notebooks are periodically printed and provided to QA Records for safe keeping (QAP-001, Scientific Notebook Control).

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-016 Revision 4 Change 0 Page 1 of 12

Title QAP–016 PROCUREMENT

EFFECTIVITY

Revision 4 of this procedure became effective on 8/15/2001. This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
ALL	0	8/15/2001

SUPERSEDED

Supersedes Procedure No. QAP-016 Rev 3, Chg. 0

Approvals			
Written by Mark R. Ehrstrom Mark Ehrstrom	Date 8/9/01	Concurrence Review English Pearcy	Date 8/13/2001
Quality Assurance Bruce Mabrito	Date 8/11/2001	Cognizant Director Henry Garcia	Date 8/13/01

CNWRA Form TOP-1 (8/93)

QAP-016 PROCUREMENT

1. PURPOSE

The purpose of this procedure is to describe the controls used in the procurement of goods and services for activities that are quality-affecting. This procedure may also be used for non-quality affecting procurements. Among the procurement activities affecting quality described in this procedure are using, at the discretion of CNWRA management, qualified suppliers, identifying quality requirements, and verifying receipt of purchased items and services. This procedure implements the requirements of the Center for Nuclear Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM), sections 4 and 7.

2. RESPONSIBILITIES

2.1 The requestor of procurement action(s) is responsible for providing required technical specifications and/or scope of work requirements in the purchase requisitions. The requestor is responsible for routing the purchase requisition through the division review process.

2.2 The Director of Quality Assurance (QA) is responsible for assuring that quality requirements are included in procurement related documents. The Director of QA is also responsible for the control of nonconformances, corrective actions, and quality assurance records. QA is not responsible for goods and services having no effect on product or data quality.

2.3 The Element Managers (EMs), Principal Investigators (PIs), and the cognizant Directors are responsible for approving purchase requisitions.

2.4 The Southwest Research Institute (SwRI) Human Resources Department (for consultants) and Purchasing Department (for goods and subcontractors) are responsible for preparing purchase and subcontract order documents. In addition, the SwRI Purchasing Department is responsible for selecting procurement sources, conducting bid evaluation and award, and determining supplier performance.

2.5 The SwRI Manager of Quality Systems Technology is responsible for qualifying suppliers, maintaining the Approved Suppliers List (ASL), and periodically evaluating and rating suppliers.

2.6 The CNWRA staff are formally qualified on CNWRA Form QAP-11, Professional Personnel Qualification and Training Record, and are responsible for final acceptance of goods and services.

3. DISCUSSION

The CNWRA utilizes core staff, as well as CNWRA students, SwRI staff, consultants, and subcontractors to perform quality-affecting activities to be integrated into CNWRA reports and products.

Activities potentially affecting quality include, but are not limited to, scientific investigations, experiments, tests, analytical services, reviews, code development, receiving inspections, and numerical analyses. The results from these activities are accepted or rejected by appropriate and qualified technical staff based on their case-by-case assessment of the resultant quality of the work relative to project requirements. QA procurement controls are not applicable to goods and services that have no effect on the quality of the final product. Trained and qualified technical staff will perform receiving inspection. Because these individuals may perform receiving inspection on items required to support their work activities, senior management will ensure that the individuals accepting these items (i) are not unduly influenced by cost and schedule, (ii) have sufficient authority to independently evaluate the acceptability of the items, and (iii) have direct access to senior management in matters related to receiving inspection.

4. PROCUREMENT PLANNING

Procurement planning activities shall be documented. During procurement planning, quality-affecting technical staff and QA personnel will provide input to supplier selection, confirmatory analyses requirements, and need for special receiving inspections to assure quality of the item.

4.1 Procurement Controls

Controls for quality-affecting procurements shall be applied to the following activities:

- Code development and numerical analysis
- Calibration services
- Sample and test materials used in scientific investigations
- "Obtaining Subcontract Services," as described in CNWRA Procedure AP-005
- "Obtaining Consultant Services," as described in CNWRA Procedure AP-006

Procurement documents for goods and services affecting quality shall be reviewed by CNWRA QA and cognizant technical staff members, to verify that appropriate technical and quality provisions are included.

4.2 Procurement of Goods

Materials used in quality-affecting activities (e.g., test materials, calibration standards, etc.) may be procured from approved sources on the SwRI ASL or shall be qualified through the method described in the Confirmatory Analyses procedure.

Note: Quality-affecting goods shall not be purchased from the "petty cash" account or without a purchase requisition.

4.3 Procurement of Services

4.3.1 The performance of activities affecting quality, which may include scientific investigations, experiments, tests, analytical services, reviews, code development, numerical analysis, receiving inspections, or similar activities, will be accomplished by qualified individuals.

4.3.2 Experimental, test, analytical, laboratory, and special process services may be purchased from suppliers listed on the SwRI ASL, or from suppliers who are provided "blind samples" by the CNWRA to confirm precision and accuracy. Commercial-grade suppliers, universities, or other sources determined to be qualified by CNWRA QA and technical staff, but not listed on the ASL, also can be used.

4.3.2.1 Calibration Services

Most calibration services are provided by the SwRI Calibration Laboratory. When SwRI Calibration Laboratory services are not used, the CNWRA will use the SwRI ASL to identify suppliers for the procurement of calibration services. Calibration services affecting quality shall be purchased from a laboratory that can provide traceability to a national or international standard. The SwRI QA Calibration Lab shall determine acceptability of laboratories not appearing on the SwRI ASL.

4.3.2.2 Procurement of Computer Codes, Software, and Databases

Prior to the procurement of services for the development of computer codes, software, and databases, the SwRI QA Department will require the selected subcontractor to complete a SwRI Quality Questionnaire (Reference Sample 1). The response to this questionnaire shall be evaluated by QA to determine acceptability of their quality program. If no quality program is provided by the subcontractor, the subcontractor shall utilize the CNWRA QA program.

4.3.2.3 Procurement of Research and Analysis

Research and analysis activities shall be performed by individuals qualified in accordance with QAP-007, Professional Personnel Qualification. Completed research and analysis activities shall be evaluated by technical staff to determine acceptability of the final product.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When quality-affecting goods or services are required, 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 the goods or services required
- Applicable codes, regulations, specifications, standards, drawings, CNWRA procedures or technical requirements
- Quality requirements, including placing the order with a supplier listed on the ASL and determining whether confirmatory analyses is required
- Requirements for certification of special processes
- Requirements for special documentation, certification requirements, and the like

5.1.2 The QA-related purchasing information data shall be applied to the purchase requisition by reference to commonly used "QA-clauses" (as maintained by the SwRI QA Department, in conjunction with the Purchasing Department) included in the written addenda to the requisition. When the existing QA clauses do not address specific requirements or the QA clauses need to be supplemented, special written addenda may be used.

5.1.3 If the purchase requisition references documents such as drawings, specifications, or requests for quotation and proposals, legible copies of these should be provided to the person developing the requisition.

5.1.4 When a purchase of quality-affecting material, equipment, or services is desired from a SwRI Division, a memorandum or a SwRI division-specific form addressing intra-SwRI services shall be used to document such activities.

5.1.5 Receiving inspection instructions may be identified on the procurement document. When receipt testing is necessary for acceptance, a brief statement describing that activity will be annotated directly on the procurement document.

5.2 Procurement Document Review

5.2.1 Procurement documents shall be initiated and/or reviewed by a technical staff person responsible for the purchase. This person shall review the document to assure that technical references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions along with any revisions included that describe the items or service to be furnished. The procurement document shall be reviewed by QA to assure that appropriate quality requirements are included.

5.2.2 Approved procurement documents shall be forwarded to either the SwRI Human Resources or Purchasing Department, which shall transfer the requirements to a consulting services contract or a purchase order or subcontract for transmittal to the goods or services provider.

5.2.3 Procurement document changes to the scope of work, quality, or technical specification requirements shall be approved in the same manner as original procurement documents.

5.2.4 Specifically for procurement of services from consultants or subcontractors, the Director of QA shall include an appropriate Quality Requirements statement that 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."

6. SELECTION AND QUALIFICATION

6.1 Approved Suppliers of Goods and Services

6.1.1 The SwRI QA Department shall maintain the ASL. The ASL identifies suppliers of goods and services who consistently provide acceptable products or services in accordance with specific technical requirements. Supplier qualification shall be based on meeting the requirements that demonstrate consistent conformance to technical and quality specifications.

6.1.2 The SwRI ASL can be used to determine appropriate and competent suppliers of goods and services based on audits and other methods that are performed.

6.2 Qualification of Non-ASL Goods

Confirmatory analyses, as described in QAP-018, Procedure for Confirmatory Analyses, will be required on goods supplied from non-ASL suppliers if they are supplying a good that has been determined to be quality-affecting.

7. ACCEPTANCE OF GOODS AND SERVICES

7.1 Acceptance of Goods

7.1.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspections. This receiving inspection will assure the item is received in its proper and expected configuration including identification, dimensional, physical, chemical, cleanliness or other characteristics, and that the item has not received unacceptable shipping damage. The receiving inspection shall assure that documentation received from the supplier defines the specific procurement requirements that have been met (e.g., code, standards, and specification); identifies any procurement requirements that have not been met; and describes those nonconformances from the procurement requirements dispositioned 'accept as is' or 'repair'. Receiving inspection shall also assure that the supplier is on the SwRI ASL, or confirmatory analyses have been performed on the quality-affecting goods.

7.1.2 The technical staff person responsible for acceptance will initial and date the SwRI Receipt Traveler (sample 2). The traveler, then, will be forwarded to the Financial Clerk who will make a copy and forward the original to QA Records. When appropriate, entries into a project record folder or scientific notebook shall be made by the appropriate technical staff member.

7.2 Acceptance of Services

7.2.1 Services received from ASL-qualified suppliers will be accepted based on review of the supplier's inspection and/or test reports by an appropriate member of the technical staff. This review will verify that both technical and quality procurement requirements are satisfied. The technical staff member or other receiving person will show acceptance of the service by approving the voucher/invoice for the service and providing entry into the scientific notebook or project folder, if appropriate.

7.2.2 Analytical services procured from non ASL-approved sources shall be accepted based on inspections and tests performed upon receipt to verify conformance to the technical and quality requirements. Blind standards and duplicate samples can be used to determine analytical accuracy and precision, which shall be evaluated against limits determined by the cognizant CNWRA technical staff member prior to issuance of the purchase order. Check samples composed of approximately 10 percent of the total number of the unknown samples can be used along with other methods, to provide confidence in the results. In cases where blind standards are not possible, the testing shall be accomplished pursuant 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, will be recorded with the analysis data and provided to the CNWRA technical staff member by the supplier. Where independent analysis is required for acceptance, analysis results from the original purchase and from the duplicate analysis must be within an acceptable tolerance for acceptance, as determined by the PI.

7.2.3 Scientific investigations, experiments, tests, reviews, code development, numerical analysis, and similar activities will be accepted based on inspections and/or testing of the product provided. An appropriate, qualified staff member will make the determination of acceptability or rejection of the procured service. If accepted, the objective evidence will be the approval of the consultant/subcontractor invoice for the service. A copy of the approved invoice will be sent to QA Records by the Financial Clerk. If not acceptable, the objective evidence will be nonpayment of the invoice, notation in a scientific notebook or project record, or a documenting memorandum to the file.

7.2.4 When CNWRA activities require the expertise of other SwRI staff, the staff member shall be qualified and shall work under the direction of a CNWRA Principal Investigator of EM. Acceptance of SwRI staff work and/or products is shown by a signature of the EM on the AP-06 Form, Document Review Request and Transmittal Control.

7.2.5 Most service procurements result in written papers, reports, analyses, and the like, that are separately published or incorporated in CNWRA publications. Objective evidence of acceptance or rejection of these services will be the documentation resulting from review in accordance with QAP-002, Review of CNWRA Documents, Reports and Papers.

7.3 Acceptance Documentation of Services

Acceptance documentation will either be recorded or placed in scientific notebooks or project record files. Acceptance documentation can include receiving inspections, test reports, copies of travelers, reports from an analyses organization, and observation of the received good or service that can discern whether it meets CNWRA requirements.

7.4 Control of Nonconformances

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

7.4.2 Nonconformances identified during receiving inspections of goods and services from non-ASL suppliers will also be processed in accordance with QAP-009.

7.4.3 Copies of supplier Nonconformance Reports will be included with the traveler, the project record folder, or in CNWRA QA records. Nonconformances can be considered in qualified supplier performance evaluations.

7.4.4 Supplier nonconformances will be evaluated individually to determine whether the good or service can be utilized by the CNWRA without adversely affecting the quality of the end product.

8. RECORDS

8.1 ASL supplier files will be maintained by the SwRI QA Department.

8.2 Procurement documentation, including subcontracts, will be maintained by the SwRI Purchasing Department.

8.3 Consultant services contracts will be maintained by the SwRI Human Resources Department.

8.4 Acceptance documentation for quality-affecting goods will be maintained by the cognizant CNWRA technical staff member in the appropriate scientific notebook or project record files. The traveler will be maintained by the Financial Clerk and will be forwarded to QA Records quarterly for permanent retention.

8.5 Any quality records (i.e., acceptance documentation, surveillance reports, nonconformance reports) generated as a result of the procurement process will be maintained by CNWRA QA in the QA Records Room. CNWRA scientific notebooks that can contain related procurement information are sent to QA following completion of the project work and maintained as permanent QA Records. CNWRA electronic scientific notebooks are periodically printed and provided to QA Records for safe keeping (QAP-001, Scientific Notebook Control).

SOUTHWEST RESEARCH INSTITUTE SUPPLIER QUESTIONNAIRE

Supplier Name:	Address:
Phone:	FAX:
Nature of Business/Product/Service:	
Number of Employees:	Number of QA/QC Personnel:

Part I **QUALITY ASSURANCE**

Does your business have a quality program? ☐ Yes ☐ No
Check the appropriate system in place at your facility:

☐ ISO 900__ ☐ 10CFR50, App B or NQA-1
☐ ANSI/NCSL Z540 ☐ ASME Section
☐ ISO Guide 25 ☐ Other _____

Has your facility received certification or accreditation of your quality system? ☐ Yes ☐ No
If so, please provide a description of your certification/accreditation and include a copy with your response.

Will you please provide SwRI copies of your organization chart and quality manual? ☐ Yes ☐ No
If no, please explain: _____

Who (name and title) heads your quality department? _____

List a minimum of three major customers who have audited your quality system to the specifications listed above and, if possible, provide evidence of their acceptance:

Company	Type of Work	Spec.	Contact

For each of the questions below, please indicate "Yes" or "No". If "yes," please list procedure or document that describes how it is accomplished.

1. Does your company provide for a review of contracts for conflicts, capabilities, and clarity? ☐ Yes ☐ No
2. Does your company have a design control process that includes verification of design adequacy? ☐ Yes ☐ No
3. Does your company have a document control system that ensures that the appropriate revisions are available at the point of use and provides control of obsolete documents? ☐ Yes ☐ No
4. Does your company provide for assessment of suppliers and subcontractors? ☐ Yes ☐ No
5. Does your company provide for identification and traceability of items during all stages of production or fabrication? ☐ Yes ☐ No _____
6. Does your company provide for control of processes which affect quality by such methods as work instructions, monitoring and surveillance, and acceptable workmanship criteria? ☐ Yes ☐ No _____

SwRI Form QA-66-6 [q:\common\forms\qa-66.frm]

7. Does your company have a program to address verification of items at receipt, in-process, and in completed stages prior to delivery? ☐ Yes ☐ No _____
8. Does your company have a system for control and calibration of inspection, measuring, and test equipment traceable to national standards? ☐ Yes ☐ No _____
9. Is the inspection and/or test status of material clearly identified? ☐ Yes ☐ No _____
10. Does your company have a system for control, segregation, and disposition of nonconforming items? ☐ Yes ☐ No _____
11. Does your company have a system to ensure effective implementation of corrective action to prevent recurrence? ☐ Yes ☐ No _____
12. Does your company have a system that addresses handling, storage, packaging, and shipping of material? ☐ Yes ☐ No _____
13. Is there a documented program at your company for the storage and maintenance of quality records? ☐ Yes ☐ No _____
14. Does your company have a program for periodic audit to verify compliance with system requirements? ☐ Yes ☐ No _____
15. Does your company have a program to verify and provide training in quality-related activities? ☐ Yes ☐ No _____
16. Does your company system address servicing? ☐ Yes ☐ No _____
17. Does your company utilize statistical techniques for evaluating process capability and product characteristics? ☐ Yes ☐ No _____

Part II SPECIAL PROCESSES

☐ Welding _____ ☐ Heat Treatment _____ ☐ Soldering _____

☐ Surface treatment (plating, anodizing, etc.) _____

☐ Other _____

Part III SOFTWARE

Does your company develop software or modify available software either as a product or in support of production? ☐ Yes ☐ No

Is software development controlled through a documented program? ☐ Yes ☐ No

Does your company have a software configuration management plan? ☐ Yes ☐ No

To what standard is your software process tailored? _____

Part IV QUESTIONNAIRE COMPLETED BY

Supplier Representative:

Signature*: _____ Date: _____

Printed Name: _____

Title: _____

SwRI Evaluation By**:

Name: _____

Date: _____

* Duly authorized representative.

** Addition requires completion of SwRI Form QA-167.

For SwRI Use Only:

Accept ☐ Reject ☐ _____

Questionnaire Response Acceptable? ☐ Yes ☐ No _____

Site Audit Required? ☐ Yes ☐ No _____

SwRI Form QA-66-6 (Cont')

SOUTHWEST RESEARCH INSTITUTE

10/21/1999 **RECEIPT TRAVELER** Page 1

Warehouse: 10

Receipt ID: 10RC-00401 **Packing Slip:** 18670 **Receiver:** Dehoyos, Teresa T.

Receipt Date: 10/21/1999

PO X89614V **Rel:** 0 **Change Ord:** 0 **Vendor:** AMERICAN CONSORTIUM

Receipt Notes: p/w for 10/19/99.

Line: 1

Item: 6750-01-0027 FILM, TYPE 600 POLAROID TRANSFER FROM FRANK/68

U/M: EA **QC Reqd:** N **Cert of Conf Reqd:** N **Source Insp Reqd:** N **Insp Type:** Y **Hazmat:** N

Deliver To: Frank Mesa/68 **Order Ref:** **Requisition:** 69656

Qty Rcv: 27.0000 **Qty Accpt:** 27.0000 **Qty Rej:**

Location: 68 **Location:** 68 **Location:**

Prime Contract	Priority	Project	Organization	Account
		INVEN.068	1.10	141-101

Notes:

Receipt Traveler
Sample 2

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-016 Revision 5 Change 0 Page 1 of 14

Title QAP–016 PROCUREMENT

EFFECTIVITY

Revision 5 of this procedure became effective on 12/10/2001. This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
ALL	0	12/10/2001

SUPERSEDED

Supersedes Procedure No. QAP-016 Rev 4, Chg. 0

Approvals			
Written by Mark R. Ehnstrom Mark Ehnstrom	Date 12/6/2001	Concurrence Review Bradley J. Werling Bradley Werling	Date 12/6/2001
Quality Assurance Bruce Mabrito Bruce Mabrito	Date 12/9/2001	Cognizant Director Henry Garcia	Date 12/10/01

CNWRA Form TOP-1 (8/93)

QAP-016 PROCUREMENT

1. PURPOSE

The purpose of this procedure is to describe the controls used in the procurement of goods and services for activities that are quality-affecting. This procedure may also be used for non-quality affecting procurements. Among the procurement activities affecting quality described in this procedure are the use of qualified suppliers, identification of quality requirements, and verification of receipt of purchased items and services. This procedure implements the requirements of the Center for Nuclear Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM), sections 4 and 7.

2. RESPONSIBILITIES

2.1 The requestor of procurement action(s) is responsible for providing required technical specifications and/or scope of work requirements on the purchase requisitions. The requestor is responsible for routing the purchase requisition through the division review process.

2.2 The Director of Quality Assurance (QA) is responsible for assuring that quality requirements are included in procurement-related documents. The Director of QA is also responsible for the control of nonconformances, corrective actions, and quality assurance records. QA is not responsible for the procurement of goods and services having no effect on final product or data quality.

2.3 The Element Managers (EMs), Principal Investigators (PIs), and the cognizant Directors are responsible for approving purchase requisitions.

2.4 The CNWRA Financial Clerk is responsible for maintaining copies of completed purchase requisitions. The Financial Clerk is also responsible for maintaining purchase requisitions with attached receipt travelers or packing slips documenting results of receiving inspection.

2.5 The Southwest Research Institute (SwRI) Human Resources Department (for consultants; see AP-006) and Purchasing Department (for goods and services, including subcontractors; see AP-005) are responsible for preparing consulting services agreements as well as purchase and subcontract order documents. In addition, the SwRI Purchasing Department is responsible for selecting procurement sources, conducting solicitation assessment, determining award, and evaluating supplier performance.

2.6 The SwRI Manager of Quality Systems Technology is responsible for qualifying suppliers, maintaining the Approved Suppliers List (ASL), and periodically evaluating and rating suppliers of quality-affecting goods and services.

2.7 The CNWRA staff are formally qualified on CNWRA Form QAP-13, Professional Personnel Qualification and Training Record, and are responsible for final acceptance of goods and services.

3. DISCUSSION

The CNWRA uses core staff, as well as CNWRA students, SwRI staff, consultants, and subcontractors to perform quality-affecting activities that are incorporated into CNWRA reports and products.

Activities potentially affecting quality include, but are not limited to, scientific investigations, experiments, tests, analytical services, reviews, code development, receiving inspections, and numerical analyses. The results from these activities are accepted or rejected by appropriate and qualified technical staff based on their case-by-case assessment of the resultant quality of the work relative to project requirements and evaluation criteria. QA procurement controls are not applicable to goods and services that have no effect on the quality of the final product or data quality. Trained and qualified technical staff will perform receiving inspection. Because these individuals may perform receiving inspection on the item(s) required to support their work activities, senior management will ensure that the individuals accepting the item(s) (i) are not unduly influenced by cost and schedule, (ii) have sufficient authority to independently evaluate the acceptability of the items, and (iii) have direct access to senior management in matters related to receiving inspection.

4. PROCUREMENT PLANNING

Procurement planning activities shall be documented. During quality-affecting procurement planning, technical staff and QA personnel will provide input to supplier selection, confirmatory analyses requirements, and need for special receiving inspections to assure quality of the item.

4.1 Procurement Controls

Controls for quality-affecting procurements shall be applied to the following activities:

- Code development and numerical analysis
- Calibration services

- Sample and test materials used in scientific investigations
- "Obtaining Subcontract Services," as described in CNWRA Procedure AP-005
- "Obtaining Consultant Services," as described in CNWRA Procedure AP-006

If the procurement is quality affecting, the purchase requisition shall clearly state: "Quality Affecting Purchase."

Procurement documents for those goods and services affecting quality shall be reviewed by CNWRA QA and cognizant technical staff members, to verify that appropriate technical and quality provisions are included.

4.2 Procurement of Goods other than Software

Quality-affecting goods (e.g., test materials, calibration standards, etc.) may be procured from approved sources on the SwRI ASL or shall be qualified through the method described in QAP-018, Procedure for Confirmatory Analyses.

Note: Quality-affecting goods shall not be purchased via the procurement card or "petty cash" account or without a purchase requisition.

4.3 Procurement of Software

The procurement of software will be controlled from initiation of procurement documents through validation testing to assure the software performs as described in development and controlling documents.

4.3.1 Procurement of Acquired Software

Acquired software (including commercially available and "freeware" software) shall be controlled and documented. This documentation will start with initiation of the purchase requisition and will conclude with the software being validated in accordance with an approved Software Validation Test Plan. "Freeware" from the web or from a client is obtained without a procurement document, but is controlled in the same manner as acquired software. The EM/PI will be responsible for describing on the purchase requisition the specification(s) for this commercially available software and any revision to that software. The EM/PI initiating the requisition shall be responsible for performing the receiving inspection on the software after delivery at the CNWRA. This inspection will assure that the correct

software has been received and that any other requirements identified on the requisition have been satisfied. If purchase requisition requirements have been fulfilled, the requirements of paragraph 7.1.2 shall be accomplished.

4.3.2 Procurement of CNWRA Developed Software

The procurement of CNWRA developed software shall be controlled and documented in accordance with Software Requirements Descriptions (SRD), Software Development Plans, and Software Validation Test Plans as described in TOP-018, Development and Control of Scientific and Engineering Software. The procurement vehicle for developed software may take the form of a purchase order, a consultant services agreement, or a subcontract. Any subcontract or consultant contract requiring code development will either include an SRD as part of the scope or require the same to be produced by the subcontractor/consultant as the first deliverable. The EM/PI shall monitor subcontractor/consultant performance to assure that software development is proceeding in accordance with the approved software plans. The EM/PI shall perform the receiving inspection on completed software to assure it performs as expected. This receiving inspection will be documented in accordance with paragraph 7.1.2.

4.4 Procurement of Services

4.4.1 The activities affecting quality will be performed by qualified individuals.

4.4.2 Experimental, test, analytical, laboratory, and special process services may be purchased from suppliers listed on the SwRI ASL, or from suppliers who are provided "blind samples" by the CNWRA to confirm precision and accuracy. Commercial-grade suppliers, universities, or other sources determined to be qualified by CNWRA QA and technical staff, but not listed on the ASL, also can be used.

4.4.2.1 Calibration Services

Most calibration services are provided by the SwRI Calibration Laboratory. When SwRI Calibration Laboratory services are not used, the CNWRA will use the SwRI ASL to identify suppliers for the procurement of calibration services. Calibration services affecting quality shall be purchased from a laboratory that can provide traceability to a national or international standard. The SwRI QA Calibration Laboratory shall determine acceptability of laboratories not appearing on the SwRI ASL.

4.4.2.2 Procurement of Research and Analysis

Research and analysis activities shall be performed by individuals qualified in accordance with QAP-007, Professional Personnel Qualification. Completed research and analysis activities shall be evaluated by technical staff to determine acceptability of the final product.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When quality-affecting goods or services are required, the requestor shall provide the following on the purchase requisition (or on an attachment to the requisition depending on the type of procurement):

- If the procurement is quality affecting, the purchase requisition shall clearly state: "Quality Affecting Purchase"
- Identify whether supplier is on the ASL; if not, indicate the method to be used to inspect and qualify the item (e.g., QAP-018)
- Scope of work, or detailed description of the goods or services required
- Applicable codes, regulations, specifications, standards, drawings, CNWRA procedures or technical requirements
- Requirements for certification of special processes
- Requirements for special documentation, certification requirements, and the like

5.1.2 The QA-related purchasing information shall be included in the purchase requisition by reference to commonly used "QA-clauses." When the existing QA clauses do not address specific requirements or the QA clauses need to be supplemented, special written addenda shall be used.

5.1.3 When the purchase requisition is complete, a copy shall be sent by the Financial Clerk to the requestor. This provides the requestor with the purchase requisition number. The purchase requisition number or the purchase order number is required in the identification process for accepted items.

5.1.4 When a quality-affecting material, equipment, or services is obtained from a SwRI Division, a memorandum or a SwRI division-specific form addressing intra-SwRI services shall be used to document such activities.

5.1.5 For goods and services not affecting quality, the purchase requisition shall be initiated by a staff member and approved by the PI.

5.2 Procurement Document Review

5.2.1 Procurement documents shall be initiated and/or reviewed by a technical staff person responsible for the purchase. This person shall review the document to assure that technical references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions along with any revisions included that describe the items or service to be furnished. The quality-affecting procurement document shall be reviewed by QA to assure that appropriate quality requirements are included. 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.

5.2.2 Approved procurement documents shall be forwarded to either the SwRI Human Resources or Purchasing Department, which shall incorporate the requirements into a consulting services contract or a purchase order or subcontract for transmittal to the goods or services provider.

5.2.3 Changes to the scope of work, quality, or technical specification requirements reflected in the purchase requisition shall be approved in the same manner as original procurement documents.

5.2.4 Specifically for procurement of services from consultants or subcontractors, the Director of QA shall include an appropriate Quality Requirements statement that 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." This is specified in AP-005 and AP-006.

6. SELECTION AND QUALIFICATION

6.1 Approved Suppliers of Goods and Services

6.1.1 The SwRI QA Department shall maintain the ASL. The ASL identifies suppliers of goods and services who consistently provide acceptable goods or services in accordance with specific technical requirements. Supplier qualification shall be contingent on meeting the requirements that demonstrate the supplier's consistent conformance to technical and quality specifications.

6.1.2 The SwRI ASL can be used to determine appropriate and competent suppliers of goods and services based on audits and other evaluative methods.

6.2 Qualification of Non-ASL Goods (Excluding Software Suppliers)

Confirmatory analyses, as described in QAP-018, Procedure for Confirmatory Analyses, will be required on goods supplied from non-ASL suppliers if they supply such goods that have been determined to be quality-affecting.

7. ACCEPTANCE OF GOODS AND SERVICES

7.1 Acceptance of Quality-Affecting Goods from ASL Suppliers

7.1.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspections. The receiving inspection shall be performed in accordance with instructions described in Sample 1 to this procedure. If there is no unsatisfactory finding after performing the steps in Sample 1, the item will be considered acceptable.

7.1.2 The technical staff person responsible for acceptance will document the status of the item on the receipt traveler or shipping slip. This documentation will contain the phrase"accepted," the date and the receiving person's initials. A copy of the green SwRI Receipt Traveler (Sample 2) or the packing slip, shall be stapled to the purchase requisition. The purchase requisition with the attached receipt traveler or packing slip shall be forwarded to the Financial Clerk who will make a copy and forward the original to QA Records.

7.1.3 Nonconformances identified during receiving inspection shall be processed in accordance with QAP-009, Nonconformance Control.

7.2 Acceptance of Quality-Affecting Goods from Non-ASL Suppliers

The normal receiving inspection process identified in Sample 1 shall be followed for all items.

7.2.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspection. The receiving inspection shall be performed in accordance with the instructions described in Sample 1. If there is no unsatisfactory finding after performing the steps in Sample 1, the item will be considered received, not accepted.

7.2.2 The technical staff person responsible for acceptance will document the status of the item on the receipt traveler or packing slip. This document will contain the phrase "received - acceptance pending," the date, and the person's initials. A copy of the green SwRI Receipt Traveler (Sample 2) or the packing slip shall be stapled to the purchase requisition. The purchase requisition with the attached receipt traveler or packing slip shall be forwarded to the Financial Clerk who will make a copy and forward the original to QA records.

7.2.3 The acceptance of quality-affecting goods from non-ASL suppliers can be accomplished through various methods (tests, confirmatory analysis, comparison, or inspection) as described in QAP-018. The method used to determine acceptance is identified in QAP-018. The results of the method will determine if the item is accepted. The process for documenting the final status of the non-ASL item shall be in accordance with QAP-018.

7.2.4 Nonconformances identified during receiving inspection shall be processed in accordance with QAP-009, Nonconformance Control.

7.3 Acceptance of Services

7.3.1 Services received from ASL-qualified suppliers will be accepted by technical staff and shall be based on review of the supplier's inspection and/or test reports. This review will verify that both technical and quality procurement requirements are satisfied. The technical staff member or other receiving person will show acceptance of the service by approving the voucher/invoice for the service and providing entry into the scientific notebook or project folder, if appropriate.

7.3.2 Analytical services procured from non ASL-approved sources shall be accepted by technical staff based on inspections and tests performed upon receipt to verify

conformance to the technical and quality requirements. Blind standards and duplicate samples can be used to determine analytical accuracy and precision, which shall be evaluated against limits determined by the cognizant CNWRA technical staff member prior to issuance of the purchase order. Check samples composed of approximately 10 percent of the total number of the unknown samples can be used along with other methods, to provide confidence in the results. In cases where blind standards are not possible, the testing shall be accomplished pursuant 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, will be recorded with the analysis data and provided to the CNWRA technical staff member by the supplier. Where independent analysis is required for acceptance, analysis results from the original purchase and the duplicate analysis must be within an acceptable tolerance for acceptance, as determined by the PI.

7.3.3 Scientific investigations, experiments, tests, reviews, code development, numerical analysis, and similar activities will be accepted by technical staff based on inspections and/or testing of the product provided. An appropriate, qualified staff member will make the determination of acceptability or rejection of the procured service. If accepted, approval of the consultant/subcontractor invoice for the service will constitute objective evidence. A copy of the approved invoice will be sent to QA Records by the Financial Clerk. If not acceptable, the objective evidence will be nonpayment of the invoice, notation in a scientific notebook or project record, or a documenting memorandum to the file.

7.3.4 When CNWRA activities require the expertise of other SwRI staff, the staff member shall be qualified and shall work under the direction of a CNWRA Principal Investigator or EM. Acceptance of SwRI staff work and/or products is shown by a signature of the EM on the AP-6 Form, Document Review Request and Transmittal Control.

7.3.5 Most service procurements produce documentary text and analyses that are incorporated in CNWRA publications. The documentation resulting from review in accordance with QAP-002, Review of CNWRA Documents, Reports and Papers, will constitute objective evidence of acceptance or rejection of these services.

7.3.6 Nonconformance identified during acceptance of any product from an ASL or non-ASL suppler shall be processed in accordance with QAP-009.

7.4 Identification of Accepted Goods

Accepted quality-affecting goods will be identified by either the purchase order or purchase requisition number. For example, when using a purchase order, the numbers' prefix would be POXXX and PRXXXX for acceptance utilizing a purchase requisition. The purchase order or purchase requisition number shall appear on the item itself, shall be placed on a tag attached to the item, or on a container holding the accepted item. Only items that have successfully passed receipt inspection will have the purchase order or purchase requisition number affixed on the item.

7.5 Acceptance Documentation of Services

Acceptance documentation will either be recorded or placed in scientific notebooks or project record files. Acceptance documentation can include receiving inspections, test reports, copies of receipt travelers, reports from an analysis organization, and observation of the received goods or services that can discern whether it meets CNWRA requirements.

7.6 Control of Nonconformances

7.6.1 Consultants/subcontractors, and service suppliers will be required to notify CNWRA of nonconformances to procurement document requirements. Notification will include a description of the nonconformance, recommended disposition, and technical justification. The nonconformance will be processed in accordance with QAP-009, Nonconformance Control (CNWRA Form QAP 9-1), to obtain the proper evaluation, disposition, and corrective action.

7.6.2 Nonconformances identified during receiving inspections of goods and services from ASL supplies and non-ASL suppliers will also be processed in accordance with QAP-009.

7.6.3 Copies of supplier Nonconformance Reports will be included with the traveler, the project record folder, or in CNWRA QA records. Nonconformances can be considered in qualified supplier performance evaluations.

7.6.4 Supplier nonconformances will be evaluated individually to determine whether the good or service can be utilized by the CNWRA without adversely affecting the quality of the end product.

8. RECORDS

8.1 ASL supplier files will be maintained by the SwRI QA Department.

8.2 Procurement documentation, including subcontracts, will be maintained by the SwRI Purchasing Department.

8.3 Consultant services contracts will be maintained by the SwRI Human Resources Department.

8.4 Technical documentation for quality-affecting goods received during receipt inspections will be maintained by the cognizant CNWRA technical staff member in the appropriate scientific notebook or project record files. The receipt traveler and other receiving documentation showing acceptance will be maintained by the Financial Clerk and will be forwarded to QA Records quarterly for permanent retention.

8.5 Any quality records (i.e., acceptance documentation, surveillance reports, nonconformance reports) generated as a result of the procurement process will be maintained by CNWRA QA in the QA Records Room. CNWRA scientific notebooks that may contain related procurement information are sent to QA following completion of the project work, and these notebooks are maintained as permanent QA Records. CNWRA electronic scientific notebooks are periodically printed and provided to QA Records for safe keeping (QAP-001, Scientific Notebook Control).

Instructions for the Performance of Quality-Affecting Item Receiving Inspections

The following instructions are to be followed to perform satisfactory receiving inspections on quality affecting goods and services at the CNWRA. Satisfactory acceptance of any good or service will be documented in accordance with procedure requirements. Unsatisfactory receiving results will be processed in accordance paragraph 7.6, "Control of Nonconformances."

Acceptance of Goods and Services

Acceptance of goods and services, which includes but is not limited to chemicals, equipment calibration, test samples, computer software, science and engineering reports, and other quality affecting purchases shall be performed by assuring the following criteria are satisfied as applicable:

- Assuring that goods or services are properly labeled
- Requested documentation listed on the purchase requesting has been and received includes physical, dimensional or other specified characteristics
- The correct amount or number of the good or service was sent
- The good or service is in the proper configuration
- The inspection shall identify any requirements that have not been met and shall identify any associated nonconformance reports documenting final resolution
- The item is clean and free from shipping damage

Sample 1

SOUTHWEST RESEARCH INSTITUTE

06/29/2001 — **RECEIPT TRAVELER** — Page 1

Warehouse: REC

Receipt ID: RC-0102604 **Packing Slip:** **Receiver:** Soto. Juan M.

Receipt Date: 06/29/2001

PO 184439S **Rel:** 0 **Change Ord:** 0 **Vendor:** GOODFELLOW CORPORATION

Receipt Notes: FED 497367112947

Line: 1
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-110, 0.025 mm DIA.

U/M: EA **QC Reqd:** N **Cert of Conf Reqd:** N **Source Insp Reqd:** N **Insp Type:** **Hazmat:**
Deliver To: L. YANG/B. 189 X2483 **Order Ref:** **Requisition:** 572932
Qty Rcv: 1.0000 **Qty Accpt:** 1.0000 **Qty Rej:**
Location: **Location:** **Location:**

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 2
Item: 25 m STAINLESS STEEL 302 WIRE, Fe 205-116, 0.05 mm DIA.

U/M: EA **QC Reqd:** N **Cert of Conf Reqd:** N **Source Insp Reqd:** N **Insp Type:** **Hazmat:**
Deliver To: L. YANG/B. 189 X2483 **Order Ref:** **Requisition:** 572932
Qty Rcv: 1.0000 **Qty Accpt:** 1.0000 **Qty Rej:**
Location: **Location:** **Location:**

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 3
Item: 25 m STAINLESS STEEL 302 WIRE, Fe 205-118, 0.1 mm DIA.

U/M: EA **QC Reqd:** N **Cert of Conf Reqd:** N **Source Insp Reqd:** N **Insp Type:** **Hazmat:**
Deliver To: L. YANG/B. 189 X2483 **Order Ref:** **Requisition:** 572932
Qty Rcv: 1.0000 **Qty Accpt:** 1.0000 **Qty Rej:**
Location: **Location:** **Location:**

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 4
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-130, 0.25 mm DIA.

U/M: EA **QC Reqd:** N **Cert of Conf Reqd:** N **Source Insp Reqd:** N **Insp Type:** **Hazmat:**
Deliver To: L. YANG/B. 189 X2483 **Order Ref:** **Requisition:** 572932
Qty Rcv: 1.0000 **Qty Accpt:** 1.0000 **Qty Rej:**
Location: **Location:** **Location:**

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 5
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-140, 0.5 mm DIA.

U/M: EA **QC Reqd:** N **Cert of Conf Reqd:** N **Source Insp Reqd:** N **Insp Type:** **Hazmat:**
Deliver To: L. YANG/B. 189 X2483 **Order Ref:** **Requisition:** 572932
Qty Rcv: 1.0000 **Qty Accpt:** 1.0000 **Qty Rej:**
Location: **Location:** **Location:**

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Sample 2

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-016 Revision 6 Change 0 Page 1 of 15

Title QAP–016 PROCUREMENT

EFFECTIVITY

Revision 6 of this procedure became effective on 8/07/2002. This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
ALL	0	8/07/2002

SUPERSEDED

Supersedes Procedure No. QAP-016 Rev 5, Chg. 0

Approvals			
Written by Mark R. Ehnstrom Mark Ehnstrom	Date 08/01/02	Concurrence Review Lietai Yang Lietai Yang	Date 08/02/02
Quality Assurance Bruce Mabrito Bruce Mabrito	Date 8/20/2002	Cognizant Director Henry Garda Henry Garda	Date 8/01/02

CNWRA Form TOP-1 (8/93)

QAP-016 PROCUREMENT

1. PURPOSE

The purpose of this procedure is to describe the controls used in the procurement of goods and services for activities that are quality-affecting. This procedure may also be used for non-quality affecting procurements. Among the procurement activities affecting quality described in this procedure are the use of qualified suppliers, identification of quality requirements, and verification of receipt of purchased items and services. This procedure implements the requirements of the Center for Nuclear Regulatory Analyses (CNWRA) Quality Assurance Manual, sections 4 and 7.

2. RESPONSIBILITIES

2.1 The requestor of procurement action(s) is responsible for providing required technical specifications and/or scope of work requirements on the purchase requisitions The requestor is responsible for routing the purchase requisition through the division review process.

2.2 The Director of Quality Assurance is responsible for assuring that quality requirements are included in procurement-related documents. The Director of Quality Assurance is also responsible for the control of nonconformances, corrective actions, and quality assurance records. Quality Assurance is not responsible for the procurement of goods and services that do not effect final product or data quality. The Element Manager or Principal Investigator shall be responsible for identifying goods or services that effect final product or data quality.

2.3 The Element Managers, Principal Investigators, and the cognizant Directors are responsible for approving purchase requisitions.

2.4 The CNWRA Financial Clerk is responsible for maintaining copies of completed purchase requisitions. The Financial Clerk is also responsible for maintaining and forwarding quarterly purchase requisitions with attached receipt travelers or packing slips documenting results of receiving inspection in accordance with paragraph 8.4 of this procedure.

2.5 For purchases that have no quality implications (e.g., office supplies non-quality affecting, and any other non-quality affecting item or services), the Director of Administration shall be responsible for assuring acceptability of the delivered product.

2.6 The Southwest Research Institute (SwRI) Human Resources Department (for consultants; see AP-006) is responsible for preparing consulting services

agreements and the Purchasing Department (for goods and services, including subcontractors; see AP-005) is responsible for preparing purchase order and subcontract documents. In addition, the SwRI Purchasing Department is responsible for selecting procurement sources, conducting solicitation assessment, determining award, and evaluating supplier performance.

2.7 The SwRI Manager of Quality Systems Technology is responsible for qualifying suppliers, maintaining the Approved Suppliers List, and periodically evaluating and rating suppliers of quality-affecting goods and services.

2.8 The CNWRA staff are formally qualified on CNWRA Form QAP-13, Professional Personnel Qualification and Training Record, and are responsible for final acceptance of goods and services.

3. DISCUSSION

The CNWRA uses individuals and organizations—including core staff, students, SwRI staff, consultants, and subcontractors—to perform quality-affecting activities that are incorporated into CNWRA reports and products.

Activities potentially affecting quality include, but are not limited to, scientific investigations, experiments, tests, analytical services, reviews, code development, receiving inspections, and numerical analyses. The results from these activities are accepted or rejected by appropriate, qualified technical staff based on their case-by-case assessment of the resultant quality of the work relative to project requirements and evaluation criteria. Quality Assurance procurement controls are not applicable to goods and services that do not effect the quality of the final product or data.

Trained and qualified technical staff will perform receiving inspection. Because these individuals may perform receiving inspection on the item(s) required to support their work activities, senior management will ensure that the individuals accepting the item(s): (i) are not unduly influenced by cost and schedule, (ii) have sufficient authority to independently evaluate the acceptability of the items, and (iii) have direct access to senior management in matters related to receiving inspection.

4. PROCUREMENT PLANNING

Procurement planning activities shall be documented. During quality-affecting procurement planning, technical staff and Quality Assurance personnel will provide input to supplier selection, confirmatory analysis requirements, and need for special receiving inspections to assure quality of the item.

4.1 Procurement Controls

Controls for quality-affecting procurements shall be applied to the following activities:

- Code development and numerical analysis
- Calibration services
- Sample and test materials used in scientific investigations
- "Obtaining Subcontract Services," as described in CNWRA Procedure AP-005
- "Obtaining Consultant Services," as described in CNWRA Procedure AP-006

If the procurement is quality affecting, the purchase requisition shall clearly state: "Quality Affecting Purchase."

Procurement documents for those goods and services affecting quality shall be reviewed by CNWRA Quality Assurance and cognizant technical staff members, to verify that appropriate technical and quality provisions are included.

Procurement documents shall provide for access to the supplier's facilities and records for inspection or audit by the CNWRA staff and/or designated representative.

4.2 Procurement of Goods Other than Software

Quality-affecting goods (e.g., test materials, calibration standards, etc.) may be procured from approved sources on the SwRI Approved Suppliers List or shall be qualified through the method described in QAP-018, Procedure for Confirmatory Analyses.

Note: Quality-affecting goods shall not be purchased via the procurement card or "petty cash" account or without a purchase requisition.

4.3 Procurement of Software

The procurement of scientific and engineering software (see TOP-018) shall be controlled from initiation of procurement documents through validation testing to assure the software performs as described in development and controlling documents.

4.3.1 Procurement of Acquired Software

Acquired scientific and engineering software (as defined in TOP-018, including commercially available and "freeware" software) shall be controlled and documented. This documentation will start with initiation of the purchase requisition and will conclude with the software being validated in accordance with an approved Software Validation Test Plan. Software obtained from sources on the SwRI Approved Suppliers List that have satisfactorily been evaluated to requirements contained in TOP-018 do not require further validation by the CNWRA. The Element Manager/Principal Investigator is responsible for describing on the purchase requisition the specification(s) for this commercially available software and any revision to that software. The Element Manager/Principal Investigator initiating the requisition is responsible for performing the receiving inspection on the software after delivery at the CNWRA. This inspection will assure that the correct software has been received and that any quality or other requirements identified on the requisition have been satisfied. If purchase requisition requirements have been fulfilled, the requirements of paragraph 7.1.2 shall be accomplished. "Freeware" from the web or from a client is obtained without a procurement document, but is controlled under TOP-018 in the same manner as acquired software.

4.3.2 Procurement of CNWRA Developed Software

The procurement of CNWRA developed software (as defined in TOP-018) shall be controlled and documented in accordance with Software Requirements Descriptions, Software Development Plans, and Software Validation Test Plans as described in TOP-018, Development and Control of Scientific and Engineering Software. The procurement vehicle for developed software may take the form of a purchase order, a consultant services agreement, or a subcontract. Any subcontract or consultant contract requiring code development will either include an Software Requirement Description as part of the scope or require the same to be produced by the subcontractor/consultant as the first deliverable. The Element Manager/Principal Investigator shall monitor subcontractor/consultant performance to assure that software development is proceeding in accordance with the approved software plans. The Element Manager/Principal Investigator shall perform the receiving inspection on completed software to assure it performs as expected. This receiving inspection will be documented in accordance with paragraph 7.1.2.

4.4 Procurement of Services

4.4.1 The activities affecting quality will be performed by qualified individuals.

4.4.2 Experimental, test, analytical, laboratory, and special process services may be purchased from suppliers listed on the SwRI Approved Suppliers List approved for nuclear work, or from suppliers who are provided "blind samples" by the CNWRA to confirm precision and accuracy. Commercial-grade suppliers, universities, or other sources determined to be qualified by CNWRA Quality Assurance and technical staff, but not listed on the Approved Suppliers List, also can be used.

SwRI divisions and individual departments may be used to provide these services as qualified by CNWRA Quality Assurance. The qualification shall consist of:

- Evaluation of the department or division history of providing similar services
- Review of audits performed on the department or division. This evaluation shall be performed annually by the Director of Quality Assurance. Records of this review shall be maintained in the Quality Assurance files.

4.4.3 Calibration Services

Most calibration services are provided by the SwRI Calibration Laboratory. When SwRI Calibration Laboratory services are not used, the CNWRA will use the SwRI Approved Suppliers List to identify suppliers for the procurement of calibration services. Calibration services affecting quality shall be purchased from a laboratory approved for nuclear calibration services and that can provide traceability to a national or international standard. The SwRI Quality Assurance Calibration Laboratory shall determine acceptability of laboratories not appearing on the SwRI Approved Suppliers List.

4.4.4 Procurement of Research and Analysis

Research and analysis activities shall be performed by individuals qualified in accordance with QAP-007, Professional Personnel Qualification. Completed research and analysis activities shall be evaluated by technical staff to determine acceptability of the final product. Results of the evaluation shall be documented in accordance with paragraph 7.5 of this procedure.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When quality-affecting goods or services are required, the requestor shall provide the following on the purchase requisition (or on an attachment to the requisition depending on the type of procurement):

- If the procurement is quality affecting, the purchase requisition shall clearly state if the purchase is a quality affecting purchase.
- Identify whether supplier is on the Approved Suppliers List; if not, indicate the method to be used to inspect and qualify the item (e.g., QAP-018)
- Scope of work, or detailed description of the goods or services required
- Applicable codes, regulations, specifications, standards, drawings, CNWRA procedures or technical requirements
- Requirements for certification of special processes
- Requirements for special documentation, certification requirements, and the like

5.1.2 The Quality Assurance-related purchasing information shall be included in the purchase requisition by reference to commonly used "Quality Assurance-clauses." When the existing Quality Assurance clauses do not address specific requirements or the Quality Assurance clauses need to be supplemented, special written addenda shall be used.

5.1.3 When the purchase requisition is complete, a copy shall be sent by the Financial Clerk to the requestor. This provides the requestor with the purchase requisition number. The purchase requisition number or the purchase order number is required in the identification process for accepted items.

5.1.4 When a quality-affecting item or service is obtained from a SwRI Division, a memorandum or a SwRI division-specific form addressing intra-SwRI services shall be used to document such activities.

5.1.5 For goods and services not affecting quality, the purchase requisition shall be initiated by a staff member, approved by the Principal Investigator, and processed under the responsibility of the Director of Administration.

5.2 Procurement Document Review

5.2.1 Procurement documents shall be initiated and/or reviewed by a technical staff person responsible for the purchase. This person shall review the document to assure that technical references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions along with any revisions included that describe the items or service to be furnished. The quality-affecting procurement document shall be reviewed by Quality Assurance to assure that appropriate quality requirements are included. 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 and if Quality Assurance is required. The Quality Assurance representative stamps the purchase requisition.

5.2.2 Approved procurement documents shall be forwarded to either the SwRI Human Resources or Purchasing Department, which shall incorporate the requirements into a consulting services contract or a purchase order or subcontract for transmittal to the goods or services provider.

5.2.3 Changes to the scope of work, quality, or technical specification requirements reflected in the purchase requisition shall be approved in the same manner as original procurement documents.

5.2.4 Specifically for procurement of services from consultants or subcontractors, the Director of Quality Assurance shall include an appropriate Quality Requirements statement as specified in AP-005 and AP-006.

6. SELECTION AND QUALIFICATION

6.1 Approved Suppliers of Goods and Services

6.1.1 The SwRI Quality Assurance Department shall maintain the Approved Suppliers List. The Approved Suppliers List identifies suppliers of goods and services who consistently provide acceptable goods or services in accordance with specific technical requirements. Supplier qualification shall be contingent on meeting the requirements that demonstrate the supplier's consistent conformance to technical and quality specifications.

6.1.2 The SwRI Approved Suppliers List can be used to determine appropriate and competent suppliers of goods and services based on audits and other evaluative methods.

6.2 Qualification of Non-Approved Suppliers List of Goods (Excluding Software Suppliers)

Confirmatory analyses, as described in QAP-018, Procedure for Confirmatory Analyses, will be required on goods supplied from non-Approved Suppliers List suppliers if they supply such goods that have been determined to be quality-affecting.

6.3 Qualification of Non-Approved Suppliers List of Services and Software

The CNWRA may use suppliers of services and software that have not been through a qualification process. The service or software provided shall meet specific technical and quality specifications that can be confirmed at the CNWRA.

7. ACCEPTANCE OF GOODS AND SERVICES

7.1 Acceptance of Quality-Affecting Goods from Qualified Individuals or From Approved Suppliers List Suppliers

7.1.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspections. The receiving inspection shall be performed in accordance with instructions described in Figure 1 to this procedure. If there is no unsatisfactory finding after performing the steps in Figure 1, the item will be considered acceptable.

7.1.2 The technical staff person responsible for acceptance will document the status of the item on the receipt traveler or shipping slip. This documentation should contain phrases such as, "accepted," "items accepted." The receipt traveler or shipping ticket shall at a minimum identify the date and the receiving person's initials. A copy of the SwRI Receipt Traveler (Figure 2) or the packing slip, shall be stapled to the purchase requisition. The purchase requisition with the attached receipt traveler or packing slip shall be forwarded to the Financial Clerk who will make a copy and forward the original to Quality Assurance Records.

7.1.3 Nonconformances identified during receiving inspection shall be processed in accordance with QAP-009, Nonconformance Control.

7.2 Acceptance of Quality-Affecting Goods from Non-Approved Suppliers List Suppliers

The normal receiving inspection process identified in Figure 1 shall be followed for all items.

7.2.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspection. The receiving inspection shall be performed in accordance with the instructions described in Figure 1. If there is no unsatisfactory finding after performing the steps in Figure 1, the item will be considered received, not accepted.

7.2.2 The technical staff person responsible for acceptance will document the status of the item on the receipt traveler or packing slip. This document will contain the phrase "received-acceptance pending," the date, and the person's initials. A copy of the SwRI Receipt Traveler (Figure 2) or the packing slip shall be stapled to the purchase requisition. The purchase requisition with the attached receipt traveler or packing slip shall be forwarded to the Financial Clerk who will make a copy and forward the original to Quality Assurance records.

7.2.3 The acceptance of quality-affecting goods from non-Approved Suppliers List suppliers can be accomplished through various methods (tests, confirmatory analysis, comparison, or inspection) as described in QAP-018. The method used to determine acceptance is identified in QAP-018. The results of the method will determine if the item is accepted. The process for documenting the final status of the non-Approved Suppliers List item shall be in accordance with QAP-018.

7.2.4 Nonconformances identified during receiving inspection shall be processed in accordance with QAP-009, Nonconformance Control.

7.3 Acceptance of Services

7.3.1 Services received from Approved Suppliers List-qualified suppliers will be accepted by technical staff and shall be based on review of the supplier's inspection and/or test reports. This review will verify that both technical and quality procurement requirements are satisfied. The technical staff member or other receiving person will show acceptance of the service by approving the voucher/invoice for the service and providing entry into the scientific notebook or project folder, if appropriate.

7.3.2 Analytical services procured from non Approved Suppliers List-approved sources shall be accepted by technical staff based on inspections and tests performed upon receipt to verify conformance to the technical and quality requirements. Blind standards and duplicate samples can be used to determine analytical accuracy and precision, which shall be evaluated against limits determined by the cognizant CNWRA technical staff member prior to issuance of the purchase order. Check samples composed of approximately 10 percent of the total number of the unknown samples can be used along with other methods, to provide confidence in the results. In cases where blind standards are not possible, the testing shall be accomplished pursuant 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, will be recorded with the analysis data and provided to the CNWRA technical staff member by the supplier. Where independent analysis is required for acceptance, analysis results from the original purchase and the duplicate analysis must be within an acceptable tolerance for acceptance, as determined by the Principal Investigator.

7.3.3 Scientific investigations, experiments, tests, reviews, code development, numerical analysis, and similar activities provided from Non-Approved Suppliers will be accepted by technical staff based on inspections and/or testing of the product provided. An appropriate, qualified staff member will make the determination of acceptability or rejection of the procured service. If accepted, approval of the consultant/subcontractor invoice for the service will constitute objective evidence. A copy of the approved invoice will be sent to Quality Assurance Records by the Financial Clerk. If not acceptable, the objective evidence will be nonpayment of the invoice, notation in a scientific notebook or project record, or a documenting memorandum to the file.

7.3.4 Most service procurements produce documentary materials and analyses that are incorporated in CNWRA publications. The documentation resulting from review in accordance with QAP-002, Review of CNWRA Documents, Reports and Papers, will constitute objective evidence of acceptance or rejection of these services.

7.3.5 Nonconformances identified during acceptance of any product from an Approved Suppliers List or non-Approved Suppliers List suppler shall be processed in accordance with QAP-009.

7.4 Identification of Accepted Goods

Accepted quality-affecting goods will be identified by either the purchase order or purchase requisition number. The prefix would be POXXX and PRXXXX for acceptance utilizing a purchase order or purchase requisition, respectively. The purchase order or purchase requisition number shall appear on the item itself, shall be placed on a tag attached to the item, or on a container holding the accepted item. Only items that have successfully passed receipt inspection will have the purchase order or purchase requisition number affixed on the item.

7.5 Acceptance Documentation of Services

Acceptance documentation will either be recorded or placed in scientific notebooks or project record files. Acceptance documentation can include receiving inspections, test reports, copies of receipt travelers, reports from an analysis organization, and observation of the received goods or services that can discern whether it meets CNWRA requirements.

7.6 Control of Nonconformances

7.6.1 Individuals and organizations supplying goods or services will be required to notify CNWRA of nonconformances to procurement requirements. Notification will include a description of the nonconformance, recommended disposition, and technical justification. Any nonconformance will be processed in accordance with QAP-009, Nonconformance Control (CNWRA Form QAP 9-1), to obtain the proper evaluation, disposition, and corrective action.

7.6.2 Nonconformances identified during receiving inspections of goods and services from Approved Suppliers List supplies and non-Approved Suppliers List suppliers will also be processed in accordance with QAP-009.

7.6.3 Copies of supplier Nonconformance Reports will be included with the traveler, the project record folder, or in CNWRA Quality Assurance records. Nonconformances can be considered in qualified supplier performance evaluations.

7.6.4 Supplier nonconformances will be evaluated individually to determine whether the good or service can be utilized by the CNWRA without adversely affecting the quality of the end product.

8. RECORDS

8.1 Approved Suppliers List supplier files will be maintained by the SwRI Quality Assurance Department.

8.2 Procurement documentation, including subcontracts, will be maintained by the SwRI Purchasing Department.

8.3 Consultant services contracts will be maintained by the SwRI Human Resources Department.

8.4 Technical documentation resulting from receipt inspections of quality-affecting goods and services will be maintained by the cognizant CNWRA technical staff member in the appropriate scientific notebook or project record files. The receipt traveler and other receiving documentation showing acceptance will be maintained by the Financial Clerk and will be forwarded to Quality Assurance Records quarterly for permanent retention.

8.5 Any quality records (i.e., acceptance documentation, surveillance reports, nonconformance reports) generated as a result of the procurement process will be maintained by CNWRA Quality Assurance in the Quality Assurance Records Room. CNWRA scientific notebooks that may contain related procurement information are sent to Quality Assurance following completion of the project work, and these notebooks are maintained as permanent Quality Assurance Records. CNWRA electronic scientific notebooks are periodically printed and provided to Quality Assurance Records for safe keeping (QAP-001, Scientific Notebook Control).

Instructions for Performing Receiving Inspections on Quality-Affecting Items

The following instructions apply to receiving inspections on quality affecting goods and services at the CNWRA. Satisfactory acceptance of any good or service will be documented in accordance with procedure requirements. Unsatisfactory goods and services will be processed in accordance with paragraph 7.6, "Control of Nonconformances."

Acceptance of Goods and Services

Receiving inspections of goods and services, including but not limited to chemicals, equipment calibration, test samples, computer software, science and engineering reports, and other quality affecting purchases, shall be performed by assuring the following criteria are satisfied as applicable:

- Assuring that goods or services are properly labeled
- Requested documentation listed on the purchase requesting has been and received includes physical, dimensional or other specified characteristics
- The correct amount or number of the good or service was sent
- The good or service is in the proper configuration
- The item is clean and free from shipping damage

The inspection shall identify any requirements that have not been met and shall identify any associated nonconformance reports documenting final resolution.

Accepted goods and services will be identified and documented in accordance with paragraphs 7.4 and 7.5 of this procedure.

Figure 1
(Example)

Page 1

SOUTHWEST RESEARCH INSTITUTE
RECEIPT TRAVELER
Warehouse: REC

06/29/2001

Receipt ID: RC-0102604 Packing Slip: Receiver: Soto, Juan M.
Receipt Date: 06/29/2001
PO 1844395 Rel: 0 Change Ord: 0 Vender: GOODFELLOW CORPORATION

Receipt Notes: FED 497367112947

Line: 1
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-110, 0.025 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 2
Item: 25 m STAINLESS STEEL 302 WIRE, Fe 205-116 0.5 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 3
Item: 25 m STAINLESS STEEL 302 WIRE, Fe 205-118, 0.1 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 4
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-130, 0.25 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 5
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-140, 0.5 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Figure 2
(Example)

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-016 Revision 6 Change 1 Page 1 of 15

Title QAP–016 PROCUREMENT

EFFECTIVITY

Revision 6 of this procedure became effective on 8/07/2002. This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
1	1	9/04/2003
2–4	0	8/07/2002
5	1	9/04/2003
6–15	0	8/07/2002

Supersedes Procedure No. QAP-016 Rev 5, Chg. 0

Approvals			
Written by Robert Brient	Date 9/3/03	Concurrence Review Budhi Sagar	Date 9/2/2003
Quality Assurance Mark Ehnstrom	Date 9/2/03	Cognizant Director Pat Mackin	Date 9/2/2003

CNWRA Form TOP-1 (8/93)

QAP-016 PROCUREMENT

1. PURPOSE

The purpose of this procedure is to describe the controls used in the procurement of goods and services for activities that are quality-affecting. This procedure may also be used for non-quality affecting procurements. Among the procurement activities affecting quality described in this procedure are the use of qualified suppliers, identification of quality requirements, and verification of receipt of purchased items and services. This procedure implements the requirements of the Center for Nuclear Regulatory Analyses (CNWRA) Quality Assurance Manual, sections 4 and 7.

2. RESPONSIBILITIES

2.1 The requestor of procurement action(s) is responsible for providing required technical specifications and/or scope of work requirements on the purchase requisitions The requestor is responsible for routing the purchase requisition through the division review process.

2.2 The Director of Quality Assurance is responsible for assuring that quality requirements are included in procurement-related documents. The Director of Quality Assurance is also responsible for the control of nonconformances, corrective actions, and quality assurance records. Quality Assurance is not responsible for the procurement of goods and services that do not effect final product or data quality. The Element Manager or Principal Investigator shall be responsible for identifying goods or services that effect final product or data quality.

2.3 The Element Managers, Principal Investigators, and the cognizant Directors are responsible for approving purchase requisitions.

2.4 The CNWRA Financial Clerk is responsible for maintaining copies of completed purchase requisitions. The Financial Clerk is also responsible for maintaining and forwarding quarterly purchase requisitions with attached receipt travelers or packing slips documenting results of receiving inspection in accordance with paragraph 8.4 of this procedure.

2.5 For purchases that have no quality implications (e.g., office supplies non-quality affecting, and any other non-quality affecting item or services), the Director of Administration shall be responsible for assuring acceptability of the delivered product.

2.6 The Southwest Research Institute (SwRI) Human Resources Department (for consultants; see AP-006) is responsible for preparing consulting services

agreements and the Purchasing Department (for goods and services, including subcontractors; see AP-005) is responsible for preparing purchase order and subcontract documents. In addition, the SwRI Purchasing Department is responsible for selecting procurement sources, conducting solicitation assessment, determining award, and evaluating supplier performance.

2.7 The SwRI Manager of Quality Systems Technology is responsible for qualifying suppliers, maintaining the Approved Suppliers List, and periodically evaluating and rating suppliers of quality-affecting goods and services.

2.8 The CNWRA staff are formally qualified on CNWRA Form QAP-13, Professional Personnel Qualification and Training Record, and are responsible for final acceptance of goods and services.

3. DISCUSSION

The CNWRA uses individuals and organizations—including core staff, students, SwRI staff, consultants, and subcontractors—to perform quality-affecting activities that are incorporated into CNWRA reports and products.

Activities potentially affecting quality include, but are not limited to, scientific investigations, experiments, tests, analytical services, reviews, code development, receiving inspections, and numerical analyses. The results from these activities are accepted or rejected by appropriate, qualified technical staff based on their case-by-case assessment of the resultant quality of the work relative to project requirements and evaluation criteria. Quality Assurance procurement controls are not applicable to goods and services that do not effect the quality of the final product or data.

Trained and qualified technical staff will perform receiving inspection. Because these individuals may perform receiving inspection on the item(s) required to support their work activities, senior management will ensure that the individuals accepting the item(s): (i) are not unduly influenced by cost and schedule, (ii) have sufficient authority to independently evaluate the acceptability of the items, and (iii) have direct access to senior management in matters related to receiving inspection.

4. PROCUREMENT PLANNING

Procurement planning activities shall be documented. During quality-affecting procurement planning, technical staff and Quality Assurance personnel will provide input to supplier selection, confirmatory analysis requirements, and need for special receiving inspections to assure quality of the item.

4.1 Procurement Controls

Controls for quality-affecting procurements shall be applied to the following activities:

- Code development and numerical analysis
- Calibration services
- Sample and test materials used in scientific investigations
- "Obtaining Subcontract Services," as described in CNWRA Procedure AP-005
- "Obtaining Consultant Services," as described in CNWRA Procedure AP-006

If the procurement is quality affecting, the purchase requisition shall clearly state: "Quality Affecting Purchase."

Procurement documents for those goods and services affecting quality shall be reviewed by CNWRA Quality Assurance and cognizant technical staff members, to verify that appropriate technical and quality provisions are included.

Procurement documents shall provide for access to the supplier's facilities and records for inspection or audit by the CNWRA staff and/or designated representative.

4.2 Procurement of Goods Other than Software

Quality-affecting goods (e.g., test materials, calibration standards, etc.) may be procured from approved sources on the SwRI Approved Suppliers List or shall be qualified through the method described in QAP-018, Procedure for Confirmatory Analyses.

Note: Quality-affecting goods shall not be purchased via the procurement card or "petty cash" account or without a purchase requisition.

4.3 Procurement of Software

The procurement of scientific and engineering software (see TOP-018) shall be controlled from initiation of procurement documents through validation testing to assure the software performs as described in development and controlling documents.

4.3.1 Procurement of Acquired Software

Acquired scientific and engineering software (as defined in TOP-018, including commercially available and "freeware" software) shall be controlled in accordance with TOP-018. The Element Manager/Principal Investigator is responsible for describing on the purchase requisition the specification(s) for this commercially available software. The Element Manager/Principal Investigator initiating the requisition is responsible for performing the receiving inspection on the software after delivery at the CNWRA. This inspection will assure that the correct software has been received and that any quality or other requirements identified on the requisition have been satisfied. If purchase requisition requirements have been fulfilled, the requirements of paragraph 7.1.2 shall be accomplished. "Freeware" from the web or from a client is obtained without a procurement document, but is controlled under TOP-018 in the same manner as acquired software.

4.4 Procurement of Services

4.4.1 The activities affecting quality will be performed by qualified individuals.

4.4.2 Experimental, test, analytical, laboratory, and special process services may be purchased from suppliers listed on the SwRI Approved Suppliers List approved for nuclear work, or from suppliers who are provided "blind samples" by the CNWRA to confirm precision and accuracy. Commercial-grade suppliers, universities, or other sources determined to be qualified by CNWRA Quality Assurance and technical staff, but not listed on the Approved Suppliers List, also can be used.

SwRI divisions and individual departments may be used to provide these services as qualified by CNWRA Quality Assurance. The qualification shall consist of:

- Evaluation of the department or division history of providing similar services
- Review of audits performed on the department or division. This evaluation shall be performed annually by the Director of Quality Assurance. Records of this review shall be maintained in the Quality Assurance files.

4.4.3 Calibration Services

Most calibration services are provided by the SwRI Calibration Laboratory. When SwRI Calibration Laboratory services are not used, the CNWRA will use the SwRI Approved Suppliers List to identify suppliers for the procurement of calibration services. Calibration services affecting quality shall be purchased from a laboratory approved for nuclear calibration services and that can provide traceability to a national or international standard. The SwRI Quality Assurance Calibration Laboratory shall determine acceptability of laboratories not appearing on the SwRI Approved Suppliers List.

4.4.4 Procurement of Research and Analysis

Research and analysis activities shall be performed by individuals qualified in accordance with QAP-007, Professional Personnel Qualification. Completed research and analysis activities shall be evaluated by technical staff to determine acceptability of the final product. Results of the evaluation shall be documented in accordance with paragraph 7.5 of this procedure.

5. PROCUREMENT DOCUMENT CONTROL

5.1 Initiation of Purchase Documents

5.1.1 When quality-affecting goods or services are required, the requestor shall provide the following on the purchase requisition (or on an attachment to the requisition depending on the type of procurement):

- If the procurement is quality affecting, the purchase requisition shall clearly state if the purchase is a quality affecting purchase.
- Identify whether supplier is on the Approved Suppliers List; if not, indicate the method to be used to inspect and qualify the item (e.g., QAP-018)
- Scope of work, or detailed description of the goods or services required
- Applicable codes, regulations, specifications, standards, drawings, CNWRA procedures or technical requirements
- Requirements for certification of special processes
- Requirements for special documentation, certification requirements, and the like

5.1.2 The Quality Assurance-related purchasing information shall be included in the purchase requisition by reference to commonly used "Quality Assurance-clauses." When the existing Quality Assurance clauses do not address specific requirements or the Quality Assurance clauses need to be supplemented, special written addenda shall be used.

5.1.3 When the purchase requisition is complete, a copy shall be sent by the Financial Clerk to the requestor. This provides the requestor with the purchase requisition number. The purchase requisition number or the purchase order number is required in the identification process for accepted items.

5.1.4 When a quality-affecting item or service is obtained from a SwRI Division, a memorandum or a SwRI division-specific form addressing intra-SwRI services shall be used to document such activities.

5.1.5 For goods and services not affecting quality, the purchase requisition shall be initiated by a staff member, approved by the Principal Investigator, and processed under the responsibility of the Director of Administration.

5.2 Procurement Document Review

5.2.1 Procurement documents shall be initiated and/or reviewed by a technical staff person responsible for the purchase. This person shall review the document to assure that technical references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions along with any revisions included that describe the items or service to be furnished. The quality-affecting procurement document shall be reviewed by Quality Assurance to assure that appropriate quality requirements are included. 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 and if Quality Assurance is required. The Quality Assurance representative stamps the purchase requisition.

5.2.2 Approved procurement documents shall be forwarded to either the SwRI Human Resources or Purchasing Department, which shall incorporate the requirements into a consulting services contract or a purchase order or subcontract for transmittal to the goods or services provider.

5.2.3 Changes to the scope of work, quality, or technical specification requirements reflected in the purchase requisition shall be approved in the same manner as original procurement documents.

5.2.4 Specifically for procurement of services from consultants or subcontractors, the Director of Quality Assurance shall include an appropriate Quality Requirements statement as specified in AP-005 and AP-006.

6. SELECTION AND QUALIFICATION

6.1 Approved Suppliers of Goods and Services

6.1.1 The SwRI Quality Assurance Department shall maintain the Approved Suppliers List. The Approved Suppliers List identifies suppliers of goods and services who consistently provide acceptable goods or services in accordance with specific technical requirements. Supplier qualification shall be contingent on meeting the requirements that demonstrate the supplier's consistent conformance to technical and quality specifications.

6.1.2 The SwRI Approved Suppliers List can be used to determine appropriate and competent suppliers of goods and services based on audits and other evaluative methods.

6.2 Qualification of Non-Approved Suppliers List of Goods (Excluding Software Suppliers)

Confirmatory analyses, as described in QAP-018, Procedure for Confirmatory Analyses, will be required on goods supplied from non-Approved Suppliers List suppliers if they supply such goods that have been determined to be quality-affecting.

6.3 Qualification of Non-Approved Suppliers List of Services and Software

The CNWRA may use suppliers of services and software that have not been through a qualification process. The service or software provided shall meet specific technical and quality specifications that can be confirmed at the CNWRA.

7. ACCEPTANCE OF GOODS AND SERVICES

7.1 Acceptance of Quality-Affecting Goods from Qualified Individuals or From Approved Suppliers List Suppliers

7.1.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspections. The receiving inspection shall be performed in accordance with instructions described in Figure 1 to this procedure. If there is no unsatisfactory finding after performing the steps in Figure 1, the item will be considered acceptable.

7.1.2 The technical staff person responsible for acceptance will document the status of the item on the receipt traveler or shipping slip. This documentation should contain phrases such as, "accepted," "items accepted." The receipt traveler or shipping ticket shall at a minimum identify the date and the receiving person's initials. A copy of the SwRI Receipt Traveler (Figure 2) or the packing slip, shall be stapled to the purchase requisition. The purchase requisition with the attached receipt traveler or packing slip shall be forwarded to the Financial Clerk who will make a copy and forward the original to Quality Assurance Records.

7.1.3 Nonconformances identified during receiving inspection shall be processed in accordance with QAP-009, Nonconformance Control.

7.2 Acceptance of Quality-Affecting Goods from Non-Approved Suppliers List Suppliers

The normal receiving inspection process identified in Figure 1 shall be followed for all items.

7.2.1 Acceptance of quality-affecting goods shall be performed by technical staff trained to perform receiving inspection. The receiving inspection shall be performed in accordance with the instructions described in Figure 1. If there is no unsatisfactory finding after performing the steps in Figure 1, the item will be considered received, not accepted.

7.2.2 The technical staff person responsible for acceptance will document the status of the item on the receipt traveler or packing slip. This document will contain the phrase "received-acceptance pending," the date, and the person's initials. A copy of the SwRI Receipt Traveler (Figure 2) or the packing slip shall be stapled to the purchase requisition. The purchase requisition with the attached receipt traveler or packing slip shall be forwarded to the Financial Clerk who will make a copy and forward the original to Quality Assurance records.

7.2.3 The acceptance of quality-affecting goods from non-Approved Suppliers List suppliers can be accomplished through various methods (tests, confirmatory analysis, comparison, or inspection) as described in QAP-018. The method used to determine acceptance is identified in QAP-018. The results of the method will determine if the item is accepted. The process for documenting the final status of the non-Approved Suppliers List item shall be in accordance with QAP-018.

7.2.4 Nonconformances identified during receiving inspection shall be processed in accordance with QAP-009, Nonconformance Control.

7.3 Acceptance of Services

7.3.1 Services received from Approved Suppliers List-qualified suppliers will be accepted by technical staff and shall be based on review of the supplier's inspection and/or test reports. This review will verify that both technical and quality procurement requirements are satisfied. The technical staff member or other receiving person will show acceptance of the service by approving the voucher/invoice for the service and providing entry into the scientific notebook or project folder, if appropriate.

7.3.2 Analytical services procured from non Approved Suppliers List-approved sources shall be accepted by technical staff based on inspections and tests performed upon receipt to verify conformance to the technical and quality requirements. Blind standards and duplicate samples can be used to determine analytical accuracy and precision, which shall be evaluated against limits determined by the cognizant CNWRA technical staff member prior to issuance of the purchase order. Check samples composed of approximately 10 percent of the total number of the unknown samples can be used along with other methods, to provide confidence in the results. In cases where blind standards are not possible, the testing shall be accomplished pursuant 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, will be recorded with the analysis data and provided to the CNWRA technical staff member by the supplier. Where independent analysis is required for acceptance, analysis results from the original purchase and the duplicate analysis must be within an acceptable tolerance for acceptance, as determined by the Principal Investigator.

7.3.3 Scientific investigations, experiments, tests, reviews, code development, numerical analysis, and similar activities provided from Non-Approved Suppliers will be accepted by technical staff based on inspections and/or testing of the product provided. An appropriate, qualified staff member will make the determination of acceptability or rejection of the procured service. If accepted, approval of the consultant/subcontractor invoice for the service will constitute objective evidence. A copy of the approved invoice will be sent to Quality Assurance Records by the Financial Clerk. If not acceptable, the objective evidence will be nonpayment of the invoice, notation in a scientific notebook or project record, or a documenting memorandum to the file.

7.3.4 Most service procurements produce documentary materials and analyses that are incorporated in CNWRA publications. The documentation resulting from review in accordance with QAP-002, Review of CNWRA Documents, Reports and Papers, will constitute objective evidence of acceptance or rejection of these services.

7.3.5 Nonconformances identified during acceptance of any product from an Approved Suppliers List or non-Approved Suppliers List suppler shall be processed in accordance with QAP-009.

7.4 Identification of Accepted Goods

Accepted quality-affecting goods will be identified by either the purchase order or purchase requisition number. The prefix would be POXXX and PRXXXX for acceptance utilizing a purchase order or purchase requisition, respectively. The purchase order or purchase requisition number shall appear on the item itself, shall be placed on a tag attached to the item, or on a container holding the accepted item. Only items that have successfully passed receipt inspection will have the purchase order or purchase requisition number affixed on the item.

7.5 Acceptance Documentation of Services

Acceptance documentation will either be recorded or placed in scientific notebooks or project record files. Acceptance documentation can include receiving inspections, test reports, copies of receipt travelers, reports from an analysis organization, and observation of the received goods or services that can discern whether it meets CNWRA requirements.

7.6 Control of Nonconformances

7.6.1 Individuals and organizations supplying goods or services will be required to notify CNWRA of nonconformances to procurement requirements. Notification will include a description of the nonconformance, recommended disposition, and technical justification. Any nonconformance will be processed in accordance with QAP-009, Nonconformance Control (CNWRA Form QAP 9-1), to obtain the proper evaluation, disposition, and corrective action.

7.6.2 Nonconformances identified during receiving inspections of goods and services from Approved Suppliers List supplies and non-Approved Suppliers List suppliers will also be processed in accordance with QAP-009.

7.6.3 Copies of supplier Nonconformance Reports will be included with the traveler, the project record folder, or in CNWRA Quality Assurance records. Nonconformances can be considered in qualified supplier performance evaluations.

7.6.4 Supplier nonconformances will be evaluated individually to determine whether the good or service can be utilized by the CNWRA without adversely affecting the quality of the end product.

8. RECORDS

8.1 Approved Suppliers List supplier files will be maintained by the SwRI Quality Assurance Department.

8.2 Procurement documentation, including subcontracts, will be maintained by the SwRI Purchasing Department.

8.3 Consultant services contracts will be maintained by the SwRI Human Resources Department.

8.4 Technical documentation resulting from receipt inspections of quality-affecting goods and services will be maintained by the cognizant CNWRA technical staff member in the appropriate scientific notebook or project record files. The receipt traveler and other receiving documentation showing acceptance will be maintained by the Financial Clerk and will be forwarded to Quality Assurance Records quarterly for permanent retention.

8.5 Any quality records (i.e., acceptance documentation, surveillance reports, nonconformance reports) generated as a result of the procurement process will be maintained by CNWRA Quality Assurance in the Quality Assurance Records Room. CNWRA scientific notebooks that may contain related procurement information are sent to Quality Assurance following completion of the project work, and these notebooks are maintained as permanent Quality Assurance Records. CNWRA electronic scientific notebooks are periodically printed and provided to Quality Assurance Records for safe keeping (QAP-001, Scientific Notebook Control).

Instructions for Performing Receiving Inspections on Quality-Affecting Items

The following instructions apply to receiving inspections on quality affecting goods and services at the CNWRA. Satisfactory acceptance of any good or service will be documented in accordance with procedure requirements. Unsatisfactory goods and services will be processed in accordance with paragraph 7.6, "Control of Nonconformances."

Acceptance of Goods and Services

Receiving inspections of goods and services, including but not limited to chemicals, equipment calibration, test samples, computer software, science and engineering reports, and other quality affecting purchases, shall be performed by assuring the following criteria are satisfied as applicable:

- Assuring that goods or services are properly labeled
- Requested documentation listed on the purchase requesting has been and received includes physical, dimensional or other specified characteristics
- The correct amount or number of the good or service was sent
- The good or service is in the proper configuration
- The item is clean and free from shipping damage

The inspection shall identify any requirements that have not been met and shall identify any associated nonconformance reports documenting final resolution.

Accepted goods and services will be identified and documented in accordance with paragraphs 7.4 and 7.5 of this procedure.

Figure 1
(Example)

Page 1

SOUTHWEST RESEARCH INSTITUTE
RECEIPT TRAVELER
Warehouse: REC

06/29/2001

Receipt ID: RC-0102604 Packing Slip: Receiver: Soto, Juan M.
Receipt Date: 06/29/2001
PO 1844395 Rel: 0 Change Ord: 0 Vender: GOODFELLOW CORPORATION

Receipt Notes: FED 497367112947

Line: 1
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-110, 0.025 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 2
Item: 25 m STAINLESS STEEL 302,WIRE, Fe 205-116, 0.5 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 3
Item: 25 m STAINLESS STEEL 302 WIRE, Fe 205-118, 0.1 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 4
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-130, 0.25 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Line: 5
Item: 50 m STAINLESS STEEL 302 WIRE, Fe 205-140, 0.5 mm DIA.

U/M: EA QC Reqd: N Cert of Conf Reqd: N Source Insp Reqd: N Insp Type: Hazmat:
Deliver To: L. YANG/B. 189 X2483 Order Ref: Requisition: 572932
Qty Rcv: 1.0000 Qty Accpt: 1.0000 Qty Rej:
Location: Location: Location:

Prime Contract	Priority	Project	Organization	Account
		R9209.01.001	1.20	910-404

Figure 2
(Example)

CNWRA Form QAP-2