

# **CNWRA** *A center of excellence in earth sciences and engineering*

A Division of Southwest Research Institute™  
6220 Culebra Road • San Antonio, Texas, U.S.A. 78228-5166  
(210) 522-5160 • Fax (210) 522-5155

November 14, 2000  
Contract No. NRC-02-97-009  
Account No. 20.01402.159

U.S. Nuclear Regulatory Commission  
ATTN: Mrs. Barbara D. Meehan  
Division of Contracts and Property Management  
Two White Flint North  
Mail Stop T7-I2  
Washington, DC 20555

Subject: CNWRA Quality Assurance Manual Change—IM 01402.159.110

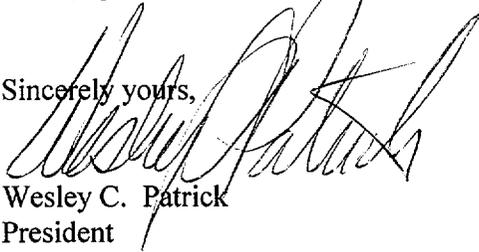
Dear Mrs. Meehan:

The Center for Nuclear Waste Regulatory Analyses has revised its Quality Assurance Manual based on recent work history and comments received during the last QA Audit. Enclosed is our CNWRA Quality Assurance Manual, Revision 4, Change 0, with an effectivity date of November 20, 2000. This policy document incorporates lessons learned and reflects changes made to streamline some of our processes. Rather than replace page for page, the entire document is changed with this revision.

This transmittal correspondence is formal notification of fulfillment of Intermediate Milestone 01402.159.110.

Please contact Bruce Mabrito at (210) 522-5149 or me if you have any questions on this matter.

Sincerely yours,

  
Wesley C. Patrick  
President

WCP/mp

cc:	J. Linehan w/o	J. Greeves w/o	CNWRA Directors
	D. DeMarco	J. Holonich w/o	CNWRA Element Managers
	E. Whitt	K. Stablein w/o	T. Nagy, SwRI Contracts w/o
	T. Carter	W. Reamer w/o	P. Maldonado
	L. Campbell w/o		



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

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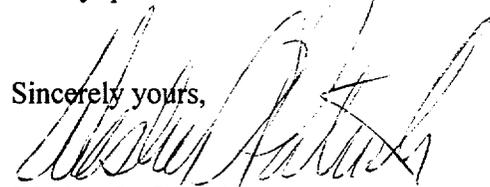
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**CNWRA  
QUALITY ASSURANCE  
MANUAL**

**UNCONTROLLED**

*Prepared by*

**Center for Nuclear Waste Regulatory Analyses  
San Antonio, Texas**

**Revision 4  
Change 0**

**November 2000**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**QUALITY ASSURANCE MANUAL**

Revision 4, Change 0

November 2000

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.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	11/20/2000

**Approvals**

Director of Quality Assurance



Date

11/13/2000

CNWRA President



Date

11/13/2000

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**QUALITY ASSURANCE MANUAL**

Section i

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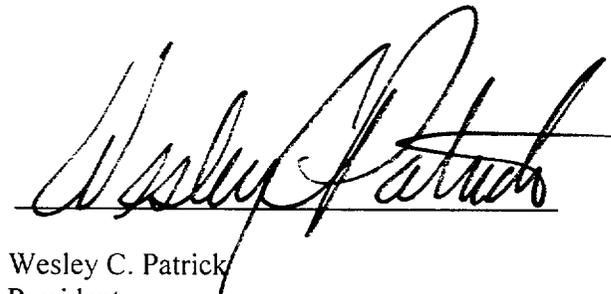
**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES  
QUALITY ASSURANCE MANUAL**

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") 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:



Wesley C. Patrick  
President  
Center for Nuclear Waste Regulatory Analyses

11/13/2000

Date

**CENTER FOR NUCLEAR WASTE  
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**QUALITY ASSURANCE MANUAL**

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## QUALITY ASSURANCE MANUAL

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### 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.

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### 1. ORGANIZATION

#### 1.1 PURPOSE

The purpose of this section is to describe 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. This CNWRA Quality Assurance Manual (CQAM) addresses the requirements of the SwRI Operating Policies and Procedures 10.1.1, Compliance Quality Assurance. The policies in this CQAM are mandatory for all CNWRA staff, consultants, and subcontractors as applicable.

#### 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.

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### 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

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- (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 Figure 1.3.
- (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:

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- (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

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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

Individuals performing data interpretation, analysis, or 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 sections 4 and 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 sections 4 and 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 Administrative Procedure (AP)-015, Differing Professional Views.

### 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.

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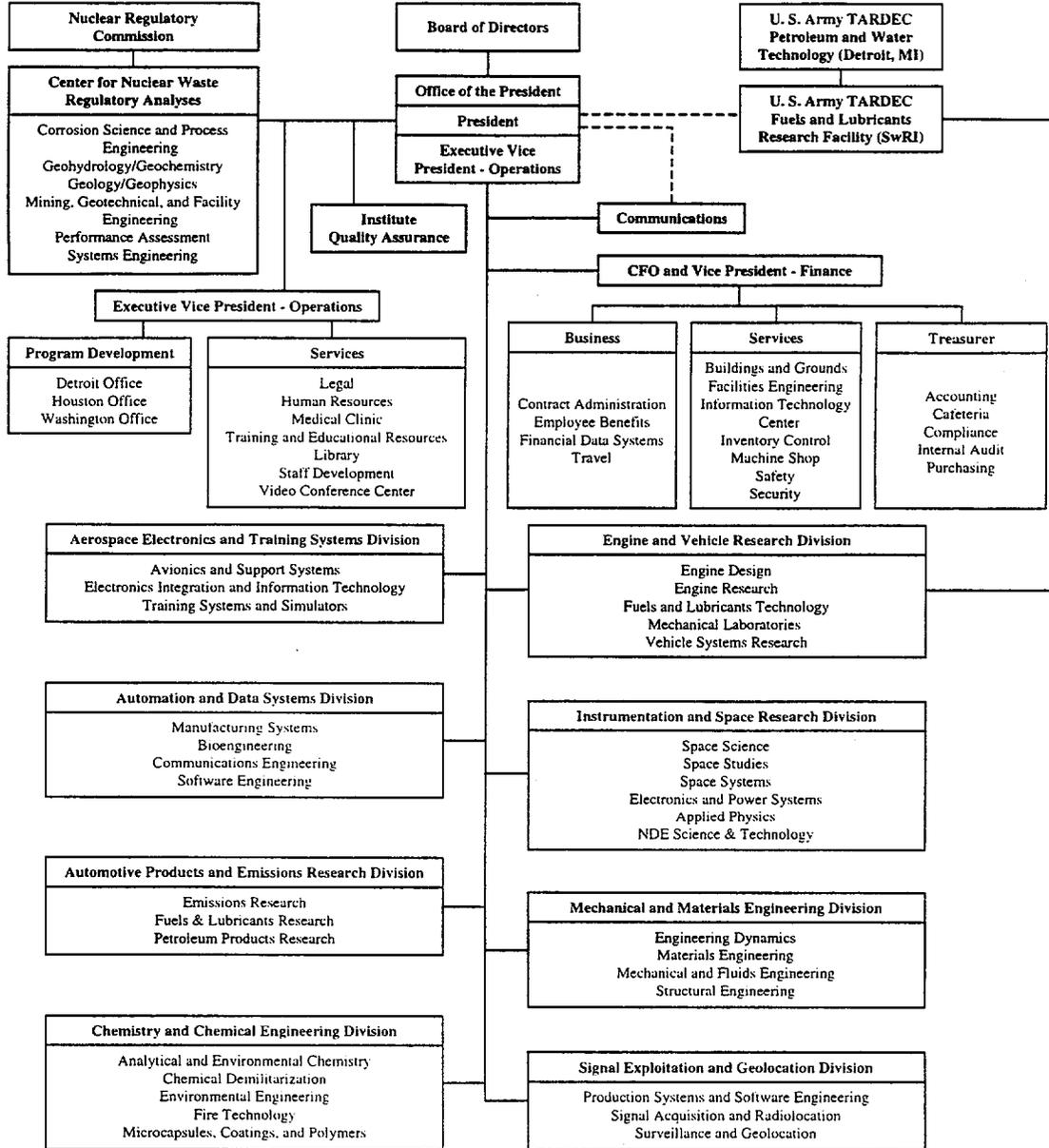
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### SOUTHWEST RESEARCH INSTITUTE™ ORGANIZATION CHART



#### 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

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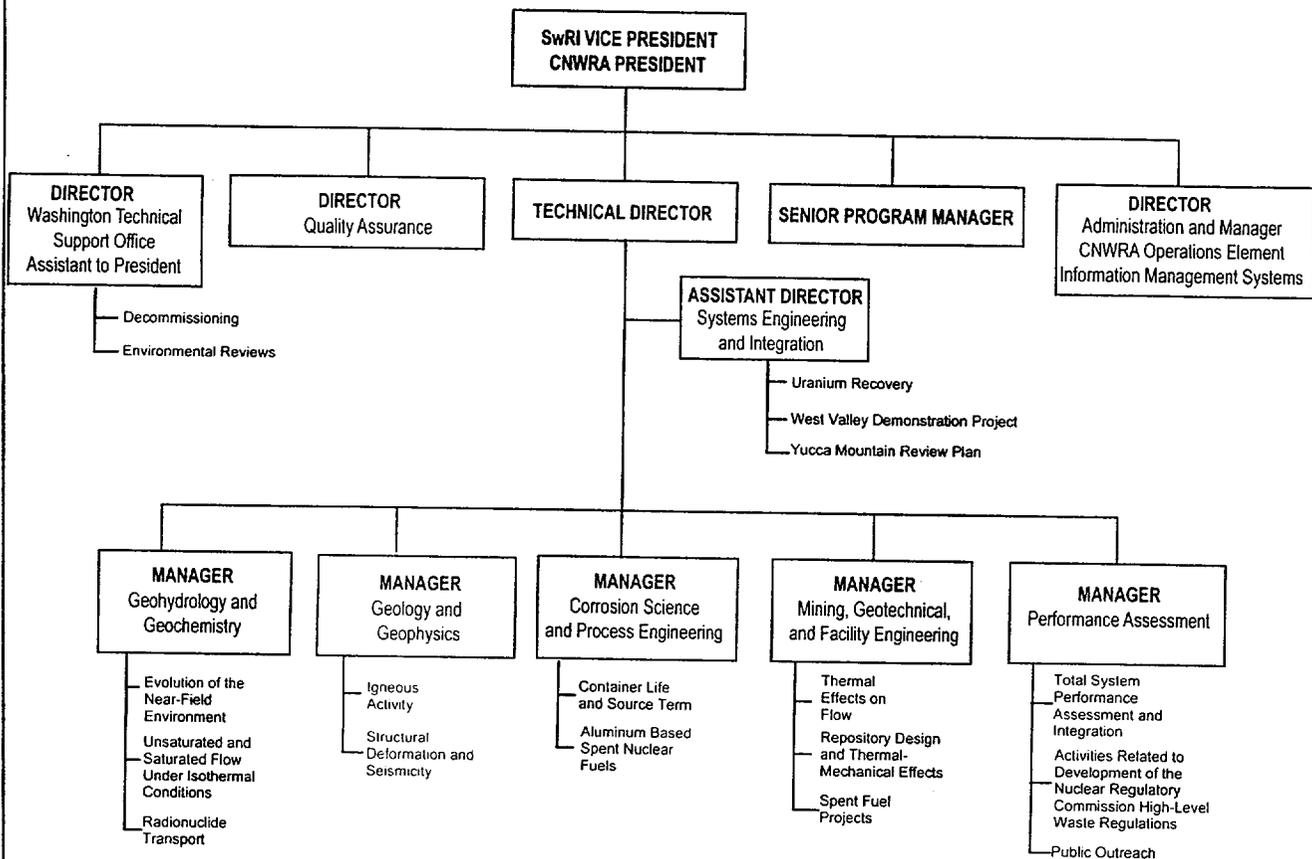


FIGURE 1.2

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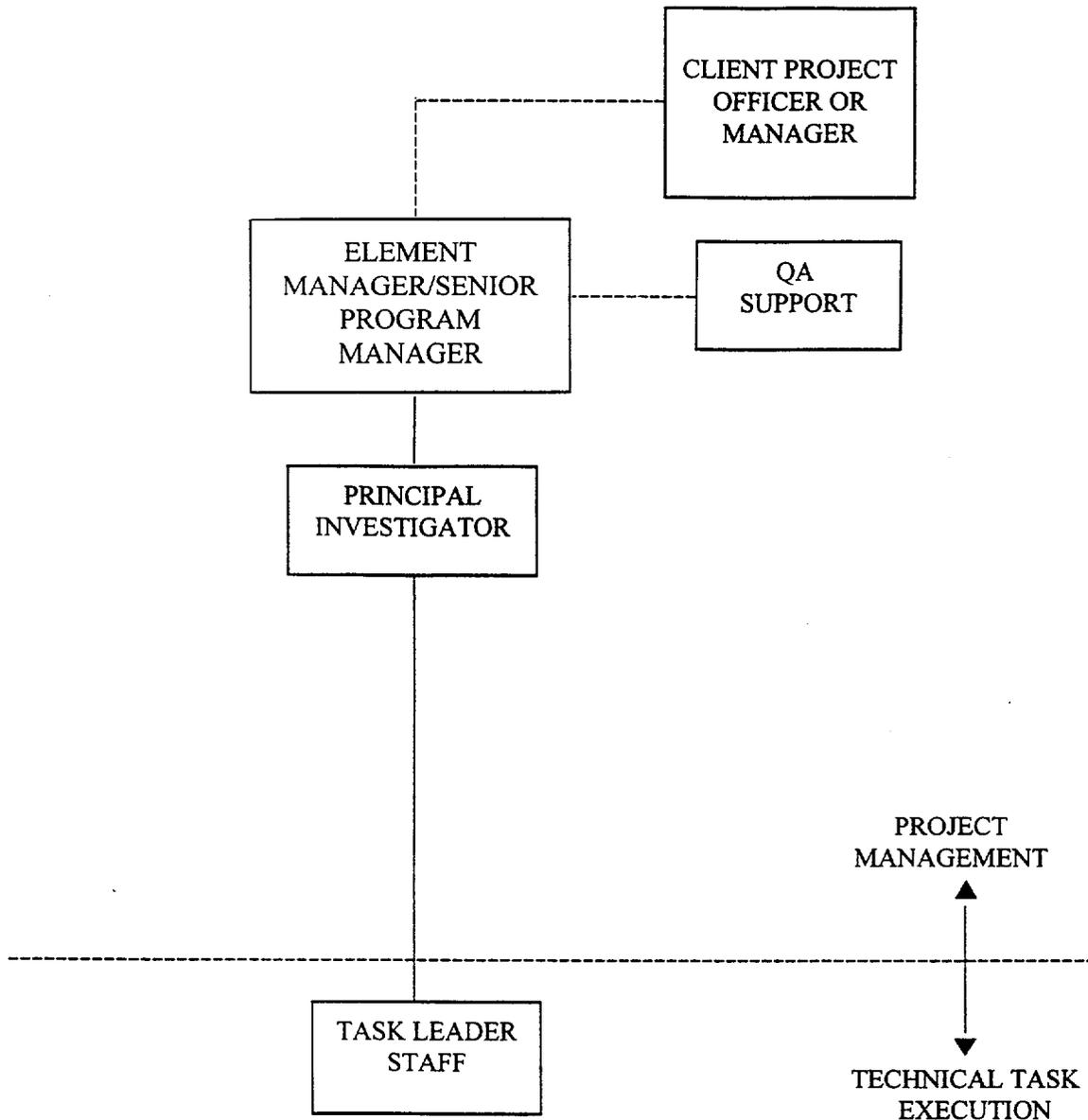
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**TYPICAL PROJECT ORGANIZATION**



**FIGURE 1.3**

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## QUALITY ASSURANCE MANUAL

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### 2. QUALITY ASSURANCE PROGRAM

#### 2.1 PURPOSE

The purpose of this section is to establish the basis for the CNWRA QA program, and to describe how the QA program is implemented through various mandatory instructions and procedures, how the effectiveness of the QA program is assessed, and 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 and, when finalized 10 CFR Part 63, Subparts 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

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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. 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 professional society and consensus industry methods and practices, excluding quality standards

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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.

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(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 in QAP-001, Scientific Notebook Control.

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.

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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 are utilized to provide a brief description of the planned project and quality assurance activities, as referenced in QAP-013, Quality Planning.

CNWRA major and intermediate milestones receive technical and programmatic reviews, with concurrence by QA. These reviews are required by QAP-002, Review of CNWRA Documents, Reports and Papers. 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.

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- 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 QA Program 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/training, professional personnel qualifications, publications, conflict of interest, and related information shall be maintained by CNWRA QA. When a determination is made that follow-up QA training is necessary, the QA Director shall ensure that such training is provided.
- (3) Instruction may be by classroom lecture, one-on-one verbal, or by electronic computer-based instruction. Training records will be maintained as QA records.

2.6.2 Qualification of Personnel

- (1) Personnel performing activities affecting quality, including scientists, engineers, analysts, auditors, and special process personnel, shall be qualified to perform their assigned tasks. Qualification shall be based on education, experience, training, and freedom from conflict of interest, as referenced in QAP-007, Professional Personnel Qualifications. 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

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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

2.6.3 Qualification Records

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

2.7 REFERENCES

CNWRA Quality Assurance Procedure-001, Scientific Notebook Control.

CNWRA Quality Assurance Procedure-007, Professional Personnel Qualifications.

CNWRA Quality Assurance Procedure-013, Quality Planning.

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.

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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.

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### CORRELATION OF QUALITY PROGRAM REQUIREMENTS

CNwRA QA MANUAL	10 CFR50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE ASSESSMENT
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. -Other activities are supplied by vendors approved. -Auditor qualifications and certifications are performed by SwRI.
Section 3 Scientific 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	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

**SAMPLE  
Figure 1**

**CORRELATION OF QUALITY PROGRAM REQUIREMENTS**

CNWRA QA MANUAL	10 CFR50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE ASSESSMENT
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 commercial off-the-shelf procurement of items and services and related activities.
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.
Section 10 Inspection	Criterion X	Section 10	10, 10S-1	CNWRA personnel performing receiving inspections meet the qualification requirements determined necessary by the unique work at the CNWRA for the NRC.
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.

**SAMPLE  
Figure 1 (cont'd)**

**CORRELATION OF QUALITY PROGRAM REQUIREMENTS**

CNWRRA QA MANUAL	10 CFR50 Appendix B	NRC Review Plan for HLW QA Programs	NQA-1-1986	COMPLIANCE ASSESSMENT
Section 12 Control of Measuring and Test Equipment	Criterion XII	Section 12	12, 12S-1	Requirements addressed; SwRI Calibration Laboratory utilized.
Section 13 Handling, Storage and Shipping	Criterion XIII	Section 13	13, 13S-1	Requirements addressed.
Section 14 Inspection, Test and Operating Status	Criterion XIV	Section 14	14	Does not apply.
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.

**SAMPLE  
Figure 1 (cont'd)**

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**3. SCIENTIFIC/ENGINEERING INVESTIGATION AND ANALYSIS CONTROL**

**3.1 PURPOSE**

The purpose of this section is to describe various methods for controlling scientific investigations and engineering analyses conducted at the CNWRA that affect product quality. The CNWRA does not produce engineering designs, therefore this section has been titled Scientific/Engineering Investigation and Analysis Control.

**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.

**3.3 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. 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

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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 that may be developed are reviewed and approved by technical, programmatic, and QA staff of the CNWRA in accordance with QAP-002, Review of CNWRA Documents, Reports and Papers.

**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.

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**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 developed, modified, or evaluated as part of CNWRA task activities. S&E software developed for any client shall meet TOP-018 requirements. S&E software that is utilized in producing CNWRA technical products shall be controlled to assure that the specific configuration of a code used is identifiable and traceable in accordance with TOP-018, Development and Control of Scientific and Engineering Software. TOP-018 assures that computer codes are properly planned, designed, documented during development, and formally released under appropriate management approval and code use is specified in the software release notice. 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 for the task shall develop and maintain the scientific notebook as specified in CNWRA QAP-001 and notebook issuance shall be controlled in accordance with QAP-001. The scientific notebook provides historical documentation of the activity including planning, conducting the activity, and documenting results, analysis, as referenced in QAP-001, Scientific Notebook Control.

**3.3.7 Control by Technical Operating 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 Errors and Deficiencies/Reporting**

The CNWRA does not perform engineering designs or engage in construction, therefore identification of errors and deficiencies in design documents is not applicable to CNWRA. When errors and deficiencies in licensee designs are identified in documents the CNWRA reviews, the NRC will be notified.

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3.3.9 Verification of Scientific Investigations, Analyses, Experiments and Tests

Surveillance of technical activities shall be conducted as needed to verify compliance with applicable procedural requirements, as referenced in QAP-004, Surveillance Control. 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 Reviews

Reviews of products of the CNWRA such as reports, papers, and presentations are described in QAP-002, Review of CNWRA Documents, Reports and Papers. Appropriate technical, peer, programmatic, and QA reviews shall be conducted in accordance with QAP-002, which also addresses the guidelines of NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories. In addition to technical or peer reviews, products shall receive programmatic reviews to verify that CNWRA contractual requirements, objectives, QA, and programmatic requirements are correctly and consistently addressed.

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3.3.12 Records

QA Records shall be maintained in accordance with section 17 of this CQAM and QAP-012, QA Records Control.

3.4 REFERENCES

CNWRA Quality Assurance Procedure-001, Scientific Notebook Control.

CNWRA Quality Assurance Procedure-002, Review of CNWRA Documents, Reports and Papers.

CNWRA Quality Assurance Procedure-004, Surveillance Control.

CNWRA Quality Assurance Procedure-018, Development and Control of Scientific and Engineering Software.

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.

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**4. PROCUREMENT DOCUMENT CONTROL**

**4.1 PURPOSE**

The purpose of this section is to define applicable regulatory and quality assurance requirements for documents related to procurement of CNWRA quality affecting goods and services.

**4.2 RESPONSIBILITY**

CNWRA Directors and Elements Managers are responsible for implementation of this section. CNWRA QA is responsible for reviewing purchase requisitions that affect product quality.

**4.3 PROCUREMENT PLANNING**

**4.3.1 Goods, Items, and Materials**

4.3.1.1 Commercial off-the-shelf (COTS) goods obtained by the CNWRA from suppliers shall be utilized after appropriate staff examine and accept the product. If special actions are required, the procurement shall be handled in accordance with section 7, Procurement Control.

4.3.1.2 Goods may also be procured from organizations on the SwRI Approved Supplier List (ASL). These organizations have been qualified by evaluation and/or audit by SwRI QA or by special review by CNWRA QA as meeting Appendix B/NQA-1-1986 applicable requirements. Procuring goods from approved suppliers provides the CNWRA with a higher degree of assurance that the product will be in compliance with CNWRA requirements.

**4.3.2 Services**

Consultant and Subcontractor services are procured in accordance with AP-006, Obtaining Consultant Services, and AP-005, Obtaining Subcontractor Services, respectively. Services may also be obtained from organizations on the SwRI ASL. Procuring services from approved consultants and subcontractors provides the CNWRA with a higher degree of assurance that the product will be in compliance with CNWRA requirements.

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### 4.3.3 Services Selection

Services of consultants and subcontractors are selected based on review by the CNWRA Source Evaluation Committee (SEC), which checks qualifications, potential conflicts of interest, and statements of work. The SEC decisions are documented and retained as QA Records. The SEC may recommend specific uses or limitations on consultants or subcontractors based on documentation presented.

### 4.3.4 Chemicals

- (a) Chemicals and chemical test standards are usually COTS. Chemical and chemical standards ordered from suppliers on the SwRI ASL have the added assurance that the item received has been generated under an accepted quality program.
- (b) When ordering reagent-grade chemicals for CNWRA chemical test standards from any source, a certificate of analysis shall be requested on the purchase document. This assures that the chemical received has been manufactured and tested in accordance with a process which assures product purity.
- (c) For chemicals procured without any certification or traceability documentation, or for chemical standards not ordered from an ASL supplier, the need to perform a confirmatory analysis shall be determined based on the application of the chemical. This confirmatory analysis decision shall be made by the PI, EM, and Director of QA and shall be documented on the purchase requisition as a special receipt instruction.

### 4.3.5 Bid Evaluation

Number and qualifications of personnel, availability of required facilities and equipment, past performance, adequacy of the vendor QA program relative to quality requirements, and cost are considered prior to award of a consultant services contract or a subcontract. In cases where the potential consultant or subcontractor has no quality program, the supplier shall be instructed to abide by appropriate areas of 10 CFR Part 50, Appendix B (which may be contained in other quality programs) or applicable portions of the CNWRA quality program. In cases where the consultant or subcontractor has a quality system, the system will be evaluated during the audit process or will be reviewed by the CNWRA Director of QA to assure the appropriate quality controls are implemented. The SEC meeting minutes will document the evaluation of consultants and subcontractors.

Bid evaluation for goods is performed during initiation of the purchase requisition and the same quality attributes are considered. Signature of the purchase requisition indicates completion of the bid evaluation process.

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4.4 PROCUREMENT DOCUMENT

Several types of procurement documents are used by the CNWRA:

- (1) Consultant Service Contracts — issued by the SwRI Human Resources Department as referenced in AP-006, Obtaining Consultant Services.
- (2) Purchase order — (individual purchase requisitions, purchase orders, standing order agreements, basic order agreements) for materials and items are included in this category and are ordered with a purchase order from the Institute Purchasing.
- (3) Subcontract Agreements—agreements with organizations (e.g., universities, independent companies) are issued by the Purchasing Department as described in AP-005, Obtaining Subcontract Services.
- (4) Memorandum or a SwRI division-specific form addressing intra-Institute services—sent to the Institute Department performing the work.

4.5 PROCUREMENT DOCUMENT CONTROL

4.5.1 Procurement Documents

Procurement documents for goods or services affecting quality shall include the following requirements, as applicable:

- (a) Description of the goods and services required.
- (b) Identification of technical specifications, including adequate acceptance and rejection criteria and any other special requirements.
- (c) Requirements for special certifications related to goods and services.
- (d) Identification of applicable quality requirements (e.g., procedures, forms, etc.), including right-of-access to the suppliers facility for inspection and audit of records, if appropriate.
- (e) Special documentation, if required, shall be included with the product or service.
- (f) All service procurements affecting quality will clearly state the intended scope of work for suppliers.

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- (g) The CNWRA Director of QA, in consultation with the PI or EM, will be in agreement with and approve any vendor deviation from procurement document requirements.

4.6 PROCUREMENT DOCUMENT REVIEW

At a minimum, the SwRI purchase requisition will be reviewed and signed by the PI or EM and the CNWRA Director of QA. Other procurement documents will be reviewed and approved in accordance with Institute policy. Reviews of consultant services contracts and subcontract agreements are performed in accordance with AP-005 and AP-006 respectively.

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 for a period of 6 years.

Qualification records for individual consultants or subcontractors are maintained in the QA Records Room as permanent records.

Qualification records for CNWRA qualified sources listed on the SwRI Approved Supplier List are maintained by the SwRI QA Department.

4.8 REFERENCES

CNWRA Quality Assurance Procedure-016, Procurement Control.

CNWRA Administrative Procedure-005, Obtaining Subcontract Services.

CNWRA Administrative Procedure-006, Obtaining Consultant Services.

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5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 PURPOSE

The purpose of this section is to establish 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 provide general technical, management, and quality assurance direction over research and technical assistance activities. Work plans or test plans may be developed to provide additional definition of activities.

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### 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.
- APs provide step-by-step method to accomplish administrative support functions.
- Scientific Notebooks—Document the methods and results of scientific investigation activities.

(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, 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.

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5.4 RECORDS

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

5.5 REFERENCES

CNWRA Quality Assurance Procedure-008, Document Control.

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**6. DOCUMENT CONTROL**

**6.1 PURPOSE**

The purpose of this section is to describe 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, 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 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.

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6.4 PREPARATION, REVIEW, AND APPROVAL

6.4.1 CNWRA Quality Assurance Manual

- (1) The CQAM shall consist of sections addressing the Introduction and applicable criteria of Appendix B and ASME/ANSI NQA-1-1986.
- (2) CQAM sections shall include descriptions of Purpose, Responsibilities (except Introduction and section 1), Records, and References, as applicable.
- (3) The CQAM shall, in general, describe the actions necessary to accomplish and verify activities affecting quality.
- (4) The CQAM Statement of Policy shall be approved by the CNWRA President.
- (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, such as TOP-012, QAP-005, or AP-018. Additional operating procedures in the same generic field may be assigned a suffix number, such as TOP-001-02 or TOP-004-02.

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- (4) TOPs, QAPs, and APs shall be reviewed for adequacy by using QAP-002, Review of CNWRA Documents, Reports and Papers.

**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 for research projects are identified in the Quality Requirements Application Matrix.
- (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 when necessary to fabricate 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.

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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. The variances shall be recorded in the scientific notebook and the revision of the TOP can follow later.

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.

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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 Acknowledgement

- (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

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- An acknowledgement 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 acknowledgement
- (2) The Director of QA shall take action, as necessary, to obtain acknowledgement 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.

6.7 REFERENCES

CNWRA Quality Assurance Procedure-008, Document Control.

CNWRA Quality Assurance Procedure-013, Quality Planning.

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**7. PROCUREMENT CONTROL**

**7.1 PURPOSE**

The purpose of this section is to assure that purchased items and services, including software, conform to requirements specified in the procurement documents.

**7.2 RESPONSIBILITY**

- (1) CNWRA Principal Investigators or appropriate technical staff are responsible for assuring that items 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 SUPPLIER SELECTION**

- (1) Supplier selection and qualification shall be based on one or more of the following criteria:
  - (a) Documented history of providing identical or similar goods and services that meet the technical requirements defined in the CNWRA or SwRI procurement documents. This procurement history affects the inclusion of any supplier on the Institute's Approved Suppliers List.
  - (b) Evaluation of the supplier's (i.e., subcontractor or consultant) technical and quality capability as determined by a survey, inspection, audit, personnel qualification or surveillance of the facilities, personnel, and implementation a quality assurance program.
  - (c) Supplier acceptance and adherence to the applicable portions of the CQAM.
- (2) Suppliers shall be evaluated periodically by CNWRA management with QA participation to verify continued satisfactory performance.
- (3) Evaluation and selection of professional technical services is accomplished by the CNWRA Source Evaluation Committee (SEC) described in AP-005, Obtaining Subcontract Services, and AP-006, Obtaining Consultant Services.

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- (4) Commercial off-the-shelf (COTS) items may be procured from suppliers provided the item is of a common or standard design. COTS items shall be identified in the purchase order by the manufacturer's published product descriptions and or unique number.

7.4 BID EVALUATION

Bid evaluation activities are discussed in section 4, paragraph 4.3.5.

7.5 SUPPLIER PERFORMANCE EVALUATION

Supplier performance evaluation for computer codes, research results, written papers, presentations, and other data 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 memorandum to the file.

The CNWRA SEC evaluates subcontractors 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 subcontractors personnel.

7.6 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 referenced quality document listed on the procurement will be evaluated by the CNWRA technical staff member for acceptance. Acceptance of the document (including report data, data, technical paper, video, analysis, etc.), will be shown by payment of the invoice, which requires technical acceptance and approval by CNWRA management.

7.7 ACCEPTANCE OF GOODS AND SERVICES

7.7.1 Methods of Acceptance

- (1) Goods and services purchased from COTS supplies shall be inspected upon receipt as meeting the specifications set forth in the purchase order or contract by the appropriate qualified CNWRA technical staff member.

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- (2) Acceptance of goods and services from ASL qualified sources shall be based on review of the required documentation and product by the appropriate CNWRA technical staff member.
- (3) The SEC, composed of the CNWRA President, Technical Director, QA Director, Administrative Director, Systems Engineering and Integration Assistant Director and the appropriate Element Manager, shall determine the acceptability of subcontractors and consultants for use.

**7.7.2 Receiving Inspection by CNWRA Technical Staff**

- (1) Receiving inspections of procured goods shall be performed by the individual procuring the item or another technically qualified staff member. This 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 identifying the procurement and that the specific procurement requirements are met. Documentation identifying procurement requirements not met and descriptions "accept as is" or "repair" shall also be identified. 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.
- (2) Receiving inspections shall be conducted by technically qualified staff. Separate review by CNWRA QA is not required. CNWRA QA monitors individual technical staff member qualifications in accordance with section 2.6.2 and the receiving inspection documentation.
- (3) COTS materials and items used by the CNWRA have no special design or "nuclear" requirements and are acceptable to be used in CNWRA testing, investigation and analysis activities. Goods and materials routinely used at the CNWRA include standard commercial laboratory equipment, standards for chemical and other analyses, standard fasteners, standard laboratory glassware, laboratory tools, geological equipment, standard microbial materials, etc. These COTS items are not subject to design or specification requirements that are

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unique to nuclear facilities, but are commonly used in various industries, and are ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog). These COTS good and materials shall be received per paragraph 7.7.2(1).

7.8 CONTROL OF SUPPLIER NONCONFORMANCES

The disposition of items and services that do not meet procurement documentation requirements shall be in accordance with section 15, Nonconformance Control.

7.9 CONFIRMATORY ANALYSIS OF COTS 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.

7.10 RECORDS

Records of the SEC procurement selection and evaluations shall be maintained in accordance with CQAM section 17.

7.11 REFERENCES

CNWRA Administrative Procedure-005, Obtaining Subcontract Services.

CNWRA Administrative Procedure-006, Obtaining Consultant Services.

CNWRA Quality Assurance Procedure-009, Nonconformance Control.

CNWRA Quality Assurance Procedure-016, Procurement Control.

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**8. IDENTIFICATION AND CONTROL OF ITEMS, SOFTWARE, AND SAMPLES**

**8.1 PURPOSE**

The purpose of this section is to provide methods 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 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.

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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.

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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 records generated by this section are maintained in 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.

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### 9. CONTROL OF PROCESSES

#### 9.1 PURPOSE

The purpose of this section is to establish methods for controlling processes that affect quality of CNWRA products.

#### 9.2 RESPONSIBILITIES

- (1) PIs are responsible for identifying processes needing 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) Processes at the CNWRA are controlled by Operations Plans, Operating Procedures, direction from the NRC staff, documentation in a scientific notebook, and by document review request and transmittal control forms.
- (2) Scientific materials investigation and analysis and other experimental types of processes shall be conducted in accordance with this section of the CQAM when the results are to be used in NRC licensing actions or when requested by the client.

#### 9.4 SPECIAL PROCESS PROCEDURES AND QUALIFICATION

- (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. Special process procedures will be mutually decided upon by CNWRA technical staff, NRC staff and CNWRA QA staff. The decision to identify a special process will be documented and retained as a QA record.

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- (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 equipment qualification requirements
  - Applicable controlled condition requirements
  - Documentation requirements
- (3) Special process procedures that are based on accepted industry standard methods and practices, and which are to be utilized for the intended purpose, do not require qualification. For special processes not covered by existing codes and standards, requirements for qualification of personnel, procedures or equipment will be as described in section 3.
- (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 SwRI/CNWRA using qualified procedures, equipment, and personnel, or by suppliers qualified in accordance with CQAM Sections 4 and 7. For those special processes conducted by organizations outside of the CNWRA, appropriate controls shall be verified through CNWRA QA surveillance.
- (5) Novel or experimental procedures utilized for special processes shall be qualified by one or more of the following methods:
- (a) A prototype test, if possible, that demonstrates that the process maintains quality or produces quality results
  - (b) A technical review
  - (c) A peer review

Procedure qualification activities shall be documented, and the results technically reviewed by the cognizant Element Manager, and reviewed for compliance with this section by the Director of QA.

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9.5 SPECIAL PROCESS PERSONNEL QUALIFICATION

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.

9.6 DOCUMENTATION OF SPECIAL PROCESSES

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.

9.7 RECORDS

- (1) 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.

9.8 REFERENCE

CNWRA Quality Assurance Procedure-013, Quality Planning.

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10. INSPECTION

The CNWRA does not perform inspections of items and activities as defined in 10 CFR Part 50 Appendix B, NRC Review Plan for HLW QA Program Descriptions, and NQA-1-1986. However, the CNWRA performs inspections on quality-affecting goods and services received (see section 7, paragraph 7.7.2) and performs surveillances on CNWRA activities. Detailed technical and programmatic reviews are also performed on CNWRA documents at the final review point. In each of these cases, qualified CNWRA staff review and evaluate the CNWRA product. The final CNWRA product is transmitted after QA verifies the review process has been satisfied. Inspection activities beyond the capability of CNWRA core staff shall be performed by approved organizations, as described in section 4.3 and section 7.3

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**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.

When the CNWRA performs special testing activities for confirmation and validation of proposed design(s), those tests will be performed with approved, formal test procedures.

**11.4 TEST RECORDS**

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. Test records shall, as a minimum, identify the item tested, date of test, tester or data recorder, and any observations and results.

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11.5 REFERENCES

CNWRA Quality Assurance Procedures-008, Document Control.

CNWRA Quality Assurance Procedures-013, Quality Planning.

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12. CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 PURPOSE

The purpose of this section is to establish 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 is 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

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SwRI calibration lab 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

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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 the 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 and 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.

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**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.

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### 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, as referenced in QAP-009, Nonconformance Control.
- (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."

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- (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.

CNWRA Quality Assurance Procedure-009, Nonconformance Control.

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13. HANDLING, STORAGE AND SHIPPING

13.1 PURPOSE

The purpose of this section is to establish 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.

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14. INSPECTION, TEST AND OPERATING STATUS

14.1 STATEMENT OF EXCEPTION

The CNWRA considers that the Inspection, Test, and Operating Status criteria apply to design, construction, and operation of nuclear power plants, fuel reprocessing plants, and the proposed HLW repository, but does not consider this criterion to apply to CNWRA activities as the CNWRA does not engage in design, construction, or operation of nuclear facilities.

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**15. NONCONFORMANCE CONTROL**

**15.1 PURPOSE**

The purpose of this section is to establish requirements for identifying, segregating, reporting, dispositioning, and controlling nonconformances of items, materials, software, and activities to specified requirements, as referenced in QAP-009, Nonconformance Control.

**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

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- (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.

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.

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15.6 NONCONFORMANCE ANALYSIS

On a quarterly basis, CNWRA Nonconformances (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 in accordance with QAP-012, QA Records Control.

15.8 REFERENCES

CNWRA Quality Assurance Procedure-004, Surveillance Control.

CNWRA Quality Assurance Procedure-009, Nonconformance Control.

CNWRA Quality Assurance Procedure-012, Quality Assurance Records Control.

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16. CORRECTIVE ACTION

16.1 PURPOSE

The purpose of this section is to establish requirements for identifying conditions adverse to quality and for initiating, obtaining, and verifying corrective action, as referenced in QAP-010, 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.

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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, cause, and corrective action shall be documented and reported to Center 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 in accordance with QAP-012, QA Records Control.

16.10 REFERENCES

CNWRA Quality Assurance Procedure-009, Nonconformance Control.

CNWRA Quality Assurance Procedure-010, Corrective Action.

CNWRA Quality Assurance Procedure-012, QA Records Control.

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**17. RECORDS CONTROL**

**17.1 PURPOSE**

The purpose of this section is to identify 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 records control 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 are generated as a result of CNWRA activities: technical reports, 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 RECORDS 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.

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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. 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.

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- (3) Certain types of CNWRA records may be required to be delivered to the Licensing Support Network, a HLW Records Repository, or a client. Since those records have not yet been identified, CNWRA QA records shall be stored so that they are available when required by such a records repository. Also, any 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.
- (6) CNWRA records retention and storage requirements may be stipulated by contract. QA record requirements will be evaluated and implemented as required by contract.

17.8 REFERENCES

CNWRA Quality Assurance Procedure-012, Quality Assurance Records Control.

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18. AUDITS

18.1 PURPOSE

The purpose of this section is to establish requirements for scheduling, preparing for, performing, reporting, and following up on audits, as referenced in QAP-011, 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 surveillance are planned and controlled and are described in QAP-004, Surveillance Control.

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.

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

18.5 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.

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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. 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

### 18.6 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 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.

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18.7 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.

18.8 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.

18.9 FOLLOWUP ACTION

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

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18.10 AUDIT RECORDS

Audit Records will be maintained as permanent QA Records as identified in QAP-012, QA Records Control.

18.11 REFERENCES

CNWRA Quality Assurance Procedure-004, Surveillance Control.

CNWRA Quality Assurance Procedure-009, Nonconformance Control.

CNWRA Quality Assurance Procedure-011, Audits.

CNWRA Quality Assurance Procedure-012, Quality Assurance Records Control.

American National Standards Institute/American Society of Mechanical Engineers N45.2.23, Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants.

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

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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.

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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 Testing

A process to inspect, test or analyze an item to verify that the item and documentation meet appropriate quality requirements or standards.

Corrective Action

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

Deviation

Departure from specified requirements.

Dedication

A process to inspect or test to ensure an item manufactured by a non-qualified supplier meets appropriate quality requirements or standards.

Document

Any written or pictorial information describing, defining, specifying, reporting, or certifying activities,

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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.

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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.

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.

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.

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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.

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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.

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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 form 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.

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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.

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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.

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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.