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April 26, 2001
Contract No. NRC–02–97–009
Account No. 20.01402.159

U.S. Nuclear Regulatory Commission
ATTN: Mrs. Deborah A. DeMarco
Two White Flint North
11545 Rockville Pike
Mail Stop T8A23
Washington, DC 20555

Subject: Submittal of a Second Draft of the Revision 4 Change 1 CNWRA Quality Assurance Manual with Responses to the NRC Draft Comments

Dear Mrs. DeMarco:

The subject draft CNWRA Quality Assurance Manual (CQAM) is being submitted for NRC approval. This draft has lines through deleted sentences and a darkened background for new text. When the signed copy of the CQAM is sent out, these deleted lines and darkened backgrounds will not be shown and some of the individual sections may change in layout appearance slightly, but the CQAM will have the quality commitments clearly stated. The changes to the CQAM are in direct response to the draft comments/recommendations provided to the CNWRA by Mr. Larry Campbell. CNWRA personnel have evaluated these latest draft comments/recommendations and have made the suggested changes to the CQAM. All 30 individual comments were considered and each was addressed in either its entirety or in some modified form.

We appreciate the input to our CQAM as we make improvements to the CNWRA quality system. We would appreciate receiving concurrence in these changes so we can begin implementing the changed CQAM promptly.

If you have any questions on this matter, please contact me at (210) 522-5149.

Sincerely,

Bruce Mabrito
Director of Quality Assurance

Enclosure
cc: L. Campbell
T. Carter

Washington Office • Twinbrook Metro Plaza #210
12300 Twinbrook Parkway • Rockville, Maryland 20852-1606

RESPONSES TO
NRC COMMENTS ON DRAFT REVISION TO CNWRA QA MANUAL
TRANSMITTED VIA COVER LETTER DATED APRIL 6, 2001

Section 1.6.2 Consultants and Subcontractors

Rewrite the first line as follows:

1. Contractors performing and subcontractors providing individuals to perform activities such as data interpretation, analysis, or services activities other than data collection (experiments or tests) . . .

[Changed to reflect the key items in this sentence.]

Section 2.3.1(1) 10 CFR Part 50, Appendix B

Rewrite the next to the last sentence as follows:

2. Further, clarifications are also provided with regard to the independence of the receiving inspection personnel and the requirement that a supplier of goods or services maintain a 10 CFR Part 50, Appendix B/NQA-1 Quality Assurance program.

[Changed to reflect the key items in this paragraph.]

Section 2.6.2 Qualification of Personnel

Add the following:

3. (4) The qualification method for personnel performing nondestructive testing shall be in accordance with industry standards (e.g., ASNT-TC-1A).

[Changed to read exactly as above.]

Figure 2.1 CORRELATION OF QUALITY PROGRAM REQUIREMENTS

4. Change the heading of the last column from "COMPLIANCE EXCEPTIONS" to "COMPLIANCE EXCEPTIONS AND CLARIFICATIONS"

[All changed to read exactly as above.]

5. For Section 2, Delete "Suppliers of goods and services are exempt for maintaining a 10 CFR Part 50 Appendix B/NQA-1 quality system," and replace with the following:

   When procuring services and products from a supplier, the supplier's quality system may be based on quality standards (e.g., ISO 9001) other than 10 CFR Part 50, Appendix

B or NQA-1 provided that: a) the applicable Appendix B and NQA-1 requirements for the service or product are adequately described in the supplier's quality system; b) the applicable requirements are confirmed as being satisfactorily implemented; and c) the purchase order for the service or product specifically invokes the approved quality system for the service or product being procured.

[Changed to reflect the meaning and intent of the above statement.]

6. For Section 2, delete "Exception is taken to allow highly trained technical staff to perform receipt inspection, ... " and replace with:

"Highly 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, CNWRA senior management will implement controls to ensure that the individuals accepting these items: a) are not 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."

[Changed to reflect these requirements.]

7. Section 4: It is unclear as to the intent of this modification or clarification. A supplier of a service may be able to perform the work with out a QA program by either working in accordance with the CNWRA QA program or having the service accepted using one of the methods described in Section 7. However, a supplier of goods can not work to the CNWRA QA program because the CNWRA QA program is not applicable for producing a good or physical product.

[Section 4 has been revised to address the above concern.]

OPEN ITEM

8. Delete the exception identified in Section 10, and either repeat or refer to the text for Item 2 on figure 2.1 (see Comment 6 above).

[Changed to reflect the statement in Comment 6 above.]

Section 3.3.8 - Reporting Errors and Deficiencies

9. Add the following somewhere in this paragraph - this was something that we agreed to.

"The NRC will be notified of errors and deficiencies found in CNWRA deliverables that have already been forward to the NRC.

[Changed to reflect this requirement.]

10. The following is an incomplete sentence, please clarify;

"In a Request for Additional Information (RAI) or such other documents as specified by contract or other directive."

[The sentence has been changed to read correctly.]

Section 7.5 - Supplier Selection

11. Revise Section 7.5(1) to read as follows:

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

[Changed to reflect this requirement.]

Section 7.7 - Supplier Performance Evaluation

12. Section 7.7 only addresses the evaluation of services. In the first sentence of Section 7.7, delete reference to payment of the invoice. There may be numerous examples of where payment has been made and there were problems with the service or product received. Replace the first sentence of Section 7.7 with the following sentences:

    "Supplier performance evaluation for computer codes, research results, written papers, presentations, other data, 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) use experience of 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, or a documenting acceptance on the receipt traveler.

    Evaluations of suppliers on the 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 be records traceable to the supplier procurement records. The frequency and extent of evaluations of suppliers of services and products not on the AVL shall be determined by the EM and PI.

[Changed to reflect the intent of the paragraphs above.]

13. In the first line of the second sentence of Section 7.7, after the work subcontractors, add: " " . . subcontractors, providing individuals for services described in Section 1.6.2 . ."

[Changed to reflect the intent above.]

Section 7.8 CONTROL OF SUPPLIER GENERATED DOCUMENTS

14. Last sentence, delete reference to "payment by invoice."

[Changed to include approval of the invoice for payment.]

Section 7.9 ACCEPTANCE OF GOODS AND SERVICES

15. Add the following to Section 7.9.1(1):

    Items such as metallic plates, chemicals, solutions, ceramic products, and instrument and control products procured from sources not on the ASL that are used in applications that support and are important to the NRC licensing process (or other client needs specified by contract) shall 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 C-22 material).

    Confirmatory analysis shall be performed in accordance with Section 7.11 of this manual shall be maintained as quality records.

[Changed to reflect the above two paragraphs, with words modified to be broadly applicable.]

16. For Section 7.9.1(2), address the clarification previously provided in Comment 5 regarding the clarification of the supplier's QA program.

[Section has been modified to adequately address this issue.]

17. Please revise the following text in Section 7.9.2:

    Incorporate the text to address the comments to Section 7 of Figure 2.1 (See comment 6 above).

[Change has been made to address the recommendations in Comment 6 above.]

18. In Section 7.9.2, please address the basis for accepting certification and documentation from a supplier. It is suggested that the guidance provided in Section 8.2.1 of Supplement 7S1of NQA-1-1986. OR use text such as "When a Certificate of Conformance is used to accept a product, the requirements of Section 8.2.1 of Supplement 7S-1 of NQA-1-1986 shall be used."

[Change has been made to address this issue to the extent possible.]

19. The following questions and comments have been formally transmitted to the CNWRA in the past and was not addressed during this manual change.

    It is unclear as to how Section 7.9(3) is performed and how it can be used to qualify a supplier. Please explain. It is suggested that the major elements of this process be identified.

[Changes have been made to the section to more clearly identify supplier qualification.]

OPEN ITEM

Section 7.12 - RECORDS

Add supplier evaluations, receiving inspection documentation, supplier nonconformances, confirmatory analysis of goods as a quality record.

[Change has been made to address the above.]

Section 9:

21. Section 9.4(2), Third Bullet (Equipment and equipment qualification methods) - equipment is stated twice. Please revise accordingly. Do you mean "Equipment and method" or what???

[Changed to reflect equipment and any special calibration or other requirements.]

OPEN ITEM

22. Section 9.4(3), First line: Please provide example of special process procedures that do not require further qualification????? I am unaware of these types of special process procedures.

[Changed to clarify intent.]

OPEN ITEM

23. Section 9.4(3)Second Line: Please insert the following after the first word "Procedures."

    "for special processes such as welding, nondestructive testing, coatings, heat treatment"

[Changed wording to that above.]

24. Section 9.4(4). Second line: Please add the following after the word "suppliers."

    "on the ASL"

[Changed wording to that above.]

Section 10:

25. Section 10.4, First Sentence: Please address some of the elements of the qualification process (e.g., demonstrate their knowledge and proficiency in : the procurement process, applicable receiving inspection methods, use of M&TE, etc.

[Changed to address these elements of the qualification process.]

26. Section 10.4, Last Line; Delete the last sentence and replace with something like the following or refer to the paragraph in the QA manual where you have added text to address the following:

"Highly 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, CNWRA senior management will implement controls to ensure that the individuals accepting these items: a) are not 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."

[Changed to reflect this requirement.]

27. Section 10.6, After the third sentence or somewhere, add something like the following:

"For certain products, confirmatory analysis may need to be performed on each item received (as discussed in Section 7.x.x.).

[Words to this effect have been added to Section 10.6.]

Section 18, Audits:

28. Section 18.4, Second Paragraph: The internal audit frequency of the CNWRA QA Program implementation: Minimum of once a year needs to be specified. Annually

[The annual commitment is now in Section 18.4.]

29. External Audit Frequency of Suppliers of the AVL is not specified either here or in Section 7. The NRC position on external audit frequency is a min. - one audit every three years. Please check with SwRI and see what their frequency is. It should be every three years for suppliers on their ASL.

[This three-year commitment minimum has been added to Section 18.4.]

OPEN ITEM

TERMS

30. The terms "Confirmatory Testing" and "Dedication" is defined. It is only suggested that the following sentence be added to the term "Confirmatory Testing."

"Confirmatory testing is considered to be one of the methods used to support the dedication of a product."

[The sentence above has been added to the Terms and Definitions Appendix.]

DRAFT

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE MANUAL	Revision 4, Change 1 April 2001 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.

Page No.	Change	Date Effective
All	1	To be Determined

Approvals

Director of Quality Assurance	Date	CNWRA President	Date
Bruce Mabrito		Wesley C. Patrick	

CNWRA Form QAP-3

DRAFT

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. 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: _____ _____
Date

Wesley C. Patrick
President
Center for Nuclear Waste Regulatory Analyses

TABLE OF CONTENTS

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 proposed 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.

1. ORGANIZATION

1.1 PURPOSE

This section describes organizational responsibilities of and relationships among the Center for Nuclear Waste Regulatory Analyses (referred to as either "CNWRA", or "Center" in this manual), the Nuclear Regulatory Commission (NRC) and other clients, Southwest Research Institute ("SwRI" or "Institute"), and CNWRA subcontractors and consultants. The CNWRA Quality Assurance Manual (CQAM) policies are mandatory for all CNWRA staff, consultants, and subcontractors.

1.2 ORGANIZATION

1.2.1 Southwest Research Institute

SwRI consists of individual research divisions, one of which is the CNWRA, reporting to the Institute President. In addition, various administrative and support groups, including an Institute Quality Assurance (QA) Department, report to this highest level of executive management. The Institute QA Department is organizationally independent from the operating research divisions. The Institute organization is illustrated in Figure 1.1.

1.2.2 Center for Nuclear Waste Regulatory Analyses

CNWRA activities are conducted by various operating Elements, which report to the Technical Director and the CNWRA President. Administrative and support groups, including CNWRA QA, report to the CNWRA President. Before initiation of activities, qualified individuals are identified within the CNWRA organization as responsible for the quality of the delegated work. The CNWRA QA group is organizationally independent of the other operating Elements. The CNWRA organization is illustrated in Figure 1.2. The CNWRA is located in San Antonio, Texas and "off-site" work is accomplished under this CQAM in the field or at the Washington, D.C. Technical Support Office, which is managed by a director reporting to the CNWRA President.

1.3 DESCRIPTION OF KEY RESPONSIBILITIES AND DUTIES

1.3.1 Institute Executive Management

The President of SwRI is the Chief Executive and Senior Officer of the Institute, designated by the Board of Directors to manage the Corporation subject to the inherent powers of the Directors as stated in the by-laws. The President of SwRI reports to the Board of Directors and approves policy, provides technical and administrative direction to the Institute Vice Presidents, and appoints the chairman of the Quality Assurance Committee.

1.3.2 Institute Quality Assurance

The Institute QA Department is responsible for monitoring and reporting to the Institute President on the effectiveness of all Institute QA programs, including the CNWRA QA program.

1.3.3 CNWRA Management

(1) The CNWRA President has the authority and responsibility for the activities of the CNWRA, as SwRI Vice Presidents are responsible for each of their Divisions. The CNWRA President reports to the Institute President, and receives contractual and technical direction from the NRC and other clients. Qualification requirements and qualifications of all CNWRA staff members are documented on the CNWRA Professional Personnel Qualification and Training Record forms.

(2) The CNWRA Technical Director has the authority and responsibility to assist the President in conducting overall administrative and operational matters of the CNWRA, be the primary technical representative of the President in liaison with CNWRA clients, integrate the technological and research activities of the CNWRA, and provide efficient manpower utilization.

(3) The CNWRA Director of QA has been assigned the overall authority and responsibility for developing, implementing, and verifying an appropriate system of quality assurance for CNWRA activities. Through the controls established in this CQAM and supporting procedures and plans, the CNWRA Director of QA has sufficient authority, access to work areas, and organizational freedom to

(a) Identify quality problems

(b) Initiate, recommend, or provide solutions to quality problems through designated channels

(c) Verify implementation of solutions

(d) Assure that further processing, delivery, installation, or operation is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred

(e) Stop work, when conditions warrant.

(4) Other CNWRA Directors and Element Managers (EMs) are responsible for developing and implementing appropriate plans and procedures controlling activities affecting quality within their respective operating Elements. Specific responsibilities shall be identified in operations plans, research project plans, proposals and operating procedures.

(5) The CNWRA President, Directors and other members of the management team have the responsibility of carrying out their charge through screening during the hiring process, assignment of individual staff members to projects and periodic performance appraisals.

1.3.4 Project Management

(1) CNWRA activities are typically conducted as projects. Project teams are assembled and organized to fulfill important organizational responsibilities and duties. A typical project organization is illustrated in Figure1.3.

(2) The project manager and principal investigator (PI) are responsible for developing and implementing plans, procedures, and instructions for project activities. In addition, they are responsible for coordinating with the CNWRA QA staff for quality verification purposes.

1.4 CNWRA QUALITY ASSURANCE

The CNWRA QA group consists of the Director of QA and assigned staff, including CNWRA, SwRI, and external support, as needed. As indicated in paragraph 1.2.2, QA is sufficiently independent of CNWRA cost and schedule, relative to safety and quality considerations, and reports directly to the highest authority within the CNWRA. Specific functions of the CNWRA QA Director include:

(1) Communicating effectively with other senior managers and assuring that an appropriate quality assurance program is effectively implemented.

(2) Verifying, through checking, surveillance, inspecting and auditing that activities affecting quality are correctly performed.

(3) Developing, revising, changing and interpreting the CQAM.

(4) Applying appropriate controls in conjunction with line staff to CNWRA activities dependent upon the specific activity, its complexity, and its importance.

(5) Performing reviews of SwRI proposal documents for possible conflicts of interest with NRC contracts.

(6) Stopping work, when conditions warrant.

(7) Having no other duties or unrelated responsibilities that would prevent full attention to QA matters.

(8) Effectively communicating with consultants and subcontractors on QA matters.

1.5 DELEGATION OF AUTHORITY

(1) Delegation of authority is documented by memorandum or by electronic mail. The person delegating the authority signs the memorandum and this delegation is kept as a nonpermanent record in the QA records room.

(2) Delegation to an individual other than one's supervisor shall be documented. Conditions of the delegation, such as its scope and duration (until revoked, for a limited period of time, or in the absence of the delegator), shall be included in the documentation.

1.6 DELEGATION OF WORK

CNWRA activities are performed by full-time CNWRA (core) and limited-term staff, by other SwRI staff, by consultants, and by subcontractors. The responsibilities of the individuals and organizations outside the CNWRA are dependent on the type of activities performed and the source of the personnel or services. Management of, and communication with, subcontractors and consultants is the responsibility of the cognizant EM and/or PI.

1.6.1 Southwest Research Institute

SwRI staff performing CNWRA activities affecting quality shall perform those activities

in accordance with the CNWRA-accepted quality program. Such project personnel shall be qualified in accordance with the CNWRA-accepted quality program.

1.6.2 Consultants and Subcontractors

Consultants and subcontractors performing activities such as ~~Individuals performing~~ data interpretation, analysis, or services and activities other than data collection (experiments or tests) shall be qualified in the same manner as CNWRA staff (CQAM section 2), regardless of their affiliation with an employer. Their activities shall be conducted in accordance with the CNWRA QA program or their own QA program. Subcontracted experiments, tests, or other data collecting activities shall be conducted in accordance with the CNWRA QA program or the subcontractor's accepted QA program. Subcontractors for these types of activities shall be qualified in accordance with CQAM section 7. Either the subcontractor's QA program or the CNWRA QA program shall provide for appropriate organizational controls to assure that quality objectives are attained and verified. Applicable requirements shall be clearly communicated to consultants and subcontractors by EMs and PIs through requests for proposals, procurement documents, and other means. Clear lines of communication shall be maintained between the CNWRA and subcontractor organizations by the cognizant EMs and PIs as provided in CQAM section 7.

1.7 RESOLUTION OF DISPUTES

Differences of opinion between QA staff and other personnel involving quality shall be presented to the CNWRA President for resolution.

Differing Professional Views among CNWRA staff, SwRI staff, consultants or subcontractors regarding health and safety related concerns that may differ from the prevailing NRC staff views, decisions, policy positions, or agency parties can be resolved through the use of a developed procedure.

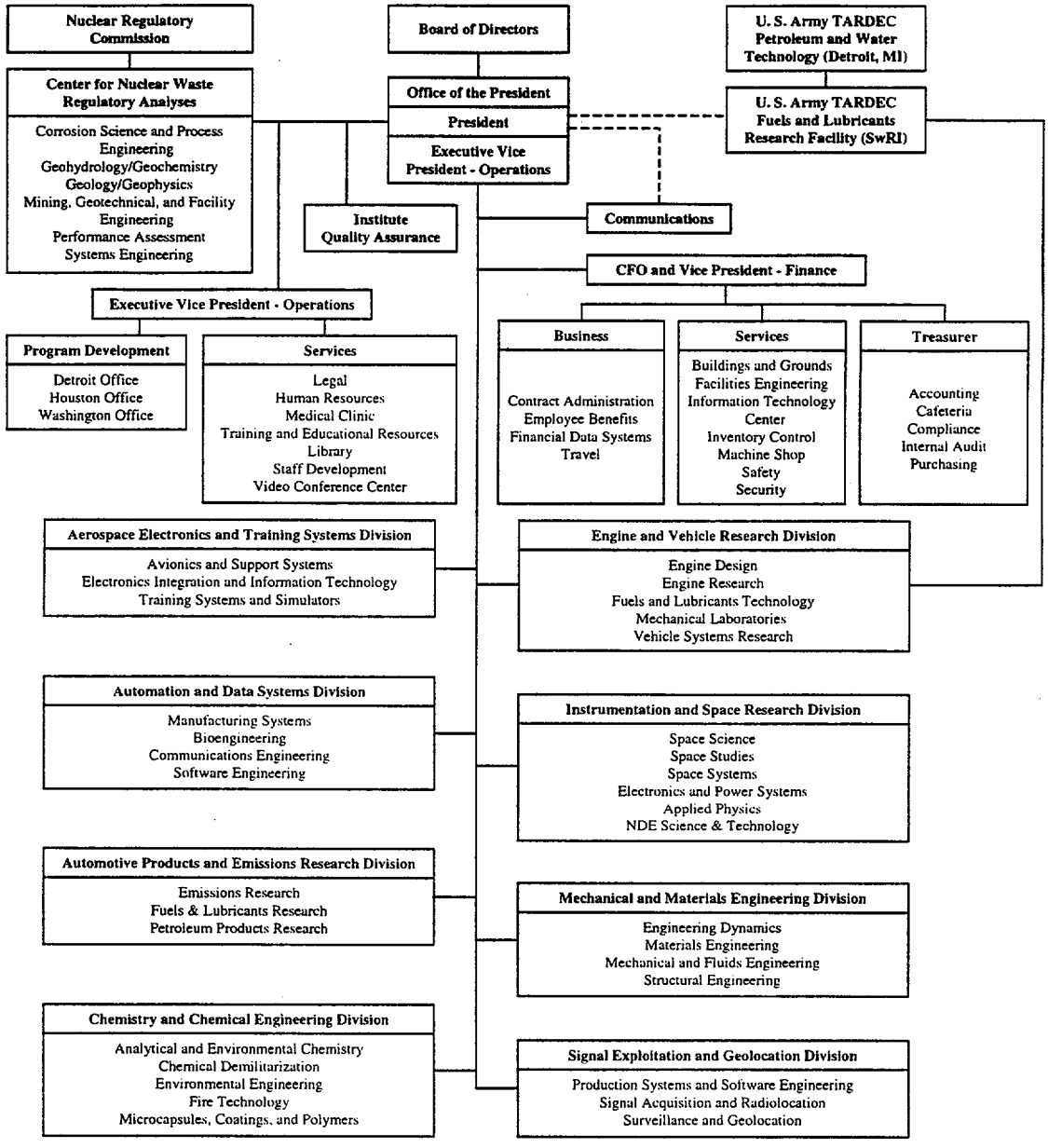
1.8 ALLEGATIONS OF INADEQUATE QUALITY

The CNWRA President and Directors shall review all allegations of inadequate quality originating from within the CNWRA or outside. The conclusions of such reviews shall be documented. Allegations that are confirmed shall be reported to the NRC.

1.9 ELECTRONIC MESSAGES AS QUALITY RECORDS

The CNWRA uses electronic systems to convey important messages or directions. E-mail QA records shall be in "hard paper copy" for filing in the QA records room. These e-mail QA records do not have to be "signed" because the security controls on individual staff computers precludes the issuing of e-mail using someone else's user ID.

SOUTHWEST RESEARCH INSTITUTE™
ORGANIZATION CHART



Standing Groups

Advisory Committee for Research	Facilities Review Panel	Medical Benefits Committee	Radiological Health & Safety Committee
Architectural Committee	Institute Quality Assurance Committee	Patent Committee	Safety Committee
Computer & Telecommunications Committee	Library Committee	Planning Council	Services Committee
DFWP/EAP Committee	Management Advisory Committee	Proposal Panel	Total Quality Management Committee

April 2000

FIGURE 1.1

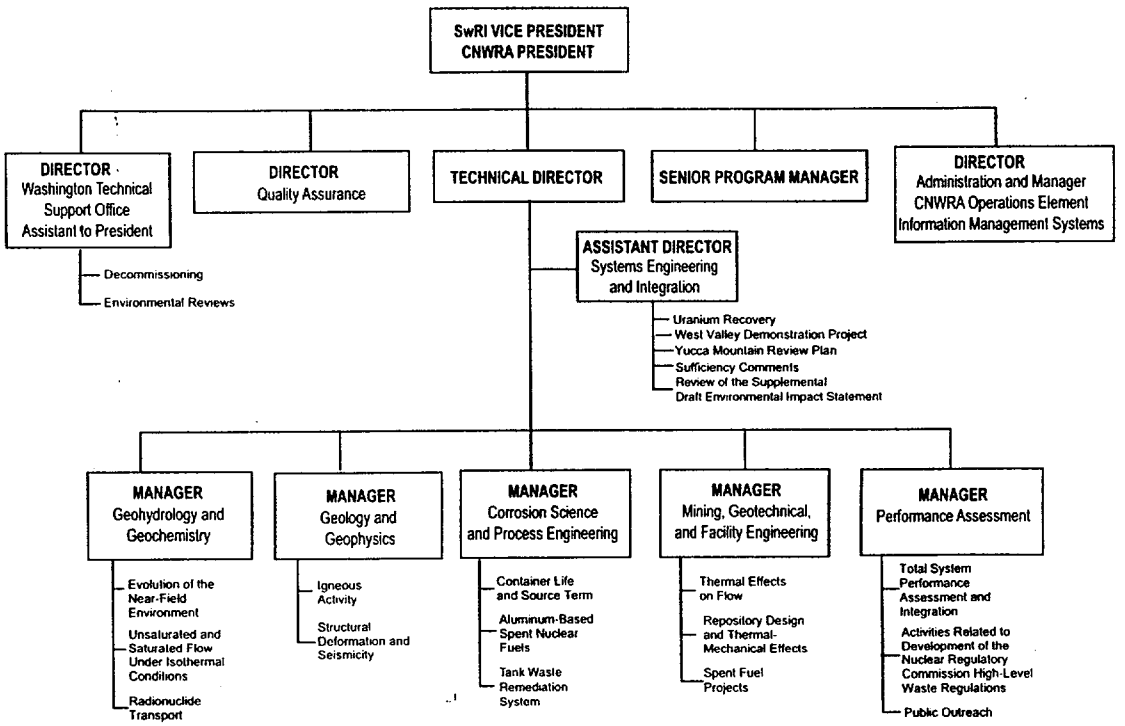

SwRI VICE PRESIDENT
CNWRA PRESIDENT
DIRECTOR
Washington Technical Support Office
Assistant to President
Decommissioning
Environmental Reviews
DIRECTOR
Quality Assurance
TECHNICAL DIRECTOR
SENIOR PROGRAM MANAGER
DIRECTOR
Administration and Manager
CNWRA Operations Element
Information Management Systems
ASSISTANT DIRECTOR
Systems Engineering and Integration
Uranium Recovery
West Valley Demonstration Project
Yucca Mountain Review Plan
Sufficiency Comments
Review of the Supplemental Draft Environmental Impact Statement
MANAGER
Geohydrology and Geochemistry
Evolution of the Near-Field Environment
Unsaturated and Saturated Flow Under Isothermal Conditions
Radionuclide Transport
MANAGER
Geology and Geophysics
Igneous Activity
Structural Deformation and Seismicity
MANAGER
Corrosion Science and Process Engineering
Container Life and Source Term
Aluminum-Based Spent Nuclear Fuels
Tank Waste Remediation System
MANAGER
Mining, Geotechnical, and Facility Engineering
Thermal Effects on Flow
Repository Design and Thermal-Mechanical Effects
Spent Fuel Projects
MANAGER
Performance Assessment
Total System Performance Assessment and Integration
Activities Related to Development of the Nuclear Regulatory Commission High-Level Waste Regulations
Public Outreach

FIGURE 1.2

TYPICAL PROJECT ORGANIZATION

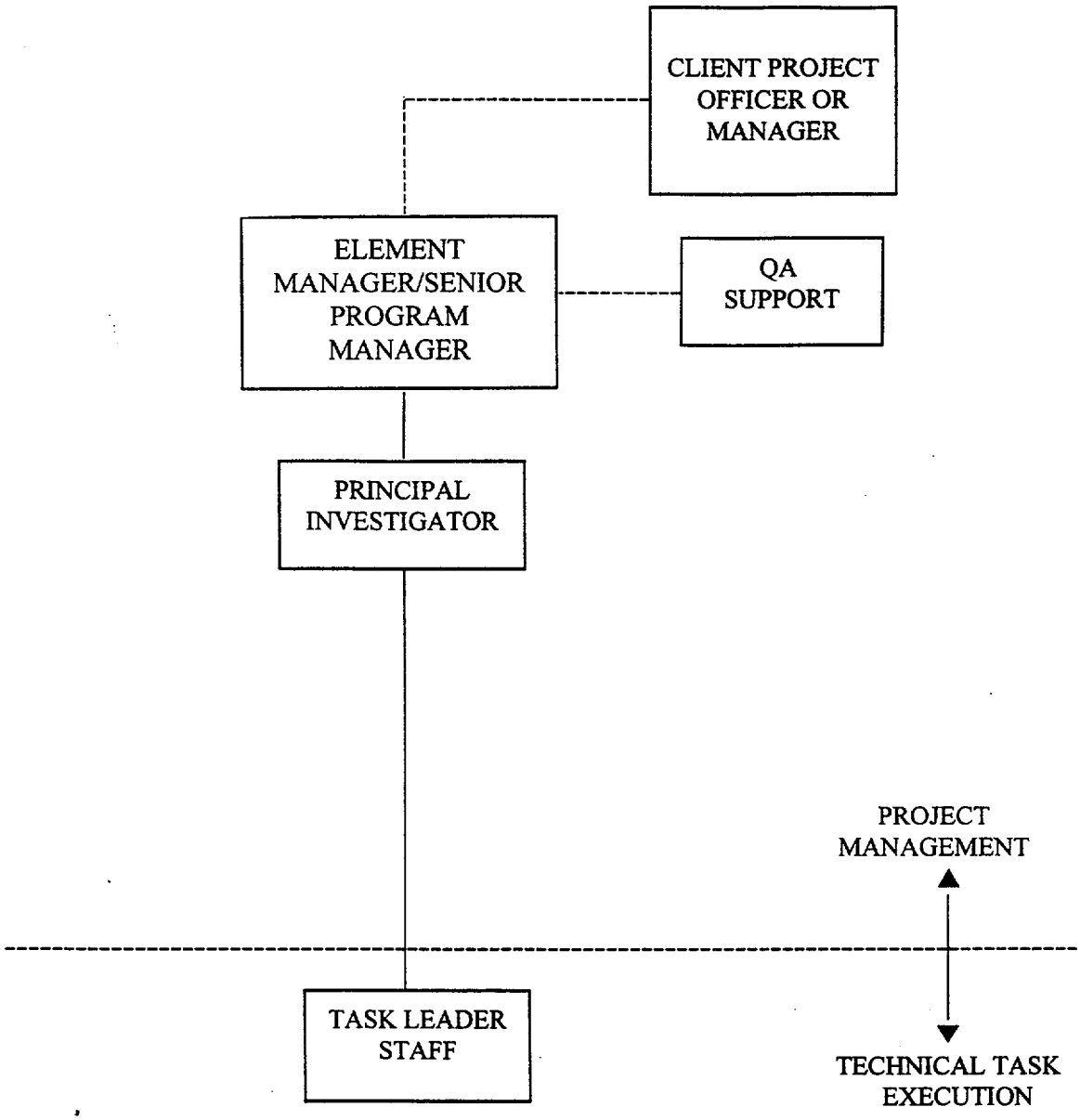


FIGURE 1.3

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 when finalized 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

structures, systems, and components, and the CNWRA mission focuses on analysis, technical assistance, research and development projects, careful interpretation of the criteria is necessary for effective and appropriate application of those criteria. Adaptations and exceptions have been made to certain nuclear QA requirements and criteria that are not applicable to scientific investigations and analyses performed by the CNWRA. These include (i) changing the "Design Control" section to "Scientific/Engineering Investigation and Analysis Control" because of the mission of the CNWRA; (ii) providing for consultants and service subcontractors to perform their work under this QA program since few have formal quality systems; and (iii) conducting receiving inspection activities at the CNWRA by professional technical staff who specify the material ordered. ~~Exceptions are also taken with regard to~~ The independence of receiving inspection personnel and the requirement that a supplier of goods or services maintain a 10 CFR Part 50 Appendix B/NQA-1 Quality system are also clarified. Figure 2.1 provides a table correlating the eighteen criteria of Appendix B, the NRC review plan for HLW QA Program and NQA-1-1986 to the CQAM.

(2) ANSI/ASME NQA-1-1986

The CQAM incorporates the applicable portions of the 1986 Edition NQA-1, QA Program Requirements for Nuclear Facilities, tailored to the specific mission of the CNWRA.

(3) The NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions was consulted as guidance for developing this QA Manual.

The CQAM is written to address applicable elements of the NRC Review Plan Revision dated March 1989. This Review Plan provides requirements specific to High-Level Waste (HLW) related activities. The CQAM has been designed to suit the specific mission of the CNWRA.

(4) Other Standards

Specific CNWRA activities may utilize other accepted industry standards and practices, however, the quality requirements contained in this CQAM shall apply. These shall be identified in operations plans, proposals, scientific notebooks and operating procedures, when applicable. Applicable standards may include, but are not limited to:

- American Society of Mechanical Engineers Codes
- American Society for Testing and Materials Methods and Practices
- Other recognized professional society and consensus industry methods and practices, excluding quality standards

2.3.2 Quality Requirements for CNWRA Activities

(1) This quality assurance program is applicable to technical and regulatory analysis activities performed by the CNWRA and resulting products. This program contains allowances for the use of suppliers who do not have a quality assurance program, but who have been selected to supply goods and perform services to the CNWRA. Further requirements are stated under sections 4 and 7.

(2) Controls applicable to CNWRA activities are dependent on the importance of the item to the HLW program or other client needs. The development, acquisition, and use (i) of data, (ii) analysis methods, and (iii) software shall follow good scientific and engineering practices and shall be controlled in accordance with specific operating procedures.

(3) Exceptions to applicable QA requirements are identified in the correlation matrix, NRC Review Plan for HLW QA Programs/ASME/ANSI NQA-1-1986, Figure 2.1.

2.4 STRUCTURE OF THE CNWRA QA PROGRAM

2.4.1 QA Program Documents

(1) CNWRA Quality Assurance Manual

The policies and programmatic controls of the CNWRA QA Program are incorporated into the CQAM. The CQAM describes the methods by which applicable quality assurance regulations and standards are addressed and the methods by which activities affecting quality are controlled and verified. As applicable regulations and standards are revised, the scope of CNWRA activities change, or programmatic changes are warranted, the CQAM shall be revised.

(2) Operating Procedures

Operating procedures, which include Technical Operating Procedures (TOPs), Quality Assurance Procedures (QAPs), and Administrative Procedures (APs) provide specific instructions for recurring activities affecting quality. Operating procedures supplement CQAM sections that require more detailed controls.

(3) Operations Plans and Proposals

Regulatory analysis, technical assistance, and research activities are controlled through operations plans or proposals which provide general management, technical, and quality controls. Plans provide direction for the conduct of activities and may identify operating procedures and other instructions that will control specific activities affecting quality.

(4) Other Instructions and Methods

Many routine tasks are adequately described in terms of methods and acceptance criteria in existing documents, such as standard methods, practices, and equipment manufacturers' instructions and calibration techniques. Such instructions are acceptable for use in CNWRA activities as long as sufficient details are provided to adequately control the activity and requirements of this manual are applied.

(5) Scientific Notebooks

For tasks of a developmental nature that cannot be planned or controlled by other means (e.g., by operations plans or operating procedures) scientific notebooks provide planning, instructional, and documentation functions. The scientific notebook approach provides sufficient detail and content so that the experimental approach may be verified and the work replicated, as referenced.

2.4.2 Control of Activities Affecting Quality

The following factors affect CNWRA product quality:

(1) Personnel who perform quality-affecting activities at and for the CNWRA.

(2) The operation and calibration of measuring and test equipment.

(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 Surveillance

Internal evaluations of the effectiveness of the implementation of the CNWRA QA Program shall be by periodic surveillances and audits. Hold points shall be incorporated into the QRAM forms as necessary to assure that required verifications are accomplished.

2.5.2 SwRI Quality Assurance Committee

The SwRI Operating Policies and Procedures specifies that the Quality Assurance Committee (QAC) shall independently monitor and review the activities of each SwRI QA program. QAC 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 QAC, as well as CNWRA management.

(2) QAC 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.

2.6.2 Qualification of Personnel

(1) Personnel performing activities affecting quality, including scientists, engineers, analysts, auditors, NDE specialists, and receiving inspection personnel shall be qualified to perform their assigned tasks. Qualification shall be based on education, experience, training, and freedom from conflict of interest, as required by CNWRA procedures Since there are many unique and diverse disciplines represented at the CNWRA, it is not feasible to implement a personnel certification program that is sufficiently inclusive to be effective. In lieu of such a certification program, the CNWRA formally qualifies each individual professional staff member. This qualification process requires the individual's functional position description and statement of qualifications to be developed by the cognizant CNWRA EM or director and annually reviewed. The annual review shall consider the individual's performance as evidenced by a formal evaluation, continuing education, and/or training activities to verify the individual continues to meet the requirements of the position description.

(2) The qualification method for scientists, engineers, analysts, and other professional personnel shall require, as a minimum:

- Statement of position requirements
- Documentation of education, experience, and training
- Evaluation by the cognizant CNWRA Director that the individual satisfies position requirements
- Annual reevaluation to determine that proficiency is maintained

(3) The qualification method for lead auditor is provided in section 18 of this CQAM.

(4) The qualification method for personnel performing nondestructive testing shall be in accordance with industry standards (e.g., ASNT-TC-1A).

2.6.3 Qualification Records

Objective evidence of personnel qualifications is maintained as a QA Record.

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. Draft 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.

CORRELATION OF QUALITY PROGRAM REQUIREMENTS

CNWRA QA MANUAL	10 CFR Part 50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE EXCEPTIONS AND CLARIFICATIONS
Introduction	Introduction	N/A	Introduction	Included in CQAM. Definitions in Appendix I of the CQAM.
Section 1 Organization	Criterion I	Section 1	1, 1S-1	Requirements addressed.
Section 2 Quality Assurance Program	Criterion II	Section 2	2, 2S-1, 2S-2, 2S-3, 2S-4, 2A-1	~~-Personnel qualification requirements are established to meet the needs of CNWRA activities.~~ **Highly 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, CNWRA senior management will ensure 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.** ~~Exception is taken to allow highly trained technical staff to perform receipt inspections.~~ **The supplier's quality system may be based on quality standards (e.g., ISO 9001) other than 10 CFR Part 50, Appendix B or NQA-1 provided that: a) the equivalent Appendix B and NQA-1 requirements for the service or product are adequately described in the supplier's quality system; b) these requirements are confirmed as being satisfactorily implemented; and c) the purchase order for the service or product specifically invokes the approved quality system for the service or product being procured.** ~~- Suppliers of goods and services are exempt from maintaining a 10 CFR Part 50 Appendix B/NQA-1 quality system.~~ -Auditor qualifications and certifications are in accordance with NQA-1.

CORRELATION OF QUALITY PROGRAM REQUIREMENTS

CNWRA QA MANUAL	10 CFR Part 50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE EXCEPTIONS AND CLARIFICATIONS
Section 3 Scientific/Engineering Investigation and Analysis Control	Criterion III	Section 3	3, 3S-1	CNWRA activities for the NRC do not include many of the requirements contained in 3 and 3S-1 because the CNWRA does not provide design inputs and design processes. CNWRA Section 3 defines the relationship of the CNWRA to the NRC in the licensing process.
Section 4 Procurement Document Control	Criterion IV	Section 4	4, 4S-1	~~Goods and service procurements are modified since consultants and small firms typically have no formal quality program.~~ Procurement documents issued to consultants and service subcontractors will specify they work under the CNWRA QA program if they do not have an approved QA program. Suppliers of goods will work to an acceptable quality program or meet the requirements in a CNWRA procurement document. Spare and Replacement parts are not addressed because the CNWRA and the NRC do not provide these items.
Section 5 Instructions, Procedures and Drawings	Criterion V	Section 5	5	Requirements addressed
Section 6 Document Control	Criterion VI	Section 6	6, 6S-1	Requirements addressed.
Section 7 Procurement Control	Criterion VII Control of Purchased Materials, Equipment, and Components	Section 7	7, 7S-1 Control of Purchased Items and Services	Tailored to CNWRA procurement of quality-affecting items and services and related activities important to licensing or other client needs specified by contract. Adapted to science and engineering studies.

CORRELATION OF QUALITY PROGRAM REQUIREMENTS

CNWRA QA MANUAL	10 CFR Part 50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE EXCEPTIONS AND CLARIFICATIONS
Section 8 Identification and Control of Items, Software, and Samples	Criterion VIII Identification and Control of Materials, Parts, and Components	Section 8	8, 8S-1 Identification of Purchased Items and Services	Requirements addressed.
Section 9 Control of Processes	Criterion IX Control of Special Processes	Section 9	9, 9S-1 Control of Processes	CNWRA QA manual addresses "special processes" as applicable to CNWRA work activities that are important to licensing or other client needs specified by contract.
Section 10 Inspection	Criterion X	Section 10	10, 10S-1	**Highly 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, CNWRA senior management will ensure 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.** ~~Exception taken to allow CNWRA technical personnel to perform receiving inspections because of the important to licensing or other client needs specified by contract.~~
Section 11 Test Control	Criterion XI	Section 11	11, 11S-1	When performing tests important to licensing of DOE proposed designs, the CNWRA staff will conduct tests with approved, formal test procedures.
Section 12 Control of Measuring and Test Equipment	Criterion XII	Section 12	12, 12S-1	Requirements addressed.

CORRELATION OF QUALITY PROGRAM REQUIREMENTS

CNWRA QA MANUAL	10 CFR Part 50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE EXCEPTIONS AND CLARIFICATIONS
Section 13 Handling, Storage and Shipping	Criterion XIII	Section 13	13, 13S-1	Requirements addressed for important to licensing activities or other client needs specified by contract.
Section 14 Inspection, Test and Operating Status	Criterion XIV	Section 14	14	Adapted to CNWRA practices for important to licensing activities or other client needs specified by contract.
Section 15 Nonconformance Control	Criterion XV Nonconforming Materials, Parts, or Components	Section 15	15, 15S-1	Requirements addressed.
Section 16 Corrective Action	Criterion XVI	Section 16	16	Requirements addressed.
Section 17 Records Control	Criterion XVII Quality Assurance Records	Section 17	17, 17S-1	Requirements addressed.
Section 18 Audits	Criterion XVIII	Section 18	18, 18S-1	Requirements addressed.

3. SCIENTIFIC/ENGINEERING INVESTIGATION AND ANALYSIS CONTROL

3.1 PURPOSE

This section describes various methods for controlling scientific investigations and engineering analyses conducted at the CNWRA that affect product quality. The title of this section has been changed from Design Control to Scientific/Engineering Investigation and Analysis Control to accurately encompass the scope of CNWRA activities.

3.2 RESPONSIBILITIES

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

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

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

3.3 SCIENTIFIC INVESTIGATION AND ANALYSIS CONTROL DESCRIPTION

CNWRA regulatory, institutional, and technical analyses; technical assistance; and research activities affecting product quality shall be planned, accomplished, and verified under controlled conditions. To better understand the terms used in describing CNWRA activities, the following definitions are provided.

- Analysis – A detailed examination or investigation of anything complex accomplished to understand the nature or to determine the essential features of a subject of interest. Analyses may be qualitative or quantitative, textual or numerical.

- Investigation – A detailed examination, study, or research (see "Scientific Investigation" in Appendix I)

3.3.1 General Assistance

General assistance and similar activities are generally identified in operations plans and proposals, that provide objectives, general task descriptions, project management and cost

information. Additionally the CNWRA receives direction by way of Standard Review Plans (SRPs). SRPs provide information that defines the process of the review required by the client. Recurring technical activities can be controlled through the use of TOPs, QAPs, APs or by documentation in scientific notebooks. For some tasks, prior knowledge of the specific analysis method is impossible, and the method is developed and enhanced as a consequence of performing the analysis itself. In those cases, scientific notebooks are the preferred method. These activities may ultimately result in the development of a formal test procedure controlling subsequent activities. Scientific and engineering investigations and analyses are broadly described in operations plans and proposals that are accepted by the CNWRA client. These and other controlling documents are reviewed and approved by technical, programmatic, and QA staff of the CNWRA.

3.3.2 Technical Assistance and Research

Operations plans and proposals provide for planning and general control of technical assistance and research, literature searches, design of experiments, conduct of experiments and tests, computer code development, data analysis and computer model analysis. Such plans identify the technical objectives, describe each task of the technical program, and describe the program management.

Scientific notebooks are utilized to plan and control technical tasks. The scientific notebook documents the decision paths leading to performance of an activity and also identifies the method used, allows for quality verification, and documents the results. The scientific notebook provides adequate control of activities affecting quality while allowing flexibility and adaptability for developmental and experimental technical activities.

3.3.3 Literature Searches

Literature searches are used to initially gather information on subjects under investigation.

3.3.4 Control of Existing Data

Quality planning (see section 2.4.2) shall identify tasks in which existing data, collected without required quality assurance program controls, may be used for interpretation or analysis. Existing data that will not be used to support conclusions affecting licensing support activities are not subject to qualification. Existing data qualification shall be accomplished by peer review, use of corroborating data, use of confirmatory testing, or collection under an equivalent QA program, in accordance with the guidelines of NUREG–1298, Qualification of Existing Data for High Level Waste Repositories.

3.3.5 Development, Use, and Evaluation of Scientific and Engineering Software

Scientific and engineering (S&E) software (i.e., software that implements mathematical models to solve scientific or engineering problems) may be acquired, developed, modified or evaluated as part of CNWRA task activities. S&E software development shall proceed in a traceable, planned, and orderly manner. A procedure shall describe the phase of CNWRA S&E software. It shall include:

- Identification and documentation of specified requirements,
- Software development planning,
- Software change and problem reporting and resolution,
- Software configuration control,
- Verification review and release,
- Software acceptance and validation testing, and
- Retirement.

Small, incidental codes of a few lines that are developed for one time use only shall be documented in the appropriate scientific notebook and a copy of the code shall be included in the final QA packet related to the deliverable.

CNWRA management shall identify the computer codes that are expected to be used in license application review and other appropriate activities and shall determine the schedules for placing them under control.

3.3.6 Control by Scientific Notebook Method

Technical activities are primarily controlled by scientific notebooks. The Principal Investigator or other assigned personnel for the assigned task shall develop and maintain scientific notebooks. The issuance of and the specific controls for Scientific Notebooks shall be described in CNWRA procedures. The scientific notebook provides historical documentation of the activity including planning, conducting the activity, and documenting results and analysis.

3.3.7 Review Guidance Provided Through Codes, Standards and/or Procedures.

Detailed TOPs should be used whenever the work is repetitive. Such TOPs shall be developed in accordance with the requirements given in CQAM section 5. TOPs shall provide descriptive methods of how to conduct recurring scientific investigations and analyses.

3.3.8 Reporting Errors and Deficiencies~~/Reporting~~

When errors and deficiencies are identified in potential licensee or licensee documents that the CNWRA reviews, the NRC will be notified in a Request for Additional Information (RAI) or such other documents as specified by contract or other directive. The NRC will be notified of errors or deficiencies found in a CNWRA deliverable that has already been forwarded to the NRC. ~~In a Request for Additional Information (RAI) or such other documents as specified by contract or other directive. The final Safety Evaluation Report (SER) or Assessment Reports (AR), or other documentation shall be provided to the CNWRA client for tracking and disposition of errors and deficiencies.~~

3.3.9 Verification of Scientific Investigations, Analyses, Experiments and Tests

Surveillance of scientific investigations, analyses, experiments, and tests shall be conducted as needed to verify compliance with applicable procedural requirements. The surveillance shall include, as appropriate, direct witnessing of experiments, reviews of personnel qualifications, and equipment used, and shall include review of the scientific notebook for required entries and documentation. Hold points may be utilized to identify a point beyond which work shall not proceed until inspected by a designated person.

3.3.10 Data Interpretation and Analysis

Interpretation and analysis, including scientific investigation data interpretation and analysis, shall be performed in a planned, controlled, and documented manner. Interpretation and analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. Scientific notebooks may be utilized to document these activities, as determined by the Element Manager or Principal Investigator. Calculations, including

data reduction, statistical analysis, and routine scientific and engineering calculations, shall be documented and verifiable. Documentation shall be sufficient to identify the data inputs and their sources and the calculation formula or algorithm such that calculations may be replicated.

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

CNWRA staff, qualified in accordance with developed procedures, shall develop and use approved practices and guidance (e.g., standard review plans) to review 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. PROCUREMENT DOCUMENT CONTROL

4.1 PURPOSE

This section establishes the minimum controls for CNWRA procurement documents. It describes controls for the preparation, revision, change, content, and issuance of procurement documents.

4.2 RESPONSIBILITIES

(1) CNWRA Director of Administration shall be responsible for ensuring that procurement documents are in compliance with the requirements of this section.

(2) CNWRA Director of QA or designee shall review and approve the quality-affecting procurement documents and changes thereto to assure that documents transmitted to the prospective supplier(s) include appropriate provisions for goods or service to meet the specified requirements.

4.3 BASIC REQUIREMENTS

Applicable design bases, regulatory requirements, and other requirements necessary to assure quality shall be included or referenced in documents for procurement of goods and services. To the extent necessary, procurement documents shall require suppliers of goods to have a quality assurance (QA) program consistent with applicable quality requirements. Consultants will work to the applicable portions of the CNWRA QA program.

4.4 PROCUREMENT DOCUMENTS

Procurement documents issued shall include the elements of Paragraphs 4.4.1 through 4.4.6 of this section.

4.4.1 Scope of Work

A description of the good or services to be provided or performed by the supplier shall be provided.

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 tests, inspection, hold points, and acceptance criteria.

4.4.3 Quality Assurance Program Requirements

Procurement documents 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 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 ~~exceptions~~ 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. ~~major exceptions include consultants and service subcontractors performing their work under this QA program because few have formal quality systems.~~

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.

4.4.6 Nonconformances

Quality-affecting procurement documents shall include the CNWRA requirements for reporting and approving disposition of supplier nonconformances.

4.5 PROCUREMENT DOCUMENT REVIEW

At a minimum, the SwRI purchase requisition will be reviewed and signed by the PI or EM and, ~~if required~~, the CNWRA Director of QA. ~~when required by developed procedures.~~ Other procurement documents will be reviewed and approved in accordance with SwRI policy. Reviews of consultant services contracts and subcontract agreements are performed in accordance with developed procedures.

4.6 PROCUREMENT DOCUMENT CHANGES

Procurement document changes regarding scope, schedule, complexity, bid evaluation, pre-contract negotiations and quality shall be subject to the same degree of review as utilized in the preparation of the original document.

4.7 RECORDS

CNWRA procurement records are maintained as administrative records in accordance with section 17 of this CQAM.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 PURPOSE

~~The purpose of~~ This section ~~is to~~ establishes requirements for accomplishing activities affecting quality through the use of documented instructions, procedures, and drawings.

5.2 RESPONSIBILITIES

(1) CNWRA Directors and Element Managers are responsible for

(a) Determining the need for instructions, procedures, and drawings for their staff

(b) Developing, implementing, and conducting activities in accordance with applicable instructions, procedures and drawings .

(2) The CNWRA Director of QA is responsible for jointly determining, with the technical management staff, the need for instructions, procedures, and drawings, and for developing and implementing the CQAM and QAPs.

(3) Individuals performing activities affecting quality are responsible for conducting their activities in accordance with applicable instructions, procedures, and drawings.

5.3 INSTRUCTIONS, PROCEDURES AND DRAWINGS

CNWRA activities shall be conducted and their quality verified in accordance with the following as appropriate:

5.3.1 CNWRA Quality Assurance Manual (CQAM)

The CQAM provides the CNWRA commitment and basic requirements and controls for developing, implementing, and maintaining the CNWRA QA Program.

5.3.2 Planning Documents

Operations plans and proposals establish ~~provide~~ general technical, management, and quality assurance requirements and controls for ~~direction over~~ research and technical assistance activities. Work plans or test plans may be developed to provide additional definition of activities.

5.3.3 Instructions

Quality-affecting activities may be described or controlled through means other than procedures and drawings. These instructions may take the form of, but are not limited to, work orders, process control, receipt travelers, scientific notebooks, or nonconformance dispositions. These instructions may be included as part of other activities described by procedures.

5.3.4 Procedures

(1) Procedures should be written to control recurring technical and administrative activities affecting quality. The following classes of procedures are utilized at the CNWRA:

- QAPs implement and supplement CQAM requirements when greater detail is necessary.
- TOPs describe methods of conducting recurring scientific investigation and analysis activities, including any standard methods or procedures used.
- APs provide step-by-step method to accomplish administrative support functions.
- Scientific Notebooks—Document the methods and results of scientific investigation activities, including any standard methods or procedures used.

(2) When appropriate, instructions, procedures and drawings shall include appropriate quantitative or qualitative acceptance criteria.

(3) Field or laboratory changes may be made to TOPs, drawings, or instructions. The changes shall be approved by the Principal Investigator prior to the beginning of work, and shall be properly documented in the scientific notebook. Changes shall be verified by the same groups required to review the original instruction, procedure, or drawing.

5.3.5 Drawings

~~Drawings,~~ When used to describe quality-affecting activities or items, drawings shall be produced in accordance with procedures that specify a systematic method for initiating, checking, approving, and issuing such drawings and controlled changes to the drawings.

5.4 RECORDS

Original copies of the CQAM, QAPs, TOPs and APs generated shall be maintained in accordance with section 17 of this CQAM. ~~the QA Records Room as permanent records.~~

~~5.5 REFERENCES~~

~~CNWRA Quality Assurance Procedure-008, Document Control.~~

6. DOCUMENT CONTROL

6.1 PURPOSE

This section describes requirements for the preparation, review, approval, change, and distribution of documents that specify quality requirements or prescribe activities affecting quality.

6.2 RESPONSIBILITIES

(1) The CNWRA Director of QA is responsible for preparation, revision, and change of the CQAM and QAPs, for review and approval of QA documents, and for coordination with technical staff to prepare QA portions of operations and project plans, proposals, TOPs, and APs.

(2) Directors and Element Managers are responsible for preparation, revision, and change of TOPs and other procedures, operations plans, project plans, and proposals controlling activities of their responsibility.

(3) The CNWRA President, Directors, and Element Managers are responsible for performing required document reviews and approvals, and for determining distribution of controlled documents.

(4) Principal Investigators are responsible for drawing approval, TOP field changes, and control of instructions, procedures, and drawings at the point of use.

(5) The Director of QA is responsible for maintaining the Master Document List and for distribution and control of quality documents.

6.3 APPLICATION OF DOCUMENT CONTROLS

The CQAM, TOPs, QAPs, and APs, operations plans, project plans, and proposals shall be controlled in regard to preparation, review, approval, changes, and distribution.Work instructions, such as industry standard methods and manufacturers' recommendation will be available to assure that the correct instruction is ready at the point of use. Unless otherwise specified by the client, proposals are typically not issued as controlled documents.

6.4 PREPARATION, REVIEW, AND APPROVAL

6.4.1 CNWRA Quality Assurance Manual

(1) The CQAM shall contain a statement of policy, an introduction, and sections addressing applicable criteria of Appendix B and ASME/ANSI NQA-1-1986.

(2) The CQAM Statement of Policy shall be approved by the CNWRA President.

(3) The CQAM shall, in general, describe the actions necessary to accomplish and verify activities affecting quality.

(4) CQAM sections shall include descriptions of Purpose, Responsibilities (except Introduction and section 1), Records, and References, as applicable.

(5) The CQAM shall be reviewed for compliance to Appendix B, NQA-1-1986 and other applicable regulations and standards by the Director of QA. The CNWRA President and Director of QA shall approve the CQAM.

6.4.2 Operating Procedures

(1) Operating Procedures (TOPs, QAPs and APs) provide developed controls and methods prescribing activities affecting quality. TOPs, QAPs, and APs shall provide sufficient detail as to methods, personnel qualification, calibration, and equipment requirements, as applicable, to perform activities under suitably controlled conditions. Specific content requirements for TOPs are described in the CQAM section providing the basic control requirement.

(2) TOPs, QAPs, and APs generally follow the format of CQAM sections and shall be prepared on CNWRA form TOP-2 or QAP-2, or equivalent. TOPs and QAPs shall contain, as a minimum, descriptions of Purpose, Responsibilities, Procedure, and Records generated as a result of the procedure.

(3) TOPs, QAPs, and APs shall be assigned unique numbers. Additional operating procedures in the same generic field may be assigned a suffix number.

(4) TOPs, QAPs, and APs shall be reviewed for adequacy in accordance with a developed procedure.

6.4.3 Operations Plan, Project Plans, and Proposals

(1) Technical assistance and research activities are planned through development of operations plans, project plans, and proposals, which provide technical direction, management, and quality controls.

(2) Plan format shall include descriptions of the technical objective, technical program by task, program management, and costs.

(3) Quality assurance requirements are identified in the Quality Requirements Application Matrix (QRAMs), which shall be completed prior to beginning quality-affecting work. QRAMs shall be reviewed and approved by the Technical Director and the Director of QA.

(4) Plans shall be uniquely titled indicative of their technical content.

(5) The Director of QA shall review operations and project plans and proposals to verify compliance with the CQAM.

(6) Operations plans and project plans shall be approved by the Technical Director, the Deputy Technical Director for Systems Engineering and Integration, the Director of Administration, and the Director of QA. Proposals shall be approved by the CNWRA President.

6.4.4 Drawings

(1) Drawings and sketches shall be prepared as necessary to control the fabrication of test items.

(2) Drawings and sketches may be in any format so long as adequate information is provided to fabricate and inspect the item.

(3) Drawings and revisions shall be reviewed and approved by the PI, and shall be controlled in accordance with developed procedures.

6.4.5 Revisions and Changes

(1) The CQAM, TOPs, QAPs, APs, operations plans and project plans, and proposals may be changed page by page or revised in total. Changes and revisions shall be designated by "Change" or "Revision" and a sequential number after the document number or title, as applicable, on the title page and on each changed page.

(2) Changes and revisions shall receive the same level of review and approval as required for originals. The document title page shall be revised with each change or revision, documenting these approvals.

(3) Field or laboratory variances to TOPs may be accomplished by documenting the change in a scientific notebook, with approval by the Principal Investigator.

(4) QRAMs are revised as modifications are made to operations plans, project plans, and proposals.

6.4.6 Master Document List

(1) A Master Document List shall be maintained and updated as new controlled documents, revisions and changes are issued.

(2) The Master Document List shall contain, as a minimum:

- Document number or name as applicable
- Revision or change number
- Date of issue
- Effective date of Master Document List

6.4.7 Release for Distribution

After required approvals are obtained, documents shall be released for controlled distribution.

6.5 DOCUMENT DISTRIBUTION

6.5.1 Distribution Lists

(1) CQAM distribution shall include, as a minimum:

- CNWRA President, Directors, and Element Managers
- SwRI Manager of Institute QA or the SwRI Vice President of Quality Systems

(2) TOP, QAP, AP, operations plan, project plan, and proposal distribution shall include, as a minimum:

- CNWRA President, Directors, and Element Managers
- Affected Principal Investigator(s) identified by the Element Managers

(3) Distribution of controlled documents shall be determined by the Element Manager responsible for the activity controlled by the document.

(4) A distribution list shall be maintained for controlled documents. The lists shall include the document name and number (as applicable), revision and change number, and recipient name.

(5) Uncontrolled copies may be issued upon approval of the Element Manager. Uncontrolled copies shall be clearly indicated as such.

(6) A log of scientific notebooks will be maintained in the CNWRA QA Records Room by QA staff.

6.5.2 Transmittal and Acknowledgment

(1) Controlled documents shall be transmitted to the recipient with the following:

- Instructions to the recipient to review the document
- Instructions to incorporate revisions or changes, destroying or clearly marking obsolete pages or earlier revisions

- 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) Principal Investigators 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.

6.6 RECORDS

Original copies of the operations plans, proposals, CQAM, QAPs, TOPs, and APs generated shall be maintained in the QA Records Room as permanent records.

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.

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.

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.

(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 implantations 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

~~Supplier~~ Contractor or consultant performance evaluations relating to ~~for~~ computer codes, research results, written papers, presentations, and ~~other data~~, 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. ~~shall be made by the PIs and/or EMs. Objective evidence of acceptability can be by payment of the invoice, notation in a scientific notebook or project record, or a documenting acceptance on the receipt traveler.~~

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 ~~who provide individuals for services~~ described in section 1.6.2 ~~or consultants~~ 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 ~~payment~~ 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 plates, chemicals, solutions, ceramic products, and instrument and control products procured from sources not on the ASL that are used in applications that support and are important to the NRC licensing process (or other client needs specified by contract) shall 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 ~~Approved Suppliers List~~ ASL qualified sources shall be based on review of the required documentation and product by the appropriate CNWRA technical staff member.

~~(3) The SEC shall determine the acceptability of subcontractors and consultants.~~

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.

~~Receiving inspections of procured goods shall be performed by the individual procuring the item or another technically qualified staff member.~~ Highly 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, CNWRA senior management will ensure 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. ~~Receiving inspection shall also assure that documentation is received from the supplier and that the specific procurement requirements are met. Documentation identifying procurement requirements not met and descriptions "accept as is" or "repair" shall also be provided.~~ 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 nonconformance from the procurement requirements dispositioned "accept as is" or "repair."

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. IDENTIFICATION AND CONTROL OF ITEMS, SOFTWARE, AND SAMPLES

8.1 PURPOSE

~~The purpose of~~ This section ~~is to~~ provides methods to identify ~~for identification~~ and control ~~of~~ items, software, and samples used in CNWRA activities affecting quality.

8.2 RESPONSIBILITIES

(1) CNWRA Directors and Element Managers are responsible for implementing this section and, as necessary, for developing and implementing TOPs, QAPs, and APs for affected activities.

(2) Principal Investigators are responsible for identifying and controlling items, software, and samples in accordance with this section and applicable operating procedures.

8.3 IDENTIFICATION

8.3.1 Purchased, Items, Materials, and Equipment

(1) Items, materials, and equipment ordered in accordance with sections 4 and 7 and affecting ~~CNWRA~~ product quality shall be clearly labeled by the seller or ~~labeled by~~ the CNWRA (such as steel plate and soil reference samples). Identification shall typically be through the use of supplier labels. Where physical identification is impractical or insufficient, physical segregation or other appropriate means shall be used.

(2) Tags, markings, or records traceable to the item shall include the item description and, when applicable, lot, heat, or batch number.

(3) Markings shall be such that future use of the item or material is not adversely affected.

8.3.2 Software

Software subject to control shall be clearly identified ~~in accordance with Development and Control of Scientific and Engineering Software, TOP-018, shall be clearly identified,~~ both physically and within the encoded information, with the software description and version.

8.3.3 Samples

Samples shall be identified from the point of collection through storage, subdivision, and analysis. Samples shall be tagged, bagged and tagged, bottled and labeled, or otherwise appropriately contained and identified. Identification shall include, as a minimum, date of collection, collection location, and a unique sample identification.

8.3.4 Limited Shelf Life Items

The expiration date of limited shelf-life items shall be clearly identified and removed by the date. Note that some chemicals are retained by laboratory staff beyond their shelf life for comparison purposes and those should be marked to reflect that retention.

8.4 TRACEABILITY CONTROL

Sample identification shall be traceable to appropriate documentation, such as purchased item receiving records, drill logs, and test records.

8.4.1 Maintenance of Identification

(1) Measures shall be taken to assure that identification is maintained over time and through subdivision of the original materials and samples. Techniques such as use of prelabeled containers and transfer of markings before subdividing shall be utilized to the maximum extent possible.

(2) When not in use for testing or analysis, samples shall be stored in limited access areas to prevent loss of identification or contamination

(3) Subsamples and subparts of samples shall be identified and controlled in the same manner as the parent material. Subsample and subpart unique identification numbers shall be based on the parent identification number.

(4) Appropriate logs shall be maintained to document sample receipt, subdivision, and disposition of tested specimens.

8.4.2 Control of Specimens

When necessary for archival purposes, scientific notebooks or appropriate operating procedures shall specify control and storage requirements of tested specimens.

8.5 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. ~~as referenced in QAP-009, Nonconformance Control.~~

8.6 RECORDS

~~The majority of the~~ Quality records generated by this section shall be ~~are~~ maintained in accordance with section 17 of this CQAM. ~~scientific notebooks and in the sample custody log, both of which are ultimately kept in the QA Records Room.~~

~~8.7 REFERENCES~~

~~CNWRA Quality Assurance Quality Assurance Procedure-009, Nonconformance Control.~~

~~CNWRA Technical Operating Procedure-012, Identification, Control, Storage, Handling, Shipping, and Archiving of Samples.~~

~~CNWRA Technical Operating Procedure-018, Development and Control of Scientific and Engineering Software.~~

9. CONTROL OF PROCESSES

9.1 PURPOSE

This section establishes methods for controlling processes that affect quality of CNWRA products.

9.2 RESPONSIBILITIES

(1) PIs are responsible for identifying processes requiring controls and developing, qualifying, and implementing special process procedures. In addition, PIs are responsible for utilizing properly qualified personnel to perform processes.

(2) The Director of QA is responsible for verifying special process controls for processes conducted by SwRI and qualified suppliers and for reviewing procedure qualification documentation.

(3) Element Managers are responsible for performing technical reviews of procedure qualification documentation.

9.3 PROCESS CONTROL

(1) Quality-affecting processes at the CNWRA shall be controlled by Operations Plans, procedures, direction from the NRC staff, documentation in a scientific notebook, and by document review request and transmittal control forms.

(2) Scientific investigation and analysis and other experimental types of processes shall be conducted in accordance with this section or section 3.3.6 of the CQAM and shall assure that process parameters are controlled and that specified environmental conditions are maintained.

9.4 SPECIAL PROCESSES

(1) Special processes are those where the results are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. Special processes are subject to the controls described here only if the results are used directly to support NRC licensing actions or when requested by the client. Special process procedures shall be developed by CNWRA technical staff and concurred in by CNWRA QA staff.

(2) Special processes shall be prescribed by Technical Operating Procedures or within the appropriate scientific notebook. As a minimum, these shall identify:

- Step-by-step description of the method
- Personnel qualification requirements
- Equipment and any special calibration or other ~~equipment qualification~~ requirements
- Applicable controlled environmental or other condition requirements
- Documentation requirements

(3) ~~Special process procedures that are based on accepted industry standard methods and practices, and that are to be utilized for the intended purpose, do not require further qualification.~~ Procedures for special processes such as welding, non-destructive testing, coatings, and heat treatment that require qualification shall be documented and the results of qualification shall be technically reviewed by technically qualified staff. The Director of QA shall review the procedure to assure all quality requirements have been satisfied. When no acceptance criteria are available for the evaluation of a special process procedure, the CNWRA shall clearly and accurately document the rationale for acceptance.

(4) Nondestructive testing, welding, heat treatment, and surface treatments are special processes that have well established methods. If utilized, these special processes shall be conducted ~~by~~ using qualified procedures, equipment, and personnel, or by suppliers on the ASL qualified in accordance with CQAM Section 7.

(5) Personnel performing special processes shall be qualified in accordance with CQAM section 2 or a qualified supplier's method. Qualification methods shall meet industry codes and standards when applicable.

(6) Objective evidence of the proper accomplishment of special processes shall be developed and documented in the appropriate scientific notebook or project files. Records shall include values of all important parameters identified in the procedure or method, identification of the procedure or method, equipment used, and special process personnel and their level of certification, as applicable.

9.5 RECORDS

(1) Process and special process procedures, procedure qualifications, and personnel qualifications documentation shall be maintained as QA records and retained as permanent records.

(2) The results of special processes and associated information shall be incorporated into scientific notebooks or project files and retained as specified in CQAM section 17.

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, and NQA-1-1986.

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 procurement documents. 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, ~~and~~ 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. Highly 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, CNWRA senior management will ensure 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 is an exception to NQA-1-1986.~~

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

Inspection planning activities for quality affecting products shall be referenced on the procurement documentation in the form of QA and technical requirements and inspection criteria. 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.

11. TEST CONTROL

11.1 PURPOSE

This section establishes controls to ensure that necessary tests are performed and executed and test results are documented and evaluated.

11.2 RESPONSIBILITIES

(1) PIs are responsible for identifying processes needing test controls and developing, qualifying, and implementing appropriate test controls.

(2) The Director of QA is responsible for verifying, when needed, that test control procedures are implemented and accurately documented.

(3) EMs are responsible for assuring that all test control parameters are met.

11.3 TEST CONTROL

Test procedures shall be developed and shall be based on specified requirements contained in applicable design or other pertinent technical documents, as required. Scientific notebooks can be used in place of test procedures provided they contain and fully describe the test process. The use of scientific notebooks is the preferred method for documenting technical activities performed at the CNWRA. Scientific notebooks provide formal documentation of planning, work, plan execution, data acquisition and reduction, and results interpretation.

11.4 TEST RECORDS

Test records shall, as a minimum, identify the type of test, item tested, date of test, tester or data recorder, and any observations and test results. Test records, certifications, reports, scientific notebooks, and any other quality records shall be maintained in the QA Records Room in accordance with section 17, Records Control.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 PURPOSE

This section establishes requirements for control, calibration, adjustment, repair, and recordkeeping for measuring and test equipment utilized for scientific investigation data collection, experiments and tests, and field investigations.

12.2 RESPONSIBILITIES

(1) Directors and Element Managers are responsible for ensuring CNWRA technical staff utilize calibrated instrumentation, where required.

(2) Principal Investigators are responsible for selection of measuring and test equipment and facilitation of the calibration of instruments when required.

(3) Personnel performing calibrations are responsible for accomplishing calibration in accordance with this section, applicable calibration systems and instrument calibration procedures and instructions.

(4) The CNWRA QA Director has established and implemented a calibration program and shall evaluate audits performed on the SwRI calibration laboratory to ensure the effectiveness in maintained.

12.3 SELECTION OF MEASURING AND TEST EQUIPMENT

Operations or project plans, proposals, scientific investigation test procedures, or the appropriate scientific notebook shall identify the type of measuring and test equipment required based on the accuracy and precision requirements of the experiment or test. To the greatest extent possible, equipment shall be selected such that the accuracy tolerance of the measuring or test equipment does not exceed 10 percent of the value of the parameter being measured.

12.4 CALIBRATION CATEGORIES

12.4.1 Equipment Subject to Periodic Recalibration

Equipment to be maintained in a calibrated condition, including calibration standards, shall be periodically recalled for recalibration prior to expiration. The CNWRA utilizes the SwRI calibration laboratory, which is an accredited ANSI/NCSL Z540.1 facility and approved suppliers listed on the SwRI ASL for the calibration of measuring and test

equipment. Controls applicable to equipment under scheduled recalibration shall address the following:

(1) A system of recall shall include notification of the user and removal from service if the calibration interval has been exceeded.

(2) Procedures for determining and adjusting the calibration interval shall be based on the manufacturer's recommendation, industry practice, and stability history of the equipment.

(a) The calibration interval may be shortened as required to assure continued accuracy as evidenced by results of preceding calibrations.

(b) The calibration interval may be lengthened when the results of previous calibrations provide definite indications that such action will not adversely affect the accuracy of the data generated by the instrument.

(c) The calibration interval may be lengthened when codes, standards, or manufacturers recommend the longer interval, when the equipment is subjected to infrequent use, and in other situations. Calibration is required before use of an infrequently used piece of equipment.

(d) A technical justification for lengthening the interval shall be prepared and attached to the calibration history.

(3) Calibrated measuring and test equipment shall be handled, stored, and preserved such that its accuracy and fitness for use is maintained.

(4) Calibrated measuring and test equipment and standards shall be identified by a unique number. Identification marking shall be clear, unambiguous, and indelible, and shall be applied in such a manner so as not to affect the function of the equipment.

(5) Calibrated measuring and test equipment and standards shall have affixed to the item itself, the case, or other logical place, a label or tag that exhibits the identifying number of the item, the date of the last calibration, the date the next calibration is due, and the identity of the calibrating personnel or organization. If it is impractical to affix a label or tag to the item and/or its case, the date of

last calibration, the date the next calibration is due, and the identity of the calibrating personnel or organization shall be entered on a record that is traceable, by the identifying number, to the item.

(6) A history of calibration and repair record shall be maintained for each calibrated item. This record shall show the name, type, and identifying number of the item, the calibration interval, and the calibration procedure used, and shall either include the required accuracy or reference other documents containing accuracy data. Whenever the item is calibrated or repaired, the date, the identity of the calibrating technician, and other data pertinent to the calibration shall be entered on the record.

(7) A list or file shall be maintained that identifies the calibrated measuring and test equipment. This list or file shall be maintained by the group having responsibility for calibration of the test and inspection equipment.

12.4.2 Equipment Calibrated Before Use

(1) Sensors, transducers, associated interface and data acquisition equipment are frequently assembled as a system for a specific experiment or test application. This and other measuring and test equipment that is not under scheduled recalibration shall be calibrated before use with appropriate measurement standards.

(2) Analytical equipment shall be calibrated before and verified periodically through its use in accordance with the manufacturer's recommendations and applicable industry standards and practices.

(3) Scientific notebooks or other methods shall be utilized to document results of calibrations before use. Entries shall include identification of the equipment being calibrated, required accuracy, standards used and their calibration status, description or reference to the method used, calibration values, other pertinent data, and identification of the individual performing the calibration.

(4) For equipment or systems whose accuracy may drift during the measurement period, recalibrations or calibration checks shall be performed during and/or after use to verify the validity of measurement data taken.

12.4.3 Equipment Not Requiring Calibration

(1) Equipment for which normal commercial practices provide sufficient accuracy do not require calibration. Appropriate care shall be exercised to verify that accuracy has not been degraded through breakage or abuse. Equipment not subject to calibration includes:

- Rulers, tape measures
- Levels
- Watches and stop watches
- Laboratory volumetric glassware.

(2) Calibration is not required for power supplies and other test equipment not used for directly performing measurements, or for equipment used for making qualitative performance checks.

12.5 CALIBRATION STANDARDS

(1) Reference standards and transfer standards shall have adequate accuracy, stability, and range to accomplish the calibrations for which they are intended. Reference standards shall be calibrated by a facility equipped to provide such services. Certification shall be provided giving the accuracy to which the reference standard has been calibrated and its traceability to nationally recognized standards, as well as the conditions under which calibration was accomplished. Where no recognized standard exists, the basis for calibration shall be documented. To the greatest degree possible, the accuracy tolerance of the calibration standard shall not exceed 25 percent of the accuracy tolerance of the item being calibrated.

(2) Laboratory chemicals and reagents utilized as analytical standards shall be selected based on the purity and concentration accuracy requirements of the analysis to be performed. Chemical and reagent grades shall meet industry practices for purity and concentration accuracy.

12.6 CALIBRATION PROCEDURES

(1) Equipment and standards subject to scheduled recalibration shall be calibrated in accordance with documented TOPs or instructions. Manufacturers' and industry standard methods may be used so long as sufficient details are provided by the method.

(2) Calibration procedures shall provide a description of the method to be used, accuracy requirements for standards, and accuracy requirements of the item being calibrated.

(3) Calibrations before use shall be performed in accordance with documented procedures or instructions when available. When not available, methods used shall be documented in the appropriate scientific notebook.

12.7 OUT-OF-TOLERANCE EVALUATIONS

(1) Whenever an item of measuring or test equipment is found out of tolerance, a nonconformance report shall be initiated in accordance with CQAM Section 15. An evaluation of the out-of-tolerance condition shall be made to determine if measurements made since the last valid calibration were adversely affected.

(2) A nonscheduled calibration shall be performed when the accuracy of an item of test or inspection equipment is in question. Measuring and test equipment found consistently to be out of calibration shall be repaired or removed from service.

12.8 PERSONNEL QUALIFICATION

Personnel performing calibration activities shall be qualified in accordance with CQAM section 2 or the SwRI quality system.

12.9 DELEGATION OF CALIBRATION WORK

(1) The calibration and control of CNWRA measuring and test equipment under scheduled recalibration may be delegated to SwRI calibration facilities having calibration systems qualified in accordance with the SwRI NQAPM and American National Standards Institute/National Conference of Standards Laboratories (ANSI/NCSL) Z540.1, "Calibration Laboratories and Measuring and Test Equipment General Requirements."

(2) Services may be obtained from suppliers having calibration systems addressing applicable requirements of Appendix B and ANSI/NCSL Z540.1.

12.10 RECORDS

(1) Calibration reports, certificates, histories, and other pertinent documentation for equipment and standards under scheduled recalibration shall be retained in the files of the calibration facility for the period of use of the item plus five years thereafter.

(2) Documentation of calibration before use shall be maintained in the appropriate scientific notebook and retained as QA records as specified in CQAM sections 3 and 17.

12.11 REFERENCES

American National Standards Institute/National Conference of Standards Laboratories Z540.1 Calibration Laboratories and Measuring and Test Equipment General Requirements.

13. HANDLING, STORAGE AND SHIPPING

13.1 PURPOSE

This section establishes general requirements for handling, storage, and shipping quality-affecting field samples, materials and equipment that are susceptible to damage.

13.2 RESPONSIBILITIES

Principal investigators are responsible for identifying materials, samples, and equipment requiring controls and for developing and implementing applicable procedures.

13.3 DETERMINATION OF REQUIREMENT

Materials, samples and equipment utilized in scientific investigations shall be controlled if susceptible to damage that may adversely affect results. The Principal Investigator shall identify potentially affected materials, samples and equipment and specify appropriate controls through TOPs or instructions.

13.4 PERSONNEL QUALIFICATIONS

Personnel performing handling, storage, and shipping activities shall be suitably trained to perform these tasks. Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment.

13.5 HANDLING, STORAGE AND SHIPPING PROCEDURES

(1) TOPs and instructions developed for handling, storing and shipping shall consider, as applicable, the needs for special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels). Controls for samples shall include, as applicable, methods to maintain the as-sampled conditions.

(2) Procedures shall include requirements for marking and labeling materials, samples, and equipment to adequately identify, maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

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 or inspected shall be identified, either on the items or in documents traceable to the items. The status of the inspections and tests shall be identified to prevent the use of items which have not satisfactorily met the inspection and 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 QA personnel upon proper disposition of the nonconformance in accordance with section 15.0, "Nonconformances Control."

Inspection and test status tags shall be removed by project personnel upon satisfactory completion of the required inspection and tests, as practical.

15. NONCONFORMANCE CONTROL

15.1 PURPOSE

This section establishes requirements for identifying, segregating, reporting, dispositioning, and controlling nonconformances of items, materials, software, and activities to specified requirements.

15.2 RESPONSIBILITIES

(1) The Director of Quality Assurance is responsible for implementation of this section.

(2) The individual identified as responsible for corrective action is responsible for proposing a disposition and for correction of the cause of the nonconformance.

15.3 IDENTIFICATION

Methods shall be developed for legible and easily recognizable marking, tagging, or other means of identification of nonconforming items in such a manner not to adversely affect its end use.

When identification of the item itself is impractical, suitable identification shall be applied, as appropriate, to the container, package, or segregated storage area.

15.4 SEGREGATION

Nonconforming items that cannot be reworked to meet requirements shall be placed, when practical, in clearly identified and designated hold areas until disposition is complete and the item is released.

When physical conditions such as size, weight, or access limitations preclude segregation, alternative methods shall be specified to prevent the inadvertent use of nonconforming items.

15.5 DISPOSITION

15.5.1 Controls for the disposition of nonconforming conditions shall be specified in Operating Procedures or written correspondence and shall include, as a minimum:

(1) The processes for proposing and approving the disposition of nonconforming characteristics

(2) Control of further processing, delivery, or use pending an evaluation and approved disposition

(3) Identification of individuals responsible for and having the authority for the evaluation and disposition

(4) Requirements that personnel performing evaluations to determine disposition have demonstrated competence in the area of evaluation, adequate understanding of the requirements, and have access to pertinent background information

The disposition, which may be accept-as-is, reject, repair, rework, scrap, or return to vendor, shall be identified on the associated Nonconformance Report and shall include the required approvals.

Notification to the client of the nonconformance including any preliminary disposition shall be made.

A technical justification shall be prepared and documented for the acceptability of a nonconforming item that is dispositioned for repair or use-as-is.

15.5.2 Repaired or Reworked Item Inspection

Repaired and reworked items shall be reinspected and/or retested, as applicable, to the same criteria required of the original item.

Acceptance criteria for repaired or reworked items shall be the same as for the original item unless the disposition of the nonconforming item has established documented, approved alternate acceptance criteria.

15.5.3. Notification of Affected Organizations

Nonconformance reports (or similar documents identifying and dispositioning nonconformances) shall be distributed to the Cognizant Element Manager and the organization responsible for the nonconformance, as a minimum.

15.6 NONCONFORMANCE ANALYSIS

On a quarterly basis, CNWRA Nononformances (NCRs), Corrective Action Requests (CARs), and other relevant information shall be evaluated for trends requiring corrective action. The results of the trend analysis shall be reported to the Institute QA Committee at their quarterly meeting and to the CNWRA President, Directors, and EMs.

15.7 RECORDS

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

16. CORRECTIVE ACTION

16.1 PURPOSE

This section establishes requirements for identifying conditions adverse to quality and for initiating, obtaining, and verifying corrective action.

16.2 RESPONSIBILITIES

(1) The Director of QA is responsible for the implementation of this section.

(2) The Element Manager is responsible for providing corrective action responses and correcting conditions adverse to quality.

16.3 INTRODUCTION

Significant conditions adverse to quality, including failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, shall be identified, reported, and corrected in accordance with this procedure. Significant conditions adverse to quality include

(1) Unsatisfactory audit findings (internal and supplier)

(2) Repetitive occurrences of nonconformances of similar type and cause, as identified in accordance with CQAM section 15

(3) Trends of nonconformances suggesting ineffective implementation of quality system elements, as identified through periodic analyses

(4) Individual occurrences of major nonconformances indicative of quality system breakdown

16.4 ROOT CAUSE DETERMINATION AND RECURRENCE CONTROL

The root cause of significant conditions adverse to quality shall be determined. Root causes can usually be attributed to procedural deficiencies or implementation deficiencies.

Corrective action shall be taken to address the root cause and preclude recurrence of the adverse condition.

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 a quarterly basis, conditions adverse to quality shall be evaluated to determine deficiency levels and trends. The results of the analysis shall be used to initiate additional corrective action measures as necessary. The trend analyses shall be reported to CNWRA management and the Institute QAC.

16.9 RECORDS

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

17. RECORDS CONTROL

17.1 PURPOSE

This section identifies the types of records subject to controls and to describe methods for collection, storage, retention, and retrieval of records.

17.2 RESPONSIBILITIES

(1) The Director of QA is responsible for implementation of Records Control actions, and for developing and implementing supplemental procedures as necessary.

(2) Individuals preparing documents that will become records are responsible for delivering the documents to QA Records after validation.

(3) Principal Investigators are responsible for controlling scientific notebooks and technical data in process.

17.3 IDENTIFICATION AND VALIDATION OF RECORDS

Two classes of records subject to QA controls are generated as a result of CNWRA activities: QA technical records, including supporting documentation, and QA programmatic records. Prior to becoming records, documents shall be validated by authorized individuals attesting to their authenticity.

17.4 CONTROL OF DOCUMENTS PRIOR TO BECOMING RECORDS

Documents, reports, and data, that when finalized will become records, shall be controlled to prevent loss, damage, and unauthorized alteration.

17.5 QA RECORD CORRECTIONS

(1) Corrections to data shall be made by a single line crossing out the original data, and inserting the corrected data. Corrections shall be documented by initials of the individual making the correction and the date of the correction.

(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 or Quality Assurance Procedures that implement the CQAM
- Provide objective evidence of the fulfillment of the particular requirements of Technical Operating Procedures
- 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

(2) Nonpermanent records are those required to show evidence that an activity was performed in accordance to applicable requirements but need not be retained for the life of the item or activity because they do not meet the criteria for permanent records. Nonpermanent records are kept for a minimum six year period following completion of the activity.

(3) Certain types of CNWRA records will be delivered to the Licensing Support Network (LSN), a HLW repository program records management system. Requirements related to the LSN are established in 10 CFR Part 2, Subpart J. Any CNWRA client requesting records shall be provided copies of the CNWRA record copy in a records turnover package.

(4) Records facilities shall have restricted access and shall be constructed to minimize the risk of damage through winds, fires, floods, temperature and humidity extremes, and insects, molds, or rodents.

(5) CNWRA product-specific electronic media are stored in the QA Records Room so they are not lost, damaged or altered.

(6) QA record requirements will be implemented as required by contract or developed procedures.

18. AUDITS

18.1 PURPOSE

This section establishes requirements for preparing, scheduling, performing, reporting, and following up on completed audits.

18.2 RESPONSIBILITY

The Director of QA is responsible for implementation of this section.

18.3 AUDIT PROGRAM

QAPs shall specify the methods by which planned and scheduled audits are performed to verify compliance with all aspects of the CNWRA QA Program. The operating procedures shall establish controls addressing the requirements of this section. CNWRA surveillances are planned and controlled in accordance with developed procedures.

18.4 AUDIT SCHEDULES

Schedules shall be developed for internal and external audits to provide adequate coverage and coordination with the quality assurance activities being conducted. Schedules shall be reviewed periodically, and revised as necessary to assure coverage is maintained current.

The frequency of audits of activities shall be specified and shall be commensurate with the status and importance of the activity. At a minimum, the CNWRA shall be audited on an annual basis. Vendors on the SwRI ASL shall be audited at least every 3 years or when quality issues arise and an earlier audit is warranted.

Supplemental audits of specific subjects shall be performed when necessary to provide adequate coverage.

18.5 LEAD AUDITOR QUALIFICATION

The qualification requirements of audit team members shall be in accordance with the SwRI quality system, which meets the requirements of ANSI/ASME NQA-1.

18.5.1 A lead auditor shall have acted as a qualified auditor in at least 5 complete audits during a 3 year time period.

18.5.2 Shall have demonstrated the capability to communicate effectively and in writing.

18.6 AUDIT PREPARATION

A documented audit plan shall be prepared for each audit, identifying the audit scope, organizations to be notified, applicable documents, schedule, and audit procedure or checklist. Personnel performing audits shall not have direct responsibility for performing the activities being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

For internal audits, the personnel responsible for the activity being audited shall not be involved in selection of the audit team. The audit team leader shall be responsible for verifying the qualifications of technical specialists utilized in the audit. Verification shall be accomplished through review of objective evidence that documents the qualification and experience of the technical specialist.

The audit team shall be identified prior to the start of each audit. The team shall consist of one or more auditors.

An audit team leader shall be appointed, and shall have the following duties:

(1) Organizes and directs the audit

(2) Ensures the preparation of the audit checklist prior to the start of the audit

(3) Coordinates preparation and issuance of the audit report

(4) Evaluates responses to audit results

18.7 AUDIT PERFORMANCE

Audit checklists shall be prepared for each audit, and shall be utilized in performing the audit. The checklists shall be developed based on operations plans, proposals, procedures, plans, and similar documents.

Objective evidence shall be examined to an extent necessary to determine if the elements of the CQAM are being implemented effectively. Objective evidence shall be evaluated through examination of work areas, activities, processes, and items, and review of documents and records.

Audit results shall be documented in the audit report by auditing personnel and shall be reviewed by management responsible for the activity being audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

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 QAC 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.

APPENDIX I
TERMS AND DEFINITIONS

Acceptance Criteria

Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Appendix B

Title 10, Code of Federal Regulations Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

Audit

A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the purpose of process control or product acceptance.

CNWRA or Center

The Center for Nuclear Waste Regulatory Analyses.

Certificate of Conformance

A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification

The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic

Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

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, or purchase order provisions, attributes, etc. Confirmatory testing is considered to be one of the methods used to support the dedication of a product.

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 the definition in proposed 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 the definition in proposed 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.

Peer Review

A documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolation, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work.

Principal Investigator

A qualified professional employee responsible for high order technical input, guidance, and project performance.

Procedure

A document that specifies or describes how an activity is to be performed.

Procurement Document

A purchase requisition, purchase order, drawing, contract, specification, or instruction used to define requirements for purchase.

Program Architecture

The overall description of the NRC HLW management regulatory program. It is a systematic, computer-assisted approach to analysis of the regulatory program including requirements, program planning and evaluation, and management. It is mission-oriented, requirements-based, and proactive; and it provides the basis for integration of all aspects of the NRC regulatory program under the Nuclear Waste Policy Act (NWPA).

Project Plan

A controlled research plan providing the objectives of a particular activity, describing the technical and quality-related aspects of the research, together with milestones and associated cost.

Proposal

An offer for consideration and/or acceptance, such as a CNWRA proposal to an organization specifying technical activities to be performed, if accepted, and the cost, schedule, and quality requirements associated with the technical activities.

Purchaser

The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.

Qualification (Personnel)

The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

Qualified Procedure

An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

Quality Assurance (QA)

All those planned and systematic actions necessary to provide adequate confidence that (i) a structure, system, or component will perform satisfactorily in service; or (ii) a CNWRA product will comply with client requirements.

Quality Assurance Record

A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

Quality Requirements Application Matrix (QRAM)

A CNWRA from completed by technical and QA personnel to describe the activities in a task and QA requirements to be applied to that activity.

Radioactive Material, Radioactive Waste, or "Waste"

Radioactive waste includes low-level, mid- and high-level waste and other radioactive materials that are subjected to NRC licensing and are provided special handling considerations, including burial in licensed facilities.

Receiving

Taking delivery of an item at a designated location.

Repair

The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

Rework

The process by which an item is made to conform to original requirements by completion or correction.

Research

All those (planned and unplanned) investigations or experimentation activities that aim to discover new facts and their interpretation.

Right of Access

The right of a Purchaser or designated representative to enter the premises of a supplier for the purpose of inspection, surveillance, or QA audit.

Scientific Investigation

An activity (e.g., research, experiment, study) performed for the purpose of investigating the natural barriers or the man-made aspects of a licensed nuclear facility or other activity that has the potential to affect health, safety, or the environment, including the overall design of the facilities and the waste package. This includes, but is not restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies or activities that are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of such facilities. Scientific Notebooks are specifically utilized to document scientific and engineering investigations, research, and experiments.

Scientific Notebook

A document that may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods, or both. These notebooks may be used in lieu of a technical procedure.

Service

Performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

Shall, Should, and May

Words used to designate the required level of compliance. "Shall" denotes a requirement; "should" denotes a recommendation or guideline; and "may" denotes permission—not a requirement, recommendation, nor guideline. The words "is, are, will, must," etc., are equivalent to "shall."

Special Process

A process, the results of which are highly dependent on control of the process or skill of the operator, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier

Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

Surveillance

The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

Systematic Regulatory Analysis (SRA)

That portion of the Program Architecture that assesses the statutory and regulatory responsibilities of the NRC in a comprehensive, structured manner. It is mission-oriented, requirements-based, and proactive; and it provides the basis for integration of all aspects of the NRC regulatory program under the NWPA. It is controlled by appropriate TOPs. SRA includes the identification of regulatory, institutional, and technical uncertainties, the development of license application review strategies and procedures; and the preparation of regulatory guidance documents.

Technical Review

A documented, traceable review performed by qualified personnel who are independent of those who performed the work, but who have technical expertise at least equivalent to that required to perform the original work. Technical reviews are in-depth, critical reviews, analyses and evaluations of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

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.

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.