CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE MANUAL	Revision 4, Change 2 January 2002 Page 1 of 1

EFFECTIVITY AND APPROVAL

Revision 4 of this manual became effective on November 20, 2000. This procedure consists of the pages and changes listed below.

Revision 4 Change 1 became effective May 30, 2001.

Revision 4 Change 2 became effective January 15, 2002.

Except where text has shifted and affected the pagination of the document, changed pages are identified by a vertical bar in the right margin of each page. Please substitute these change 2 pages with the appropriate pages contained in your manual. These changes were prompted by CNWRA audit findings, continual process improvement, and by client requests.

Approvals			
Director of Quality Assurance Bruce Mabrito	Date 1/10/2002	CNWRA President Wesley C. Patrick	Date 1/10/202

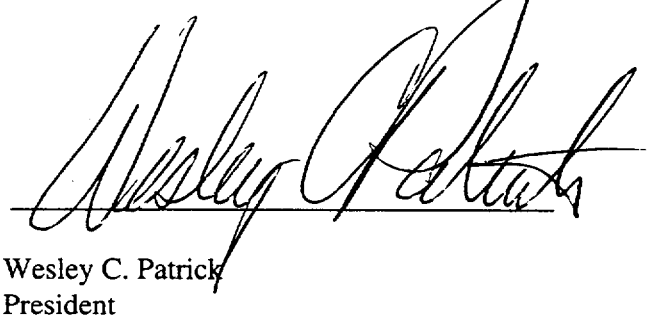
CNWRA Form QAP-3

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE MANUAL

Statement of Policy

As part of the Southwest Research Institute (SwRI) Quality Management System identified in the Operating Policies and Procedures 10.1.1, the Center for Nuclear Waste Regulatory Analyses (CNWRA) has established a policy to ensure that the services provided to the U.S. Nuclear Regulatory Commission (NRC) and other clients conform to the Charter, the CNWRA Contract, and applicable codes, standards and specifications. This mandatory policy extends to the work of the CNWRA for clients other than the NRC, to the extent applicable. Conformance to this policy is ensured through this CNWRA Quality Assurance Manual (CQAM), CNWRA procedures, and appropriate Southwest Research Institute (SwRI) Operating Policies and Procedures.

This CQAM describes the Quality Assurance (QA) program established at the CNWRA to comply with applicable Title 10, Code of Federal Regulations, Part 50, Appendix B (hereinafter referred to as "Appendix B"), The NRC Review Plan for HLW QA Program Descriptions (Rev. 2, March 1989), and ASME NQA-1-1986 requirements. For the HLW repository program, the requirements of 10 CFR, Part 63, Disposal of High-Level Radioactive Waste in a Proposed Geologic Repository at Yucca Mountain, Nevada, Subpart G-Quality Assurance, which are essentially the same as those in Appendix B, are applicable. In recognition of the importance of this requirement, the President of the CNWRA hereby delegates to the CNWRA Director of QA the authority for maintaining this CQAM and the CNWRA QA program as they relate to CNWRA activities.

Approved:  1/10/2007
Date

Wesley C. Patrick
President
Center for Nuclear Waste Regulatory Analyses

INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (the CNWRA or Center) is chartered to provide sustained high quality technical assistance and research in support of the Nuclear Regulatory Commission (NRC) waste management program under the Nuclear Waste Policy Act of 1982, as amended (NWPA). The CNWRA is committed to maintain an organization characterized by high technical competence, permanence, stability, and the capability to provide independent, objective recommendations on complex technical issues. Founded in 1987, the CNWRA is a not-for-profit Federally Funded Research and Development Center organized to serve the NRC, and to the extent approved by NRC, other clients. The CNWRA is structured as a division of Southwest Research Institute (SwRI or the Institute).

The requirement for a CNWRA quality assurance (QA) program originates with the contract between the CNWRA and the NRC. Specifically, a QA program is established and tailored to address the unique work of the CNWRA. Since Title 10, Code of Federal Regulations, Part 50 (10 CFR Part 50), Appendix B (hereafter referred to as Appendix B), Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, is invoked by Subpart G of 10 CFR Part 60 and 10 CFR Part 63, the regulatory criteria for high level waste disposal, the CQAM complies with and implements the appropriate criteria of Appendix B and ASME/ANSI NQA-1-1986.

The objectives of the CQAM are to

(1) Establish policies that assure the quality of services and data provided is adequate to support the NRC during the licensing process.

(2) Establish the CNWRA policies relating to QA.

(3) Provide a uniform and consistent approach to the attainment of an acceptable level of quality within available resources for products developed under the CNWRA contract.

This QA program applies to activities that are quality affecting to CNWRA products. Specifically, these activities include regulatory, institutional, and technical uncertainty identification and reduction, which are accomplished through analyses, research, development, investigations, and technical assistance to the NRC. In addition, this CNWRA Quality Assurance Manual (CQAM) defines the quality assurance program implemented for other clients of the CNWRA. Activities of a purely administrative or fiscal nature are not within the scope of this QA program. This QA program applies to applicable personnel and organizations—the CNWRA, SwRI, and CNWRA subcontractors and consultants—performing activities affecting quality. Definitions of terms pertinent to this program are found in Appendix I.

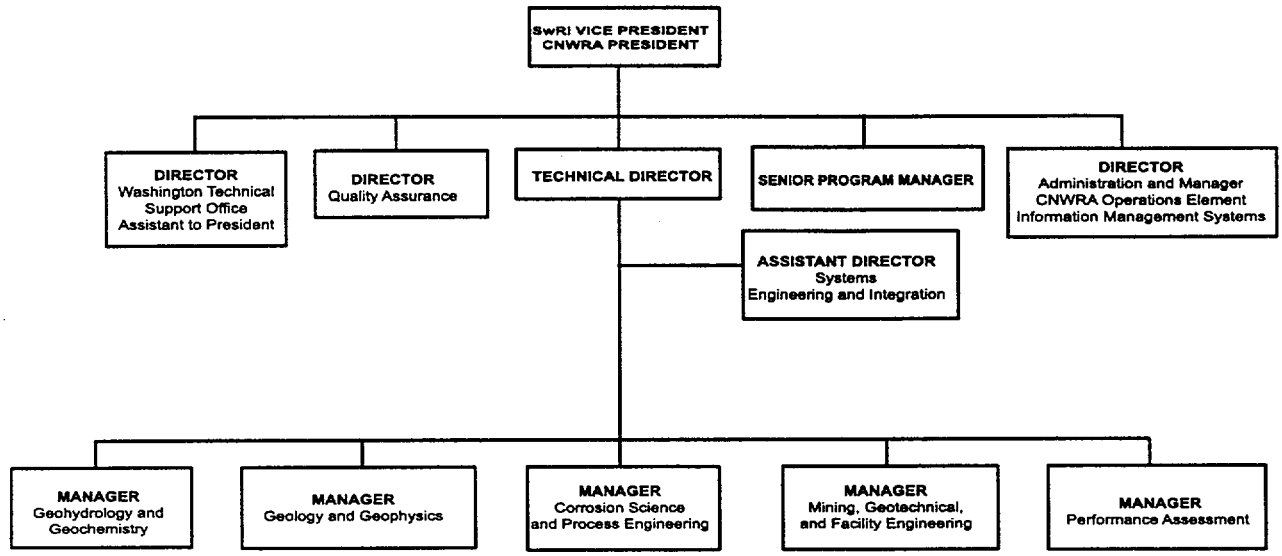

SwRI VICE PRESIDENT
CNWRA PRESIDENT
DIRECTOR
Washington Technical
Support Office
Assistant to President
DIRECTOR
Quality Assurance
TECHNICAL DIRECTOR
SENIOR PROGRAM MANAGER
DIRECTOR
Administration and Manager
CNWRA Operations Element
Information Management Systems
ASSISTANT DIRECTOR
Systems
Engineering and Integration
MANAGER
Geohydrology and
Geochemistry
MANAGER
Geology and Geophysics
MANAGER
Corrosion Science
and Process Engineering
MANAGER
Mining, Geotechnical,
and Facility Engineering
MANAGER
Performance Assessment

FIGURE 1.2

2. QUALITY ASSURANCE PROGRAM

2.1 PURPOSE

This section establishes the basis for the CNWRA QA program, describes how the QA program is implemented through various mandatory instructions and procedures, defines how the effectiveness of the QA program is assessed, and describes how individuals performing activities affecting quality are qualified.

2.2 RESPONSIBILITIES

(1) The CNWRA President has overall responsibility for the development, implementation, and maintenance of the CNWRA QA Program.

(2) The CNWRA Director of QA, as delegated by the President, is responsible for planning and conducting QA program audits, responding to nonconformances when required, developing and revising QA procedures, providing guidance on QA matters to staff, serving as the CNWRA software custodian, conducting surveillances, providing QA program indoctrination and training, maintaining QA records, reviewing and concurring with CNWRA procedures, and revising and changing the CQAM.

(3) The SwRI QA Committee is responsible for monitoring the CNWRA QA program as specified in the SwRI Operating Policies and Procedures Manual.

2.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

2.3.1 Applicable Regulations and Standards

(1) 10 CFR Part 50, Appendix B

Through its charter and contract with the NRC, the CNWRA is obligated to develop, implement, and maintain a quality assurance system meeting the requirements of 10 CFR Part 60, Subpart G, and 10 CFR Part 63, Subpart G, which specifies compliance to Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. This CQAM is written in sections corresponding to the Introduction and eighteen criteria of Appendix B. Since Appendix B was initially directed toward nuclear facility

(3) Design, development and use of controlled scientific and engineering software for independent analyses and reviews.

(4) The use of special materials in confirmatory testing.

CNWRA activities affecting quality are conducted in accordance with the CQAM and these activities are performed to procedures identified in paragraph 2.4.1.(2). The portions of the CQAM that are applicable, the level of control, and specific controls applied depend on the type of activity and its importance, and are determined by QA and technical staff through quality planning and procedure development. Quality planning activities shall be conducted to determine the specific procedures applicable to individual activities. The Quality Requirements Application Matrix (QRAM) forms provide a brief description of the planned project and quality assurance activities, required by CNWRA procedures.

CNWRA products receive technical and programmatic reviews, with concurrence by QA. These reviews are required by the CNWRA quality program and shall be performed in accordance with established procedures. Readiness reviews, per se, are not utilized for CNWRA products.

2.5 MANAGEMENT ASSESSMENT

2.5.1 Internal Audits and Surveillances

Internal evaluations of the effectiveness of the implementation of the CNWRA QA Program shall be by periodic surveillances and audits. A schedule of planned CNWRA surveillances shall be prepared annually. Surveillances are determined by the significance of the work, duration of CNWRA activity, and concentration of CNWRA resources. Hold points shall be incorporated into the QRAM forms as necessary to assure that required verifications are accomplished.

2.5.2 SwRI Advisory Committee for Quality Improvement

The SwRI Operating Policies and Procedures specifies that the Advisory Committee for Quality Improvement (ACQI) shall independently monitor and review the activities of each SwRI QA program. ACQI membership consists of representatives from each division (including the CNWRA) having QA programs. Institute QA and CNWRA QA management are non-voting members. CNWRA QA provides periodic trend analyses and reports to the ACQI, as well as CNWRA management.

(1) ACQI functions include the following:

- Recommend any actions necessary to assure the adequacy of Institute quality assurance programs.
- Serve as a review board as necessary to evaluate deficiencies and nonconformances reported by quality assurance audits and monitor corrective action programs. Assure that sufficient follow-up reviews have been made to determine that the final corrective action is timely and effective.
- Annually review the implementation of each quality assurance program and submit a written report of findings.

2.6 INDOCTRINATION, TRAINING, AND QUALIFICATION

2.6.1 Indoctrination and Training

(1) CNWRA staff, SwRI personnel, and contractor/consultant personnel performing activities affecting quality shall receive QA indoctrination to familiarize them with the CNWRA QA program and its implementation. Indoctrination shall, as a minimum, cover the following topics:

- CNWRA and Institute policies and procedures related to QA
- Responsibility of individuals performing quality-affecting activities
- Summary of the QA program, with emphasis on how the requirements apply to work and/or project product quality

(2) A record of indoctrination and training, professional personnel qualifications, individual publications, conflict of interest determinations, and related information shall be maintained by CNWRA QA. When follow-up training is necessary, the QA Director shall ensure that such training is provided.

(3) Instruction may be by classroom lecture, on-the-job training, mentoring, one-on-one verbal, or computer-based. Training records will be maintained as QA records. Training objectives, content, attendees, and dates of training will be documented in training records.

2.7 REFERENCES

Nuclear Regulatory Commission Contract No. NRC-02-97-009.

Nuclear Regulatory Commission. 10 CFR Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories, Subpart G, Quality Assurance.

Nuclear Regulatory Commission. 10 CFR Part 63, Disposal of High-Level Radioactive Waste in a Proposed Geologic Repository at Yucca Mountain Nevada.

Nuclear Regulatory Commission. 10 CFR Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

American National Standards Institute/American Society of Mechanical Engineers NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, 1986.

Nuclear Regulatory Commission. Nuclear Regulatory Commission, Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2, March 1989.

3.3.11 Review of Designs, Safety Analysis Reports, and License Applications

CNWRA staff, qualified in accordance with developed procedures, shall develop, revise, and use approved practices and guidance (e.g., standard review plans and specialized review methods) as necessary to control the review of designs and proposed designs. The CNWRA shall perform design reviews to determine if the design meets client requirements. These reviews do not constitute "design verification" as defined in NQA-1, Design Control.

3.3.12 Review of CNWRA Products

Reviews of products of the CNWRA such as reports, papers, and presentations shall be performed in accordance with approved procedures that consider technical, programmatic, and quality assurance requirements. Peer review procedures shall address the guidelines of NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories.

3.3.13 Records

QA Records shall be maintained in accordance with section 17 of this CQAM.

3.4 REFERENCES

Nuclear Regulatory Commission, Qualification of Existing Data for High-Level Waste Repositories, NUREG–1298, February 1988.

Nuclear Regulatory Commission, Peer Review for High-Level Nuclear Waste Repositories, NUREG–1297, February 1988.

4.4.2 Technical Requirements

Technical requirements shall be specified in CNWRA procurement documents. When necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items, material, equipment, or services to be furnished.

The CNWRA procurement documents shall identify required receiving inspection activities, and acceptance requirements.

4.4.3 Quality Assurance Program Requirements

Procurement documents for quality-affecting items shall require that the supplier have a documented QA program that implements applicable portions or all of the requirements of 10 CFR Part 50, Appendix B, or the quality requirements of 10 CFR Part 63, or ANSI/ASME NQA-1-1986. The extent of the program required shall depend upon the type and use of the material, equipment, item or service being procured. If necessary, procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.

Adaptations and clarifications have been made to certain nuclear QA requirements and criteria that are not applicable to scientific investigations and analyses performed by the CNWRA. These adaptations and clarifications are summarized in CQAM section 2.

4.4.4 Right of Access

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

4.4.5 Documentation Requirements

Procurement documents shall identify the documentation required to be submitted to the CNWRA for information, review, or approval. When the CNWRA requires the supplier to maintain specific QA records, the retention times and disposition requirements shall be prescribed.

- An acknowledgment stating that the document has been reviewed and understood, revisions or changes have been incorporated, and obsolete documents have been properly discarded
- Instructions for returning the acknowledgment

(2) The Director of QA shall take action, as necessary, to obtain acknowledgment of receipt when the forms have not been returned within a month of transmittal.

6.5.3 Distribution to the Point of Use

(1) Element Managers shall provide to staff assisting them the operations plans, project plans, proposals, TOPs, instructions, drawings, and methods necessary to control activities affecting quality.

(2) The Principal Investigator shall provide for removal or destruction of obsolete or inappropriate instructions from the workplace.

(3) Procedures contained in a CNWRA electronically maintained system that references current revisions and changes (e.g., a division Intranet) may be used by authorized CNWRA staff.

6.5.4 Documents of External Origin

The central collection point for documents of external origin is the CNWRA Library. These documents are archived and issued for use as a service of the CNWRA Library. Documents are logged into the library using an electronic database system developed by the CNWRA. A query may be conducted to perform word and document searches for retrieval purposes. The CNWRA staff member is responsible for determining if the CNWRA library copy is acceptable for use on the project work.

6.6 RECORDS

Original copies of the operations plans, proposals, CQAM, QAPs, TOPs, and APs generated shall be archived in the QA Records Room as permanent records and are available to appropriate staff upon request.

7. PROCUREMENT CONTROL

7.1 PURPOSE

This section establishes controls on quality-affecting goods, and services, including software, whether purchased directly or through subcontractors, to conform to requirements specified in the procurement documents.

7.2 RESPONSIBILITY

(1) CNWRA Principal Investigators or qualified technical staff are responsible for assuring that goods and services comply with procurement document requirements.

(2) Element Managers are responsible for approval of consultant and subcontract service invoices, thus documenting acceptance of progress reports or work products.

(3) CNWRA QA will monitor the receiving inspection process in accordance with this section and applicable procedures.

7.3 BASIC REQUIREMENT

The procurement of goods and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the suppler, source inspection, audit, and examination of goods or service upon delivery or completion.

7.4 PROCUREMENT PLANNING

7.4.1 General

The procurement of quality-affecting goods or services shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. CNWRA QA shall participate in evaluation and selection of suppliers and verification of suppliers' activities.

Client supplied (including the U.S. Department of Energy - supplied) samples, materials, and items used in CNWRA activities affecting quality shall be received, identified, and controlled in accordance with CQAM Section 8. Procurement controls described in CQAM Sections 4 and 7 do not apply.

7.4.2 Procurement Methods

Procurement planning shall be accomplished as early as practicable. Planning shall provide for the integration of (1) through (10) below.

(1) Procurement document preparation, review and change control;

(2) Selection of procurement sources;

(3) Pre-award audit by SwRI QA based on importance to licensing;

(4) Bid evaluation and award;

(5) SwRI control of supplier performance;

(6) Verification (surveillance, receiving inspection, or audit) activities by SwRI, including notification for hold and witness points;

(7) Control of nonconformances;

(8) Corrective action;

(9) Acceptance of received material, equipment, items, or services important to licensing;

(10) QA records.

7.5 SUPPLIER SELECTION

The selection of quality-affecting suppliers shall be based on evaluation of their capability to provide goods or services in accordance with the requirements of the procurement documents prior to award of contract.

Procurement source evaluation and selection measures shall be implemented as referenced in documented procedures. Goods and services obtained from the National Institute of Standards and Technology (NIST) are acceptable when appropriate objective evidence is provided.

Measures for evaluation and selection of procurement sources, shall be documented and shall include one or more of the following items:

(1) Evaluation of supplier's history of providing an identical or similar product that was confirmed by the CNWRA as meeting the requirements specified in the purchase order and performed satisfactorily in a test or experiment. The supplier's history shall reflect current capability. The basis for the acceptance of the supplier history shall be documented.

(2) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated (e.g., confirmatory analysis).

(3) Suppliers shall be evaluated periodically by SwRI Purchasing or SwRI QA to verify continued satisfactory performance. Suppliers' technical and quality capability as determined by a direct evaluation of the facility and personnel and the implantation of the quality assurance program.

(4) Evaluation and selection of professional technical services is accomplished by the CNWRA Source Evaluation Committee (SEC).

7.6 BID EVALUATION

Procurement documents, for quality-affecting items, shall provide for access to the supplier's facilities and records for inspection or audit by the CNWRA, designated representative, and/or other parties authorized by the CNWRA. Bid evaluation shall determine the extent of conformance by potential suppliers to the procurement documents. This evaluation shall be performed by appropriate individuals to evaluate the critical aspects of the procurement. Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation.

7.7 SUPPLIER PERFORMANCE EVALUATION

Contractor or consultant performance evaluations relating to computer codes, research results, written papers, presentations, and other services, and products, shall be documented and shall take into account, where applicable: (1) review of supplier furnished documents and records, nonconformance notices written by the supplier and CNWRA, and corrective actions; (2) results of previous source verifications, audits, receiving inspections, reviews and evaluations; (3) experience with identical or similar products furnished by the same supplier, and (4) results of other sources. Objective evidence of acceptability of a service or product can be documented by notation in a scientific notebook or project record, notation of acceptance on the receipt traveler, or approval of the invoice.

Evaluations of suppliers on the Approved Supplier List (ASL) shall be conducted annually unless there is little or no activity by the supplier. The results of the annual evaluation shall either be entered into the procurement records for the supplier or into records traceable to the supplier procurement records. The required frequency and extent of evaluations of suppliers of services and products not on the ASL shall be determined by the EM and PI.

The CNWRA SEC evaluates consultants and subcontractors described in section 1.6.2 prior to commencement of work, based on input provided by the EM or PI. The SEC recommendation is documented by CNWRA QA and a copy is maintained in CNWRA QA records on consultants and organizations. Annual evaluations are performed by the CNWRA on all consultants and subcontractor personnel.

7.8 CONTROL OF SUPPLIER GENERATED DOCUMENTS

PIs and EMs shall be responsible for the acquisition, evaluation, receipt inspection, and storage of supplier generated documents in scientific notebooks or project files. Supplier generated documents that identify acceptance to a standard or other quality requirement listed on the procurement documents will be evaluated by the CNWRA technical staff member. Acceptance of the product will be shown by approval of the invoice for payment, which requires technical acceptance, and approval by CNWRA management.

7.9 ACCEPTANCE OF GOODS AND SERVICES

7.9.1 Methods of Acceptance

(1) Items such as metal samples, chemicals, solutions, instrument and control products that are used as standards or standard reference materials shall be procured from sources on the ASL, or be subjected to confirmatory analysis, or other confirmatory methods. Depending on the application and the importance of the activity for which these items are used, the confirmatory analysis may be performed on a sample basis. However, because of the importance of certain activities, circumstances may require that each item received be tested (e.g., experiments and tests on the corrosion properties of waste package alloys).

(2) Confirmatory analysis shall be performed in accordance with section 7.11 of this manual and shall be maintained as quality records.

(3) Goods and services purchased shall be verified or inspected upon receipt by the appropriate qualified CNWRA technical staff member to determine whether they meet the specifications set forth in the purchase order or contract.

(4) Acceptance of goods and services from ASL qualified sources shall be based on review of the required documentation and product by the appropriate CNWRA technical staff member.

7.9.2 Receiving Inspection by CNWRA Technical Staff

CNWRA personnel shall be qualified to perform receiving inspections. This qualification shall assure:

- The CNWRA staff member has the technical knowledge to perform receiving inspection
- There is documentation establishing the basis for this qualification
- The CNWRA staff member understands the protocol of documenting receiving inspection results.

Trained and qualified technical staff will perform receiving inspection. Because these individuals may be performing receiving inspection on items required to support their work activities, senior management will ensure through inspection procedures that the individuals accepting these items: a) are not unduly influenced by cost and schedule; and b) have sufficient authority to independently evaluate the acceptability of the items; and c) have direct access to senior management in matters related to receiving inspection. 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 also assure that documentation received from the supplier identifies the procurement and the specific procurement requirements 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 analysis has been performed in accordance with section 7.11 of this manual, or source verification has been performed to verify conformance to procurement documents.

When the procurement is for a service, acceptance can be based on technical verification of the data produced, surveillance and/or audit at the activity, or review of objective evidence for conformance to the procurement document requirements. This acceptance will be performed by a knowledgeable and qualified CNWRA staff member. Qualification of CNWRA staff personnel is described in section 2, paragraph 2.6.2.

7.10 CONTROL OF SUPPLIER NONCONFORMANCES

The disposition of items and services that do not meet procurement documentation requirements shall be in accordance with written procedures.

7.11 CONFIRMATORY ANALYSIS OF GOODS

Because of importance to quality, expense, and/or end use, an item or material may require a more rigorous certification or material verification. When this special confirmatory analysis process is determined to be necessary, the additional analysis shall be clearly described on the purchase requisition for the original item. The additional special confirmatory analysis activities will be performed by approved organizations listed on the SwRI ASL, or by qualified SwRI staff.

7.12 RECORDS

Records of the SEC procurement selection and evaluations, receiving inspection, documentation, supplier nonconformance, and confirmatory analysis of goods shall be maintained in accordance with CQAM section 17.

8.5 CLIENT-SUPPLIED SAMPLES, MATERIALS AND ITEMS

Client–supplied (including the U.S. Department of Energy–supplied) samples, materials, and items used in CNWRA activities affecting quality shall be received, identified, and controlled in accordance with this section. Samples, materials, and items shall be inspected upon receipt for damage, confirmation of source, and proper identification and traceability. Receipt inspection results shall be recorded in the applicable scientific notebook.

8.6 IDENTIFICATION OF NONCONFORMING ITEMS AND SAMPLES

(1) Samples and items determined to be nonconforming in accordance with CQAM section 15 shall be identified with a "Hold Tag" or equivalent means. The Hold Tag shall be dated and reference the applicable nonconformance report.

(2) In addition to tagging, and when tagging is impractical, nonconforming samples and items shall be segregated from acceptable items, software and samples to preclude their inadvertent use.

(3) QA staff are solely authorized to remove hold tags and remove nonconforming items and samples from segregated storage. QA staff shall follow the disposition specified by the applicable Nonconformance Report.

8.7 RECORDS

Quality records generated by this section shall be maintained in accordance with section 17 of this CQAM.

10. INSPECTION

10.1 PURPOSE

This section establishes inspection requirements consistent with 10 CFR Part 50 Appendix B, the NRC Review Plan for HLW QA Program Descriptions, NQA-1-1986, and is invoked by Subparts G of 10 CFR Part 60 and 10 CFR Part 63.

10.2 RESPONSIBILITIES

10.2.1 CNWRA Directors and Element Managers are responsible for implementation of this section.

10.2.1 CNWRA QA is responsible for reviewing internal inspection plans, sampling plans, combined inspection and monitoring plans, and performing surveillance activities.

10.3 INSPECTION

The CNWRA shall perform inspections on quality-affecting goods and services in accordance with the procurement procedure. The results of these inspections shall be documented. Surveillances on CNWRA activities shall be performed by CNWRA QA. Detailed technical and programmatic reviews shall also be performed on CNWRA documents at the final review point. In all cases, only qualified CNWRA staff shall review and evaluate work products. The final CNWRA product is not transmitted until QA verifies the review process has been satisfied.

10.4 REPORTING INDEPENDENCE AND QUALIFICATION OF PERSONNEL

CNWRA personnel performing receiving inspections shall be qualified to perform such work based on their education, experience, demonstrated knowledge and proficiency in the procurement process, applicable receiving inspection methods, etc. Technical personnel performing experimental and analysis activities may also be assigned responsibility to perform receiving inspections. Trained and qualified technical staff will perform receiving inspections. Because these individuals may be performing receiving inspection on items required to support their work activities, CNWRA senior management will ensure that the individuals accepting these items: a) are not unduly influenced by cost and schedule; b) have sufficient authority to independently evaluate the acceptability of the items; and c) have direct access to senior management in matters related to receiving inspection.

10.5 INSPECTION HOLD POINTS AND FINAL INSPECTION

Inspection hold points, shall be established. These include technical and programmatic reviews of the documents in the review process and confirmatory analyses on material received by the CNWRA, when required. QA verification on the document review sheet is equivalent to a final inspection on products.

10.6 INSPECTION, PLANNING, AND SAMPLING

Receiving inspection planning activities for quality affecting products shall be described in the procurement procedure. To determine satisfactory performance of vendors not currently listed on the SwRI ASL, confirmatory analyses shall be accomplished. A modified sampling plan for non-ASL organizations shall be used to establish a history of providing products which perform satisfactorily in actual use through confirmatory analysis. The Quality Requirements Application Matrix shall by completed by EMs and jointly approved by the Technical Director and the QA Director. Nonconformances identified in inspection, planning and sampling shall be documented in accordance with section 15. Special circumstances may require confirmatory analysis of multiple items from the same purchase order (as discussed in section 7, paragraph 7.11).

10.7 IN-PROCESS INSPECTION

QA surveillances are performed at the CNWRA as in-process inspections.

10.8 RECORDS

QA records shall be maintained in accordance with section 17 of this CQAM.

14. INSPECTION, TEST AND OPERATING STATUS

14.1 PURPOSE

This section establishes the requirement for identification and control of items requiring inspection and tests.

14.2 BASIC REQUIREMENT

The status of inspection and test activities shall be identified to assure required actions have been performed and to prevent inadvertent use of items which have not passed required inspections or tests.

14.3 RESPONSIBILITIES

(1) The Technical Director is responsible for overall implementation of this section.

(2) Element Managers and Principal Investigators are responsible for preparing operating procedures and scientific notebooks implementing this section, as appropriate.

(3) The Director of QA is responsible for ensuring compliance to this policy.

14.4 PROCEDURE

14.4.1 General

Quality-affecting items being tested shall be identified, either on the items or in documents traceable to the items. The status of the tests shall be identified to prevent the use of items that have not satisfactorily met the test requirements. Procedures or instructions controlling the work activity shall include status identification provision in the appropriate scientific notebook.

14.4.2 Status Identification

Identification shall consist of items such as tags, markings, etchings, shop travelers, stamps, bags or inspection records, as practical.

14.4.3 Removal of Status Identification

Tags identifying nonconforming items shall be removed by CNWRA personnel or directed personnel upon proper disposition of the nonconformance in accordance with section 15.0, "Nonconformance Control."

15.6 NONCONFORMANCE ANALYSIS

On an annual basis, CNWRA Nononformances (NCRs), Corrective Action Requests (CARs), and other relevant information shall be evaluated for trends requiring corrective action. This annual evaluation shall typically be performed approximately six months after the annual CNWRA audit to provide sufficient time to identify adverse trends and allow the results to be published and acted upon. The results of the analysis shall be used to initiate additional corrective action measures as necessary. The results of the trend analysis shall be reported to CNWRA management and the Institute ACQI through the Institute QA manager.

15.7 RECORDS

CNWRA records of nonconformance are maintained in the QA Records Room.

16.5 STOP WORK AUTHORITY

The CNWRA Director of QA has the authority to stop work in those situations where continued processing or activities could result in recurring conditions adverse to quality. Sufficient corrective action shall be required to preclude recurrence before stop work orders shall be lifted.

16.6 DOCUMENTATION AND REPORTING OF NONCONFORMANCES

Significant conditions adverse to quality, the cause of the condition, and corrective action shall be documented and reported to CNWRA QA management, management of the nonconforming activity, and appropriate CNWRA management.

16.7 CORRECTIVE ACTION VERIFICATION

Corrective action measures shall be verified upon completion by QA to determine whether the prescribed actions were completed and are appropriate and sufficient to preclude recurrence.

16.8 TREND ANALYSIS

On an annual basis, conditions adverse to quality shall be evaluated to determine deficiency levels and trends. This annual evaluation shall typically be performed approximately six months after the annual CNWRA audit to provide sufficient time to identify adverse trends and allow the results to be published and acted upon. The results of the trend analysis shall be reported to CNWRA management and the Institute ACQI through the Institute QA manager.

16.9 RECORDS

CNWRA records of corrective actions are maintained in the QA Records Room.

(2) Typewriter correction fluid (white out) or correction tape is not permitted on QA records or data. However, a modified document can be photocopied and an original signature affixed to make it acceptable to become QA record.

17.6 RECORDS PROCESSING

(1) Validated records shall be controlled to assure proper identification and retrieval.

(2) Records shall be examined upon receipt to confirm their completeness and reproducibility.

(3) Each record shall be assigned a unique records control number.

(4) An index of all records processed shall be maintained and updated as additional records are processed.

17.7 RECORDS STORAGE

(1) The CNWRA maintains both permanent and nonpermanent records in accordance with developed procedures. Permanent records are those that:

- Provide objective evidence of fulfillment of the particular requirements of the CQAM
- Are needed to substantiate the results or basis for licensing and prelicensing reviews
- Support regulatory decisions
- Would be needed by an independent third party to reconstruct the work that was conducted or results that were obtained

18.8 AUDIT REPORTS

Audit reports shall be prepared and reviewed by the audit team leader. The reports shall include, as appropriate:

(1) Description of the audit scope

(2) Identification of the auditors

(3) Identification of the persons contacted during audit activities

(4) Summary of audit results, including a statement on the effectiveness of the quality assurance program elements being audited

(5) Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization

Distribution of the audit internal reports shall include, as a minimum, management of the audited activity, CNWRA management, and the Institute ACQI chair.

18.9 AUDIT RESPONSE

The management personnel responsible for providing corrective action responses to adverse findings shall be identified. The responsible organization shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and provide written responses.

The auditing organization shall be responsible for evaluating the adequacy of the audit responses.

Audit responses shall be tracked to assure that all findings are appropriately addressed, prioritized, and trended.

18.10 FOLLOWUP ACTION

Followup action, including verification of implementation of corrective action as scheduled and/or reaudit of deficient areas, shall be taken.

18.11 AUDIT RECORDS

Audit Records will be maintained as permanent QA Records in accordance with CQAM section 17.

Cognizant Director, Cognizant Element Manager

The individual with overall responsibility for the activity of interest.

Computer Program

A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.

Condition Adverse to Quality

An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

Confirmatory Analysis/Testing

A process to inspect, test or analyze an item to verify that the item and documentation meet appropriate quality requirements or standards. Confirmatory testing also includes determining that the critical technical attributes or characteristics meet specifications, catalog description, purchase order provisions, attributes, etc. Confirmatory testing is considered to be one of the methods used to support the dedication of a product.

Controlled Document

Documents such as Operation Plans, CQAM, and CNWRA Procedures–having specified requirements governing their preparation, approval, revision, and distribution.

Corrective Action

Measure(s) taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.

Deviation

Departure from specified requirements.

Dedication

"Dedication" is an acceptance process undertaken to provide reasonable assurance that a commercial

grade item to be used as a basic component will perform its intended safety or waste-isolation function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 63, subpart G, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspection, tests, or analyses performed by a purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witnessing at hold points at the manufacturer's facilities; and analyses of historical records for acceptable performance.

Document

Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance (QA) Record until it satisfies the definition of a QA Record as defined in this appendix.

Element

The term describing the first level of work break down structure for the CNWRA, relating to the major organizational units.

Experiment

A method to examine the validity of a theory or existence of a phenomenon. An experiment must provide the latitude to modify, change, and alter input and stimuli. Because of its exploratory nature, experimentation requires flexibility and freedom from strict prescriptive procedures. In lieu of detailed procedures, the experimental processes and results shall be documented.

External Audit

An audit of those portions of another organization's QA program not under the direct control or within the organizational structure of the auditing organization.

Guideline

A suggested practice that is not mandatory in programs intended to comply with a standard. The word should denotes a guideline; the word shall denotes a requirement.

High-Level Radioactive Waste (HLW)

(1) Irradiated reactor fuel.

(2) Liquid wastes resulting from operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel.

(3) Solids into which such liquid wastes have been converted.

Important to Licensing

Those technical, regulatory, and institutional aspects of an NRC program or project that may affect the process or schedule associated with licensing a facility. Included in "important to licensing" are those attributes and components that ensure technical adequacy, procedural compliance, adherence to schedules mandated by statutes, and thorough and readily retrievable documentation.

Important to Safety

Those engineered structures, systems, components and products essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, exceeding the limits of 10 CFR Part 20, consistent with 10 CFR Part 63 to the extent applicable.

Important to Waste Isolation

Those features including the site, engineered barrier system, seals for shafts and boreholes, seals, and any other items and related activities which are relied on for demonstrating that regulatory performance objectives will be met, consistent with 10 CFR Part 63 to the extent applicable.

Inspection

Examination or measurement to verify whether an item or activity conforms to specified requirements.

Inspector

A person who performs inspection activities to verify conformance to specific requirements.

SwRI or Institute

Southwest Research Institute (SwRI).

Internal Audit

An audit of those portions of an organization's QA program retained under its direct control and within its organizational structure.

Item

An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

Measuring and Test Equipment

Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or to acquire data to verify conformance to specified requirements.

Nonconformance

A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective Evidence

Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity based on observations, measurements, or tests that can be verified.

Observation

An auditing term indicating a condition, while not a deficiency, may result in a deficiency if uncorrected.

Operating Procedures

Controlled QA program documents, which include Technical Operating Procedures (TOPs), Quality Assurance Procedures (QAPs), and Administrative Procedures (APs). These procedures provide detailed methods and acceptance criteria necessary to accomplish an activity.

Operations Plan

A controlled plan providing the objectives of a particular CNWRA Element, describing the technical approach, management, fiscal, and general QA requirements.

Testing

An element of verification for determining the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operational conditions.

Traceability

Ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Use-As-Is

A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Uncontrolled Documents

Documents whose distribution is not required to be recorded and kept as a QA Record.

Validation (Computer Code)

Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended.

Verification

The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

Verification (Computer Code)

Assurance that a computer code correctly performs the operations specified in a numerical model.