QUALITY ASSURANCE MANUAL

GEOSCIENCES AND ENGINEERING DIVISION

Revision 5
Change 4

July 2008

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EFFECTIVITY AND APPROVAL

Revision 5 of this manual became effective on August 15, 2005. This manual consists of the pages and changes listed below.

Page No.	Change	Date Effective
1–2	4	7/23/2008
3-4	0	8/15/2005
5	2	9/27/2007
6–8	0	8/15/2005
9–10	4	7/23/2008
11	0	8/15/2005
12	2	9/27/2007
13–14	0	8/15/2005
15–17	4	7/23/2008
18	4	7/23/2008
19–20	2	9/27/2007
21–31	0	8/15/2005
32	2	9/27/2007
33–36	0	8/15/2005
37	2	9/27/2007
38–58	0	8/15/2005
59	2	9/27/2007
60	0	8/25/2005

Change 1 provides updated organization charts.

Change 2 provides an updated organization chart and editorial corrections.

Change 3 provides an updated organization chart.

Change 4 provides an updated organization chart.

Approvals

Director Quality Assurance	Date	Vice President Geosciences & Engineering Division	Date
Robert Rust	7/9/2008	Wesley Patterson	7/9/2008

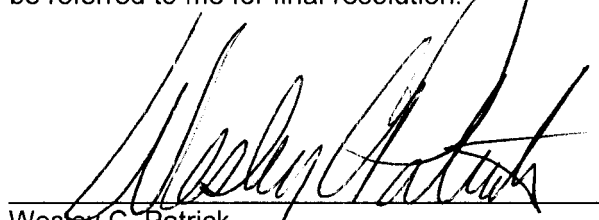
QUALITY ASSURANCE PROGRAM POLICY STATEMENT

The Geosciences and Engineering Division (Division) of Southwest Research Institute® (SwRI®) has developed a comprehensive quality assurance (QA) program that establishes the requirements and management measures to control Division activities for the U.S. Nuclear Regulatory Commission (NRC) and other clients. This program consists of this policy statement, the Quality Assurance Manual (QAM), and implementing procedures. The primary bases for the QAM are NRC QA regulations and ASME NQA–1–1986, Quality Assurance Program Requirements for Nuclear Facilities. Principles and practices from other quality assurance programs such as ISO 9001 are incorporated to the extent that they both enhance the overall program and do not reduce any commitment made with respect to NRC requirements. Application of this program is tailored to meet the needs of specific contracts and clients.

The QAM and its implementing procedures establish the requirements and methods that prescribe the actions to be taken by Division management, staff, consultants, and subcontractors during the performance of quality-affecting activities to ensure QA requirements are consistently met. This QA program is based on the principle that line and staff organizations are responsible and accountable for the quality of assigned work. The QA organization is charged with verifying the achievement of quality through audits, surveillances, assessments, and reviews.

This program has my complete support. It is to be followed at all times in conducting all quality-affecting activities of the division. Compliance with the provisions of this QA program is mandatory. The authority to administer the QA program described in the QAM and implementing procedures is assigned to the Division Director of QA, who reports directly to me.

Division management and staff, management and staff of other divisions of SwRI, and division consultants and subcontractors are given authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. All matters concerning quality that cannot be resolved at the normal organizational interfaces shall be referred to me for final resolution.



Wesley C. Patrick
Vice President, Geosciences and Engineering Division

7/9/2008
Date

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INTRODUCTION

The requirement for a quality assurance (QA) program originates with the contract between Southwest Research Institute® (SwRI®) and the U.S. Nuclear Regulatory Commission (NRC) for operation of the federally funded research and development center. The QA program initially was established and continues to be maintained to meet NRC requirements for work conducted by the Center for Nuclear Waste Regulatory Analyses, one of two departments in the Geosciences and Engineering Division (Division). Subsequently, it has been revised and tailored to address all work of the Division.

The objectives of the Quality Assurance Manual are to

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

(2) Establish the policies relating to implementation and maintenance of the QA program.

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

This QA program applies to activities that affect the quality of Division products. Specifically, these activities include analyses, research, development, investigations, and technical assistance. This QA program applies to personnel and organizations—the Division, SwRI, and subcontractors and consultants—performing activities affecting quality. Terms pertinent to this program are defined in the Appendix.

1 ORGANIZATION

1.1 Purpose

This section describes organizational responsibilities within the Geosciences and Engineering Division (Division) and relationships among the U.S. Nuclear Regulatory Commission (NRC) and other clients, Southwest Research Institute (SwRI), subcontractors, and consultants. The Division organization is described in more detail in the Geosciences and Engineering Division Management Plan. Controls shall be established to address the applicable elements of NQA–1–1986, Supplement 1S–1, and Appendix A–1.

1.2 Organization

The Division is an operating unit of SwRI (Figure 1-1). It comprises two departments; the first is the Center for Nuclear Waste Regulatory Analyses (CNWRA). CNWRA was established in 1987 with NRC as its sole sponsor. The second organization unit—the Department of Earth, Material, and Planetary Sciences (DEMPS)—was established in 2005 to, among other things, provide a means to diversify and stabilize the Division through significant growth in federally funded programs. The primary Division facilities are located in San Antonio, Texas, and offsite activities are accomplished under this Quality Assurance Manual (QAM) in the field and at the Washington, DC, Technical Support Office, which is managed by a director or an Assistant Director reporting to the Division Vice President. The Division organization is illustrated in Figure 1-2.

1.3 Description of Key Responsibilities and Duties

1.3.1 Southwest Research Institute Executive Management

The President of SwRI is the Chief Executive and Senior Officer and was designated by the Board of Directors to manage the corporation subject to the inherent powers of the Directors as stated in the bylaws. The President of SwRI reports to the Board of Directors and approves policy, provides technical and administrative direction to the SwRI Vice Presidents, and appoints the chairman of the Advisory Committee for Quality and Environmental Systems.

1.3.2 Institute Quality Systems

The Institute Quality Systems (IQS) department is responsible for monitoring and reporting to the SwRI President on the effectiveness of all SwRI Quality Assurance (QA) programs, including the Division QA program.

1.3.3 Division Management

(1) The Division Vice President has the authority and responsibility for all aspects of Division activities. The Vice President reports to the SwRI President.

(2) The CNWRA President receives technical direction from NRC, has the authority and responsibility to conduct the overall administrative and operational matters of CNWRA, and performs as the primary technical representative of the Vice President with CNWRA clients.

(3) The Director of DEMPS has the authority and responsibility to conduct the overall administrative and operational matters of DEMPS and performs as the primary technical representative of the Vice President with DEMPS clients.

(4) The Director of QA has the overall authority and responsibility for developing, implementing, and verifying an appropriate system of QA for Division activities. Through the controls established in this QAM and supporting procedures and plans, the Director of QA has sufficient authority, access to work areas, and organizational freedom to

(a) Identify quality problems

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

(c) Verify implementation of solutions

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

(e) Stop work, when conditions warrant.

(5) Other Directors, Assistant Directors, and Managers are responsible for developing and implementing appropriate plans and procedures to control activities affecting quality within their respective operating units. Specific responsibilities shall be identified in the Division Management Plan and further defined, as needed, in operations plans, proposals, and implementing procedures.

(6) The Division management team has the responsibility of carrying out their responsibilities through selecting, assigning, and evaluating Division staff, consultants, and subcontractors.

1.3.4 Project Management

(1) Division 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 Division QA staff in quality planning for project activities.

1.4 Division Quality Assurance

The Division QA group consists of the Director of QA and assigned staff, including Division, SwRI, and external support, as needed. QA is sufficiently independent of cost and schedule, relative to safety and quality considerations, and reports directly to the highest authority within the Division. Specific duties of the Director of QA include

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

(2) Checking, conducting surveillance, inspecting, and auditing to verify that activities affecting quality are correctly performed.

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

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

(5) Stopping work, when conditions warrant.

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

(7) Communicating effectively with consultants and subcontractors on QA matters.

1.5 Delegation of Authority

Delegation of authority 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

Division activities are performed by Division staff, other SwRI staff, consultants, and subcontractors. The responsibilities of the individuals and organizations outside the Division are dependent on the type of activities performed and the source of the personnel or services. Management of and communication with subcontractors and consultants are the responsibilities of the cognizant Manager or PI. The Division shall retain the responsibility for all delegated work.

1.6.1 Southwest Research Institute

Standard services (i.e., chemical analysis, calibration, machining) may be obtained from other SwRI organizations as internal procurement, as described in Sections 4 and 7.

1.6.2 Consultants and Subcontractors

Individuals performing activities such as data interpretation, analysis, or services (i.e., consultants including SwRI staff) and subcontractors shall be qualified in the same manner as the Division staff (in accordance with Section 2), and their activities shall be conducted in accordance with the Division QA program. Applicable requirements shall be clearly communicated to outside consultants and subcontractors by Managers and PIs through requests for proposal, statements of work, procurement documents, and other means.

1.7 Resolution of Disputes

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

Professional views among the Division staff, SwRI staff, consultants, or subcontractors regarding health- and safety-related concerns that may differ, or may differ from the prevailing NRC staff views, decisions, policy positions, or agency practices shall be resolved in accordance with contract requirements using the applicable procedure.

1.8 Allegations of Inadequate Quality

The Division Vice President shall review all allegations of inadequate quality originating from within or outside the Division. The conclusions of such reviews shall be documented. Allegations that are confirmed shall be reported to the client.

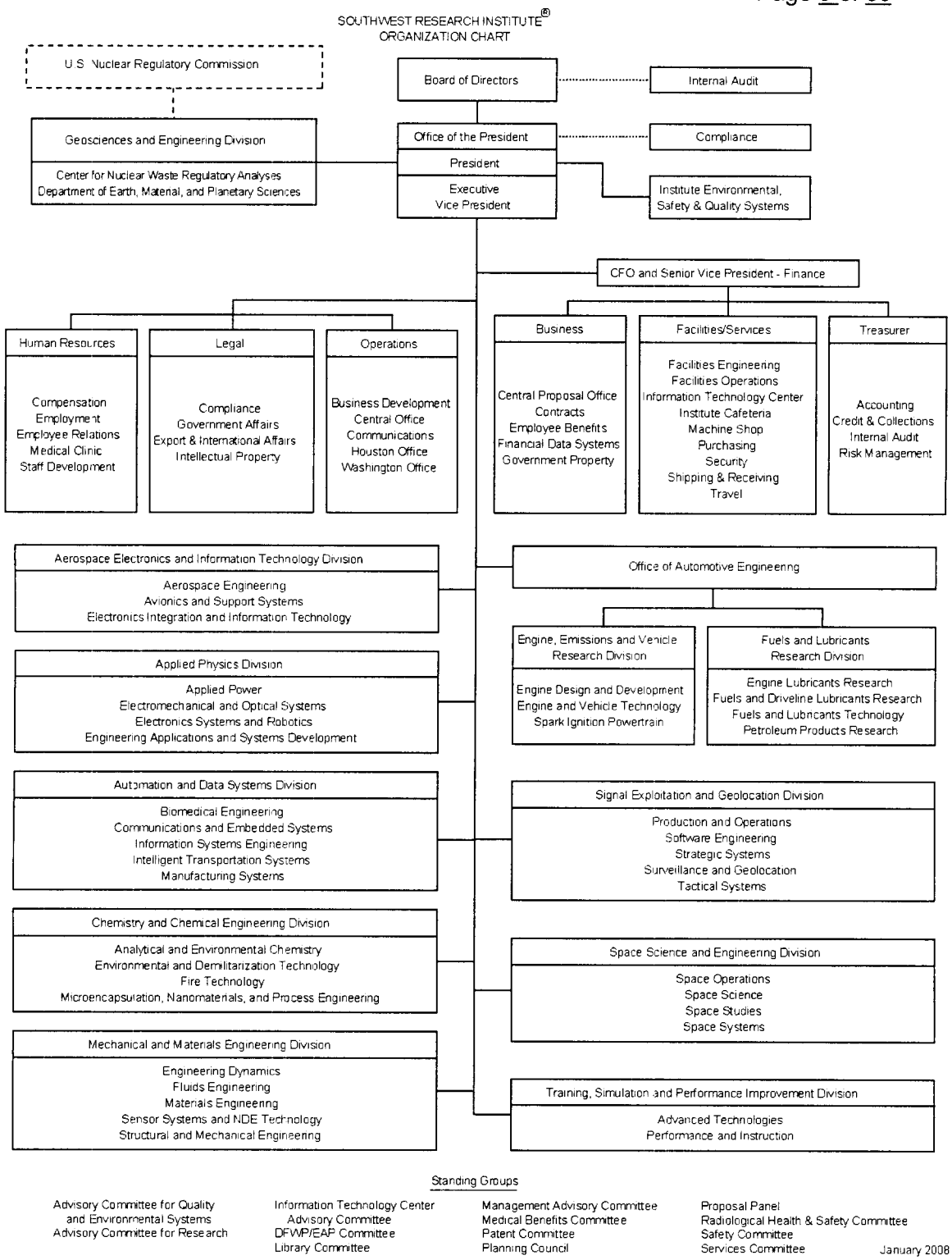
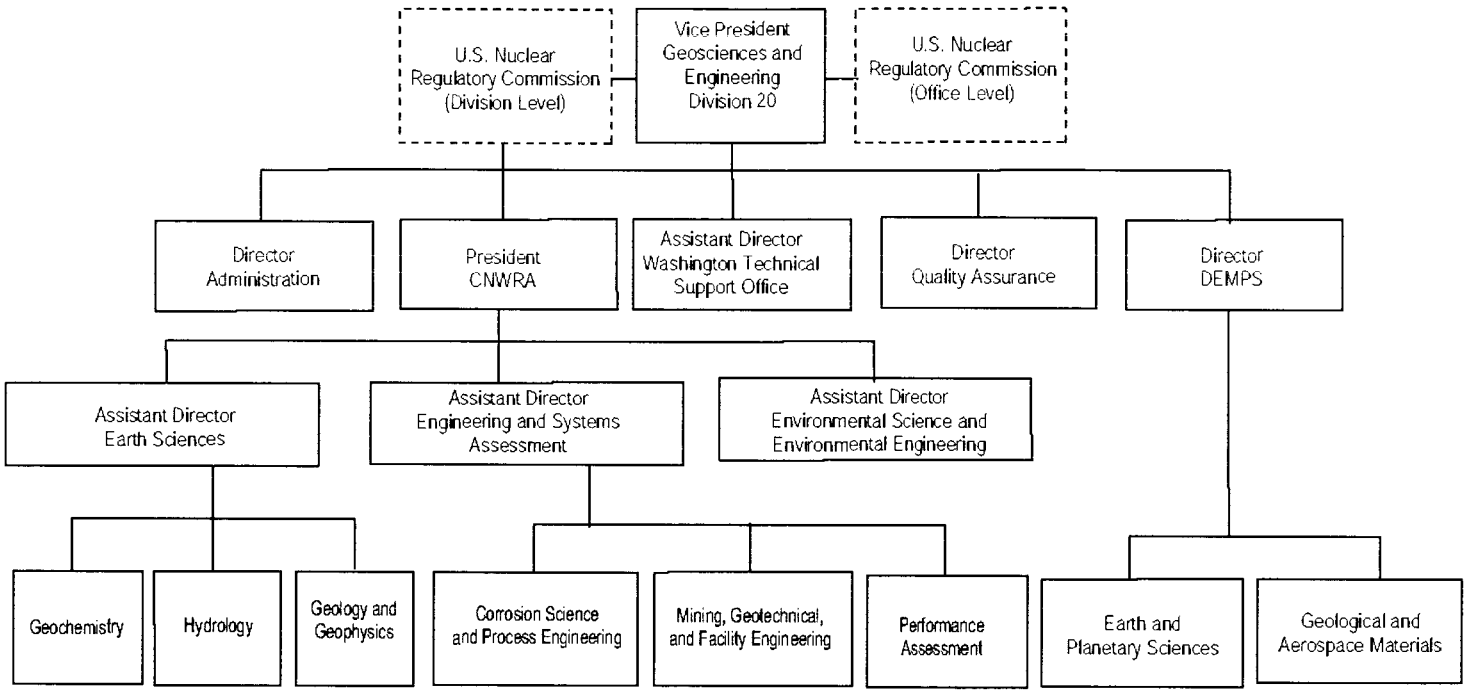


Figure 1-1. SwRI Organization Chart



Key: CNWRA = Center for Nuclear Waste Regulatory Analyses
DEMPS = Department of Earth, Material, and Planetary Sciences
—— = Reporting relationship
– – = Communications relationship

Figure 1-2. Divisional Organization Chart

TYPICAL PROJECT ORGANIZATION

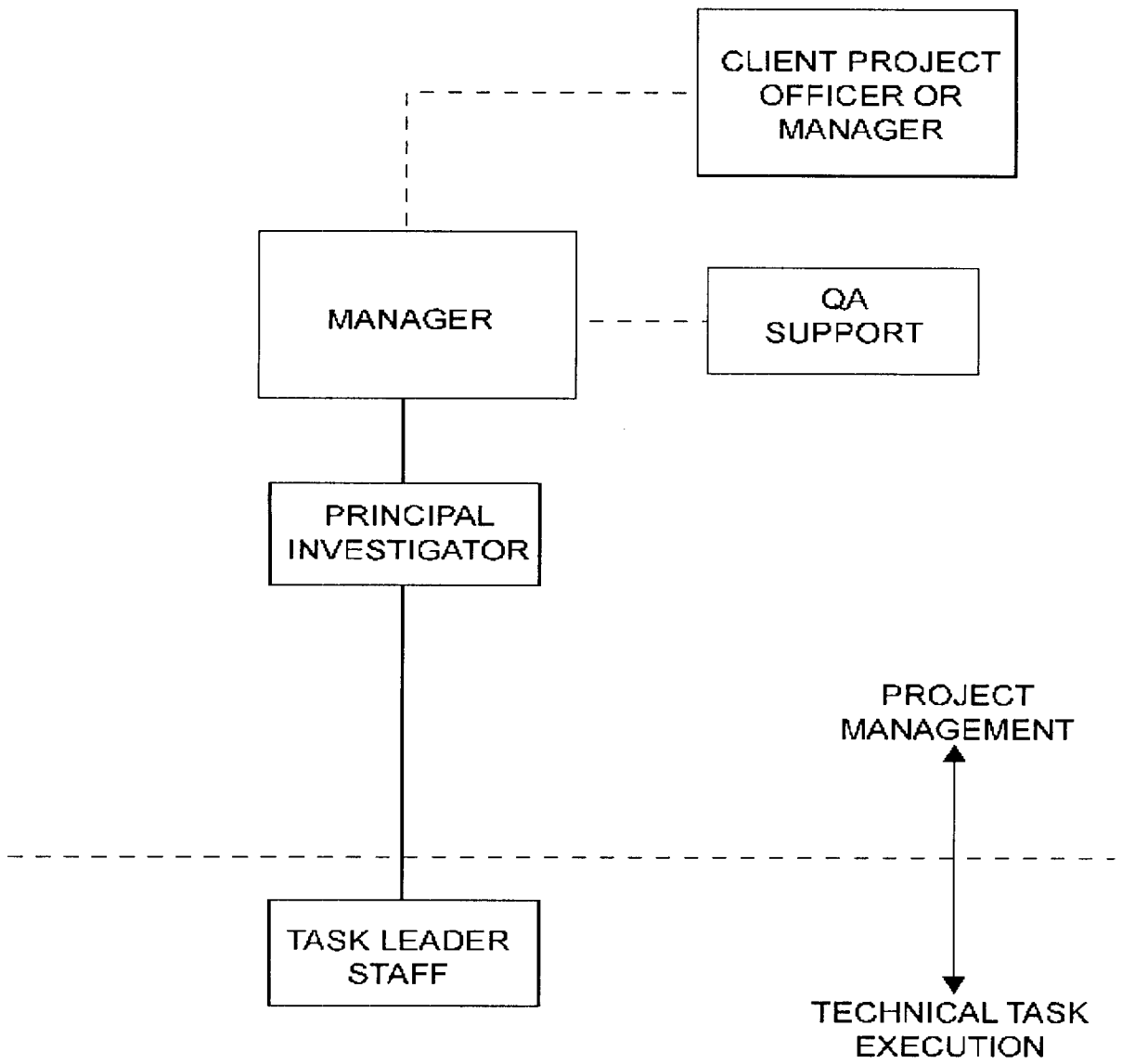


Figure 1-3. Typical Project Organization

2 QUALITY ASSURANCE PROGRAM

2.1 Purpose

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

2.2 Quality Assurance Program Description

2.2.1 Applicable Regulations and Standards

(1) Title 10, Code of Federal Regulations QA Criteria

Through its contracts with NRC, the Division is obligated to develop, implement, and maintain a QA system meeting nuclear QA program requirements, including 10 CFR Part 60, Subpart G (which refers to 10 CFR Part 50, Appendix B); 10 CFR Part 63, Subpart G; 10 CFR 70.22(f) (which refers to 10 CFR Part 50, Appendix B); 10 CFR Part 71, Subpart H; and 10 CFR Part 72, Subpart G. For application to Division activities, these requirements are equivalent. Because the regulatory requirements were initially directed toward the design, construction, and operation of structures, systems, and components and the Division mission focuses on analysis, technical assistance, and research and development projects, careful interpretation of the criteria is necessary for their effective and appropriate application. Adaptations and exceptions have been made to certain nuclear QA requirements and criteria that are not applicable to activities performed by the Division. A correlation of NRC quality assurance program criteria to the QAM with explanations for exceptions is provided in Table 2-1.

(2) ANSI/ASME NQA–1–1986

The QA program addresses the applicable guidance of the 1986 Edition of NQA–1, QA program requirements for nuclear facilities, tailored to the specific activities of the Division. Applicable NQA–1 supplements and appendixes are identified in the appropriate sections of this Division QAM and in Table 2-2.

(3) NRC Review Plan for High-Level Waste Repository QA Program Descriptions.

Applicable elements of the review plan dated March 1989 shall be addressed in this QAM, procedures, or instructions. This review plan provides requirements specific to high-level waste (HLW) related activities.

(4) Other Standards

Specific Division activities may utilize other accepted industry standards and practices; however, the quality requirements contained in this QAM shall apply. These requirements shall

be identified in operations plans, proposals, quality planning documents, 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

2.2.2 Quality Requirements for Division Activities

(1) This QA program is applicable to technical assistance and research performed by and for the Division, resulting products, and activities affecting the quality of these products.

(2) Controls applicable to Division activities are dependent on the importance to the client programs or other client needs.

(3) The development, acquisition, and use of (i) data, (ii) analysis methods, and (iii) software shall follow good scientific and engineering practices and shall be controlled in accordance with developed procedures.

(4) This program contains provisions for the use of suppliers that do not have an acceptable QA program, provided that appropriate controls are applied as stated under Sections 4 and 7.

(5) Exceptions to NRC regulatory QA requirements are identified in the correlation matrix (Table 2-1).

2.3 Structure of the Division Quality Assurance Program

2.3.1 Quality Assurance Program Documents

(1) Division QAM

The policies and programmatic controls of the Division QA program are incorporated into the QAM. The QAM describes the methods by which applicable QA 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 activities changes, or programmatic changes are warranted, the QAM 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

QAM sections where more detailed controls are required. Operating procedures applicable to specific activities shall be identified in quality planning documents.

(3) Operations Plans and Proposals

Operations plans and proposals establish management, technical, schedule, cost, and quality assurance objectives. Plans provide general direction for the conduct of activities. As plans and proposals are developed, the quality planning process is used to identify operating procedures and other instructions to control specific activities affecting quality.

(4) Other Instructions and Methods

Many routine tasks (e.g., standard methods, practices, and equipment manufacturers' instructions and calibration techniques) are adequately described in terms of methods and acceptance criteria in existing documents. Such instructions are acceptable for use in activities as long as sufficient details are provided to adequately control the activity and the 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., operating procedures), scientific notebooks provide planning, instructional, and documentation functions. The scientific notebook approach provides sufficient detail and content so that the experimental or calculational approach may be verified and the work replicated.

2.3.2 Control of Activities Affecting Quality

The portions of the QAM that are applicable, the level of control, and the specific controls applied depend on the type of activity and its importance. They are determined by the QA and technical staff through quality planning and procedure development and shall be sufficient to assure that activities are conducted under suitably controlled conditions including assurance that all prerequisites for a given activity are satisfied.

2.4 Management Assessments

2.4.1 Internal Audits and Surveillances

Internal evaluations of the QA program implementation effectiveness shall be through periodic audit and surveillance.

2.4.2 Southwest Research Institute Advisory Committee for Quality and Environmental Improvement

The SwRI Operating Policies and Procedures manual specifies that the purpose of the Advisory Committee for Quality and Environmental Improvement (ACQEI) is to advise and inform SwRI executive management about the effectiveness of quality and environmental systems in support of business operations. The ACQEI consists of members from the various technical divisions and services groups. The ACQEI reports yearly to SwRI executive management.

2.5 Indoctrination, Training, and Qualification

2.5.1 Indoctrination and Training

The Division staff, SwRI personnel, contractors, and consultant personnel performing activities affecting quality shall receive indoctrination on the Division QA program and its implementation. Indoctrination shall, as a minimum, cover the following topics

- Division policies and procedures related to QA
- Responsibility and authority of individuals performing quality-affecting activities
- QA program summary, with emphasis on how the requirements apply to activities and product quality

Controls related to indoctrination and training shall address applicable elements of NQA–1–1986, Supplement 2S–4.

2.5.2 Qualification of Personnel

(1) Personnel performing activities affecting quality shall be qualified to perform their assigned tasks. Labor sources shall be selected following applicable SwRI Operating Policies and Procedures. Qualification shall be based on education, experience, training, information access restrictions, if any, and freedom from conflict of interest. Training shall be provided, if needed, to (i) achieve initial proficiency; (ii) maintain proficiency; and (iii) adapt to changes in technology, methods, or job responsibilities.

(2) Controls related to personnel qualification shall address applicable elements of NQA–1–1986, Supplement 2S–1.

(3) The qualification method for lead auditors is identified in Section 18.

2.6 References

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

U.S. Nuclear Regulatory Commission Contract No. NRC–02–02–012.

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

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

U.S. Nuclear Regulatory Commission. 10 CFR Part 70, Domestic Licensing of Special Nuclear Material.

U.S. Nuclear Regulatory Commission. 10 CFR Part 71, Packaging and Transportation of Radioactive Material.

U.S. Nuclear Regulatory Commission. 10 CFR Part 72, Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste.

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

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

Table 2-1. Correlation of NRC Quality Assurance Program Criteria and Quality Assurance Manual Sections

NRC Quality Assurance Criteria	Corresponding Quality Assurance Manual Section
Introduction and Applicability (scope of QA Program)	INTRODUCTION
Organization. (Delegation of work)	1.6 DELEGATION OF WORK
(1) (authority and duties of persons and organizations) (quality assurance functions)	1.3 DESCRIPTION OF KEY RESPONSIBILITIES AND DUTIES 1.4 DIVISION QUALITY ASSURANCE
(2) (persons and organizations performing quality assurance functions)	1.3 (4) The Director of Quality Assurance 1.4 DIVISION QUALITY ASSURANCE
(3) (organizational structure for executing the quality assurance program)	1.4 DIVISION QUALITY ASSURANCE
Quality assurance program (complies with the requirements of this subpart) (program must be documented by written policies, procedures, or instructions)	2.2 QUALITY ASSURANCE PROGRAM DESCRIPTION 2.2.1 Applicable Regulations and Standards
(1) (activities to be covered by the quality assurance program and the major organizations participating in the program)	2.2.2 Quality Requirements for Division Activities
(quality assurance program must control activities affecting the quality ...to an extent consistent with their importance to safety.)	2.3.2 Control of Activities Affecting Quality
(2) (activities affecting quality must be accomplished under suitably controlled conditions.)	2.3.2 Control of Activities Affecting Quality
(3) (need for special controls, processes, test equipment, tools, and skills to attain the required quality, need for verification of quality by inspection and test.)	2.3.2 Control of Activities Affecting Quality
(indoctrination and training of personnel performing activities affecting quality)	2.5.1 Indoctrination and Training 2.5.2 Qualification of Personnel
(4) (regularly review the status and adequacy of the quality assurance program)	2.4 MANAGEMENT ASSESSMENTS
Design control	Exception is taken to design control because it is not within the Division scope of activities. Instead, criteria for Scientific and Engineering Investigations and Analysis are described.
Procurement document control	4.2 PROCUREMENT DOCUMENTS
(scope of work and technical requirements)	4.2.1 Scope of Work
procurement documents require contractors or	4.2.2 Technical Requirements
subcontractors to provide a quality assurance program	4.2.3 Quality Assurance Requirements
(f) Instructions, procedures, and drawings.	5.2 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Table 2-1. Correlation of NRC Quality Assurance Program Criteria and Quality Assurance Manual Sections (continued)

NRC Quality Assurance Criteria	Corresponding Quality Assurance Manual Section
Document control (issuance of documents)	6.2 APPLICATION OF DOCUMENT CONTROLS
(documents, including changes, are reviewed for adequacy and approved for release by authorized personnel)	6.3 PREPARATION, REVIEW, AND APPROVAL
(distributed to and used at the location where the prescribed activity is performed.)	6.4 DOCUMENT DISTRIBUTION
(changes to documents)	6.3.5 Revisions and Changes
Control of purchased material, equipment, and services (measures to assure that purchased material, equipment, and services conform to the procurement documents).	7.2 PROCUREMENT PLANNING
(1) (source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery)	7.3 SUPPLIER SELECTION 7.4 SUPPLIER PERFORMANCE EVALUATION 7.5 CONTROL OF SUPPLIER GENERATED DOCUMENTS 7.6 ACCEPTANCE OF ITEMS AND SERVICES
(2) (Documentary evidence ...available at the high-level waste repository site)	Not applicable to Division activities.
(3) (effectiveness of the control of quality by contractors and subcontractors must be assessed)	7.4 SUPPLIER PERFORMANCE EVALUATION
Identification and control of materials, parts, and components (measures must assure that identification of the item is maintained ...throughout ...use of the item.)	8.2 IDENTIFICATION 8.3 TRACEABILITY CONTROL
(prevent the use of incorrect or defective material, parts, and components)	8.4 IDENTIFICATION OF NONCONFORMING ITEMS AND SAMPLES
Control of special processes (measures to assure that special processes ... are controlled and accomplished by qualified personnel using qualified procedures)	9.2 PROCESS CONTROL 9.3 SPECIAL PROCESSES
Inspection (to verify conformance)	10.1 PURPOSE 10.2 INSPECTION
(performed by individuals other than those who performed the activity being inspected)	10.3 QUALIFICATION OF PERSONNEL
(1) (for each work operation, indirect control by monitoring processing methods)	The Division does not have any work processes, so in-process inspection is not applicable.
(2) (mandatory inspection hold points)	10.2 INSPECTION

Table 2-1. Correlation of NRC Quality Assurance Program Criteria and Quality Assurance Manual Sections (continued)	
NRC Quality Assurance Criteria	**Corresponding Quality Assurance Manual Section**
Test control (test program)	11.1 PURPOSE
(1) (test program scope) (2) (test procedures)	11.2 TEST CONTROL
(3) (test results)	11.3 TEST RECORDS
Control of measuring and test equipment	12.2 SELECTION OF MEASURING AND TEST EQUIPMENT 12.3 CALIBRATION CATEGORIES 12.4 CALIBRATION STANDARDS 12.5 CALIBRATION PROCEDURES 12.6 OUT-OF-TOLERANCE EVALUATIONS 12.7 PROCUREMENT OF CALIBRATION WORK
Handling, storage, and shipping	13.2 DETERMINATION OF REQUIREMENT 13.3 PERSONNEL QUALIFICATIONS 13.4 HANDLING, STORAGE AND SHIPPING PROCEDURES
Inspection, test, and operating status (status of inspections and tests by markings)	14.2 STATUS IDENTIFICATION
(operating status)	Not applicable: The Division will not operate a licensed facility.
Nonconforming materials, parts, or components (identification, documentation, segregation, disposition, and notification to affected organizations)	15.2 IDENTIFICATION 15.3 SEGREGATION 15.4.3 Notification of Affected Organizations
(reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures)	15.4 DISPOSITION
Corrective action (conditions adverse to quality are promptly identified and corrected)	16.1 PURPOSE
(significant conditions - measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition)	16.2 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY 16.3 ROOT CAUSE DETERMINATION AND RECURRENCE CONTROL
(reported to appropriate levels of management)	16.5 DOCUMENTATION AND REPORTING
Quality assurance records (1) (scope)	17.3 CONTROL OF DOCUMENTS PRIOR TO BECOMING RECORDS
(2) (closely related data)	17.2 IDENTIFICATION AND VALIDATION OF RECORDS
(3) (inspection and test records)	10.4 INSPECTION RESULTS 11.3 TEST RECORDS
(4) (identifiable and retrievable)	17.6 RECORDS PROCESSING

Table 2-1. Correlation of NRC Quality Assurance Program Criteria and Quality Assurance Manual Sections (continued)

NRC Quality Assurance Criteria	Corresponding Quality Assurance Manual Section
(record retention)	17.6 RECORDS STORAGE
Audits (system of planned and periodic audits) (performed in accordance with the written procedures or check lists)	18.2 AUDIT PROGRAM 18.3 AUDIT SCHEDULES 18.6 AUDIT PERFORMANCE
(by appropriately trained personnel not having direct responsibilities in the areas being audited)	18.4 AUDITOR QUALIFICATION
(audit results) (followup action)	18.7 AUDIT REPORTS 18.9 FOLLOWUP ACTION

Table 2-2. Correlation of NQA–1–1986 Supplements and Appendixes and Quality Assurance Manual Sections	
NQA–1–1986 Supplements and Appendixes	**Applicability or Exception**
1S–1, Supplementary Requirements for Organization	QAM Section 1
2S–1, Supplementary Requirements for the Qualification of Inspection and Test Personnel	QAM Section 2 and implementing procedures Requirements apply to all persons performing activities affecting quality. Certification is not applied to persons performing scientific or engineering investigations and analysis.
2S–2, Supplementary Requirements for the Qualification of Nondestructive Examination Personnel	QAM Section 9
2S–3, Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel	QAM Section 18 and SwRI Institute Quality Systems procedures
2S–4, Supplementary Requirements for Personnel Indoctrination and Training	QAM Section 2 and implementing procedures
3S–1, Supplementary Requirements for Design Control	The Division does not perform design activities, so exception is taken to Design control criteria.
4S–1, Supplementary Requirements for Procurement Document Control	QAM Section 4 and implementing procedures
6S–1, Supplementary Requirements for Document Control	QAM Section 6 and implementing procedures
7S–1, Supplementary Requirements for Control of Purchased Items and Services	QAM Section 7 and implementing procedures
8S–1, Supplementary Requirements for Identification and Control of Items	QAM Section 8 and implementing procedures
9S–1, Supplementary Requirements for Control of Processes	SwRI or qualified suppliers' procedures
10S–1, Supplementary Requirements for Inspection	SwRI Institute Quality Systems procedures
11S–1, Supplementary Requirements for Test Control	The Division does not construct structures, systems, or components, so design verification testing is not applicable. Testing in support of scientific investigations is addressed in Section 3 of the QAM.
12S–1, Supplementary Requirements for Control of Measuring and Test equipment	QAM Section 12, Division and SwRI Institute Quality Systems procedures
13S–1, Supplementary Requirements for Handling, Storage, and Shipping	QAM Section 13 and implementing procedures

Table 2-2. Correlation of NQA–1–1986 Supplements and Appendixes and Quality Assurance Manual Sections (continued)	
NQA–1–1986 Supplements and Appendixes	**Applicability or Exception**
15S–1, Supplementary Requirements for Nonconforming Items	QAM Section 15 and implementing procedures
17S–1, Supplementary Requirements for Quality Assurance Records	QAM Section 17 and implementing procedures
18S–1, Supplementary Requirements for Audits	QAM Section 18 and implementing procedures
1A–1, Nonmandatory Guidance on Organization	QAM section 1
2A–1, Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel	No inspection of structures, systems, or components requiring implementation of this guidance will be performed.
2A–2, Nonmandatory Guidance on Quality Assurance Programs	Most elements of the guidance are not applicable to the Division QA program at this stage.
2A–3, Nonmandatory Guidance on the Education and Experience of Lead Auditors	QAM Section 18 and SwRI Institute Quality Systems procedures
3A–1, Nonmandatory Guidance on Design Control	The Division does not perform design activities, so exception is taken to Design control criteria.
4A–1, Nonmandatory Guidance on Procurement Document Control	The guidance primarily applies to procurement of licensed facility structures, systems, or component, so is not applicable to Division purchases.
7A–1, Nonmandatory Guidance on Control of Purchased Items and Services	Division purchases are primarily for standard items or services, so the detailed processes for purchases of structures, systems, or components is not applicable.
17A–1, Nonmandatory Guidance on Quality Assurance Records	The categories of records in the guidance are oriented toward design, construction, and operations, so are not relevant to Division activities.
18A–1, Nonmandatory Guidance on Audits	QAM Section 18 and implementing procedures

3 SCIENTIFIC/ENGINEERING INVESTIGATION AND ANALYSIS CONTROL

3.1 Purpose

This section describes various requirements for controlling scientific investigations and engineering analyses.

Scientific Investigation and Analysis Control Description

Regulatory, institutional, and technical analyses; technical assistance; and research activities affecting product quality shall be planned, accomplished, and verified under controlled conditions.

3.1.1 Technical Assistance and Research

Operations plans and proposals identify the technical objectives, describe each task of the technical program, and describe the program management. Scientific notebooks may be used to plan and control technical tasks and document results.

3.1.2 Literature Searches

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

3.1.3 Control of Existing Data

Existing data (i.e., data collected or developed without QA program controls) shall be qualified before they are used in a direct challenge of potential licensee data or positions. Existing data qualification shall be accomplished by peer review, use of corroborating data, use of confirmatory testing, or collection of these data under an equivalent QA program, in accordance with the guidelines of NUREG–1298, Qualification of Existing Data for High-Level Waste Repositories. Division management and the NRC staff shall determine when data qualification is necessary.

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

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

- Identification and documentation of software requirements
- Software development planning
- Software change and problem reporting and resolution
- Software configuration control
- Verification, review, and release for use

- Software acceptance and validation testing
- Retirement

Small, incidental software that is developed for one time use may be exempted from software development criteria provided that the calculations performed using the software are documented and a copy of the software is placed in QA records.

Software use shall be controlled, and calculations shall be documented. Software used to support regulatory reviews shall be validated to provide additional confidence in its application. Division management shall identify the S&E software that is expected to be used in Division activities and shall determine the schedules for placing the software under configuration control and for validation.

3.1.5 Control by Scientific Notebook Method

Technical activities may be controlled using scientific notebooks. The scientific notebook records the decision paths leading to the performance of an activity, 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. The issuance of and specific controls for scientific notebooks shall be described in Division procedures.

3.1.6 Guidance Provided Through Codes, Standards, and Procedures

Detailed TOPs should be used whenever work is repetitive. When appropriate, TOPs will be based on industry standard methods. TOPs provide descriptive methods of how to conduct scientific investigations, particularly laboratory and field investigations.

3.1.7 Verification of Scientific Investigations, Analyses, Experiments, and Tests

Surveillance of scientific investigations, analyses, experiments, and tests shall be conducted as needed to verify compliance with applicable procedural requirements. The surveillance may include, as appropriate, direct observation of quality-affecting activities.

3.1.8 Data Interpretation and Analysis

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. Calculations, including data reduction, statistical analysis, and routine S&E calculations, shall be documented and verifiable. Documentation shall be sufficient to identify the data inputs and their sources and the software or calculation formula or algorithm such that calculations may be replicated. Scientific notebooks may be utilized to document these activities.

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

The Division staff may develop, revise, and use approved practices and guidance (e.g., review plans and specialized review methods), as necessary, for the review of externally developed designs and proposed designs, safety analysis reports, and license applications. The Division shall perform reviews to determine whether the documents meet client requirements. These reviews do not constitute “design verification” as defined in NQA–1, Design Control.

3.1.10 Review of Division Products

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

3.2 References

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

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

4 PROCUREMENT DOCUMENT CONTROL

4.1 Purpose

This section establishes the requirements for preparing, issuing, and changing procurement documents for quality-affecting items and services. Controls shall address applicable elements of NQA–1–1986, Supplement 4S–1.

4.2 Procurement Documents

Procurement documents issued shall include the information described in the following sections.

4.2.1 Scope of Work

A description of the items or services to be provided or performed by the supplier shall be provided in procurement documents.

4.2.2 Technical Requirements

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

The procurement documents shall identify required receiving inspection activities and acceptance requirements as described in Section 7.

4.2.3 Quality Assurance Program Requirements

Procurement of quality-affecting items or services may be though qualified suppliers or nonqualified suppliers. As described in Section 7, purchases from nonqualified suppliers require that the Division determine the acceptability of the procured items or services.

Procurement documents issued to qualified suppliers shall require that the supplier have a documented QA program that implements applicable portions or all of the requirements of 10 CFR Part 63 or equivalent. The extent of the program required shall depend upon the type and use of the material, equipment, item, or service being procured. If necessary, procurement documents shall require the supplier to incorporate the appropriate QA program requirements in subtier procurement documents.

4.2.4 Right of Access

Procurement documents issued to qualified suppliers shall include provisions for access to the supplier’s facilities and records for inspection or audit by the Division staff or a designated representative.

4.2.5 Documentation Requirements

Procurement documents shall identify the documentation that the supplier must submit with the procured items or services. When the Division requires the supplier to maintain specific QA records, the retention times and disposition requirements shall be prescribed.

4.2.6 Nonconformance

Procurement documents to qualified suppliers shall include requirements for reporting and approving the disposition of supplier nonconformances.

4.3 Procurement Document Review

At a minimum, purchase shall be reviewed and approved by the PI or Manager and the Director of QA. Consultant service contracts and subcontract agreements shall be reviewed in accordance with developed procedures.

4.4 Procurement Document Changes

Procurement document changes regarding scope, schedule, complexity, bid evaluation, precontract negotiations, and quality shall be subject to the same degree of review as the original document.

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 Purpose

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

5.2 Instructions, Procedures, and Drawings

Division activities shall be conducted and their quality verified in accordance with the following, as appropriate.

5.2.1 Division Quality Assurance Manual

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

5.2.2 Planning Documents

Operations plans and proposals establish general management, technical, schedule, cost, and quality controls for Division activities. The format and content of operations plans and proposals shall address client or potential client requirements.

5.2.3 Procedures

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

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

(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 PI prior to beginning the work. Changes shall be verified by the same groups required to review the original instruction, procedure, or drawing.

5.2.4 Scientific Notebooks

Scientific notebooks record the methods and results of scientific investigation activities. Scientific notebooks shall be used for quality-affecting activities when procedures have not been developed or are not appropriate, or where the exploratory nature of the work goes beyond what is addressed by established procedures or methods.

5.2.5 Instructions

Quality-affecting activities may be described or controlled through means other than procedures and drawings. Instructions may take the form of, but are not limited to, work orders, process controls, receipt travelers, or nonconformance dispositions.

5.2.6 Drawings

When used to describe quality-affecting activities or items, controls shall be established for initiating, checking, approving, and issuing drawings and changes to the drawings.

6 DOCUMENT CONTROL

6.1 Purpose

This section describes requirements for preparing, reviewing, approving, changing, and distributing documents that specify quality requirements or prescribe activities affecting quality. Controls shall address applicable elements of NQA–1–1986, Supplement 6S–1.

6.2 Application of Document Controls

The QAM, TOPs, QAPs, APs, and operations plans shall be controlled in regard to preparation, review, approval, changes, and distribution.

6.3 Preparation, Review, and Approval

6.3.1 Quality Assurance Manual

(1) The QAM shall contain a statement of policy, an introduction, and sections addressing applicable QA program criteria.

(2) The QAM shall be approved by the Division Vice President and the Director of QA.

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

6.3.2 Operating Procedures

(1) Operating Procedures (TOPs, QAPs, and APs) provide 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.

(2) TOPs, QAPs, and APs shall be assigned unique numbers.

(3) TOPs, QAPs, and APs shall be reviewed and approved in accordance with a developed procedure.

6.3.3 Operations Plans and Proposals

(1) Operations plans and proposals shall be uniquely titled indicative of their subject. The format and content of these documents shall address client or potential client requirements.

(2) Unless otherwise specified by the client, proposals are typically not issued as controlled documents.

(3) Developed procedures specify review and approval requirements for operations plans and proposals.

6.3.4 Drawings

(1) Drawings and sketches shall be prepared, as necessary, to control the fabrication of quality-affecting items.

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

(3) Developed procedures specify review and approval requirements for drawings.

6.3.5 Revisions and Changes

(1) The QAM, TOPs, QAPs, APs, operations plans, and proposals may be changed page by page or revised in total.

(2) Changes and revisions shall receive the same level of review and approval as required for originals.

(3) Field or laboratory variances to TOPs may be documented in a scientific notebook, with approval by the PI. If revision of the TOP is necessary, the revision shall be completed and approved within 20 working days of the variance.

(4) Quality planning shall be repeated if modifications are made to operations plans or proposals that significantly alter or invalidate the previous planning.

6.3.6 Master Document List

A list of controlled documents shall be maintained and updated as new documents, revisions, and changes are issued.

6.3.7 Release for Distribution

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

6.4 Document Distribution

6.4.1 Distribution Lists

Documents shall be distributed to staff consistent with their work assignments. Distribution lists shall be maintained so that current documents are distributed to the correct personnel for use and so that obsolete documents are removed.

6.4.2 Distribution to the Point of Use

(1) The QAM and operating procedures shall be distributed to individuals working in Division offices and laboratories through the Division Intranet. Individuals working outside of Division offices and laboratories shall have distribution by hardcopy or electronic copy. Obsolete documents shall be discarded.

(2) Managers shall provide their staff with the operations plans, project plans, proposals, operating procedures, instructions, drawings, and methods necessary to control activities affecting quality.

(3) PIs shall provide supplemental instructions to the project staff when needed and shall provide for removal or destruction of obsolete or inappropriate instructions from the workplace.

6.4.3 Documents of External Origin

Documents of external origin (i.e., those not issued by the Division) shall be identified by the PI, indexed, and maintained in the Division library.

7 PROCUREMENT CONTROL

7.1 Purpose

This section establishes requirements to ensure conformance with procurement documents for quality-affecting items and services, including software, whether purchased directly, through subcontractors, or obtained from SwRI sources. Controls shall address applicable elements of NQA–1–1986, Supplement 7S–1.

7.2 Procurement Planning

Procurement planning shall be accomplished as early as practicable. When needed for complex procurement, planning shall integrate procurement document control (Section 4) and the elements of this section.

Client-supplied or U.S. Department of Energy (DOE)-supplied samples, materials, and items used in activities affecting quality shall be identified and controlled in accordance with QAM Section 8. Procurement controls do not apply to such items.

7.3 Supplier Selection

The selection of quality-affecting suppliers shall be based on evaluation of their capability to provide goods or services in accordance with the requirements prior to issuing the procurement documents. SwRI IQS procedures may be used for supplier qualification activities.

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

(1) Evaluation of supplier's history of providing an identical or similar product that was confirmed as meeting the requirements specified in the purchase order and performed satisfactorily.

(2) Review of supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.

(3) Audit or preaward survey of the potential supplier's quality system and facilities.

(4) Review of third party accreditation documentation for suppliers of test or calibration services (i.e., ISO 17025).

7.4 Supplier Performance Evaluation

Evaluations of suppliers on the Approved Supplier List (ASL) shall be conducted in accordance with SwRI IQS procedures. The effectiveness of the supplier's control of quality shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or services.

7.5 Control of Supplier Generated Documents

Supplier generated documents that attest to compliance with a standard or other quality requirements listed on the procurement documents shall be evaluated for compliance with the standard or other requirements.

7.6 Acceptance of Items and Services

Methods of acceptance shall include the following.

(1) Standards or standard reference materials shall be procured from sources on the ASL or shall be subjected to confirmatory analysis or other confirmatory methods.

(2) Acceptance of goods and services from suppliers on the ASL shall be based on review of the required documentation and product.

(3) Goods and services purchased from unqualified suppliers shall be verified or inspected upon receipt to determine whether they meet the specifications set forth in the purchase document.

7.7 Control of Supplier Nonconformances

Items and services that do not meet procurement document requirements shall be controlled as nonconformances in accordance with Section 15.

7.8 Confirmatory Analysis

Because of importance to quality, expense, and end use, an item or material may require a more rigorous verification of supplier-generated certificates or analyses. When confirmatory analysis is determined to be necessary, the type of confirmation shall be clearly described in the procurement documents or plans. Confirmatory analyses shall be performed by organizations listed on the SwRI ASL or by qualified SwRI laboratories.

8 IDENTIFICATION AND CONTROL OF ITEMS, SOFTWARE, AND SAMPLES

8.1 Purpose

This section provides requirements to identify and control items, software, and samples used in activities affecting quality. Client-supplied (including the DOE-supplied) samples, materials, and items used in activities affecting quality shall be received, identified, and controlled in accordance with this section. Controls shall address applicable elements of NQA–1–1986, Supplement 8S–1.

8.2 Identification

8.2.1 Purchased Items, Materials, and Equipment

(1) Items, materials, and equipment affecting product quality shall be clearly labeled. 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, heat number, part number, serial number, or other appropriate unique identification number.

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

(4) Markings shall be maintained or replaced as necessary throughout the life of the item or material.

8.2.2 Software

Software subject to control shall be clearly identified, both physically and within the encoded information, with the software title and version number.

8.2.3 Samples

Samples shall be identified from the point of collection through storage, subdivision, analysis, and when necessary, through archiving. Samples shall be appropriately identified with a unique sample identification and, when appropriate, date of collection and collection location.

8.2.4 Limited Shelf-Life Items

Limited shelf-life items shall have the expiration date clearly identified. Some chemicals may be retained beyond their shelf life for comparison purposes, provided these are marked to preclude unintended use.

8.3 Traceability Control

(1) Sample identification shall be traceable to appropriate documentation, such as procurement records, collection logs, or test records.

(2) Measures shall be taken to ensure that identification is maintained over time and through subdivision of the original materials and samples.

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

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

8.4 Identification of Nonconforming Items and Samples

Samples and items determined to be nonconforming (in accordance with Section 15) shall be clearly identified to prevent unintended use.

9 CONTROL OF PROCESSES

9.1 Purpose

This section establishes requirements for controlling processes affecting quality, which may include, but are not limited to welding, heat treating, and nondestructive evaluation.

9.2 Process Control

(1) Quality-affecting processes shall be controlled by procedures or scientific notebooks.

(2) Scientific investigation and analysis and other experimental types of processes shall be conducted in accordance with Section 3 of the QAM.

9.3 Special Processes

(1) Special processes are those where the results are highly dependent on the control of the process, the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test.

(2) Special processes shall be performed in accordance with applicable codes, standards, specifications, criteria, and other requirements. As a minimum, special process procedures shall specify

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

(3) Nondestructive testing, welding, heat treatment, and surface treatments are special processes that have well-established methods. Special processes shall be conducted by Division staff, SwRI staff, or qualified suppliers using qualified procedures, equipment, and personnel. Personnel qualification shall be in accordance with applicable codes and standards. Nondestructive evaluation personnel shall be qualified in accordance with NQA–1–1986, Supplement 2S–2.

(4) Objective evidence of the proper accomplishment of special processes shall be developed and documented.

10 INSPECTION

10.1 Purpose

This section describes the requirements for inspecting quality-affecting items. Inspections shall be performed when quality-affecting characteristics need to be verified (i.e., to verify that purchased or other items meet specified requirements).

10.2 Inspection

Inspection requirements and acceptance criteria, when inspection is needed, shall be identified in drawings or procurement documents. Because of the scope of the Division's work, in-process inspection and hold points are not necessary.

10.3 Qualification of Personnel

Personnel performing receiving inspections shall be familiar with procurement document requirements and applicable receipt inspection methods. Inspection of fabricated items shall be performed by properly qualified individuals other than those performing the work being inspected. SwRI IQS inspectors qualified in accordance with NQA–1–1986, Supplement 2S–1, shall be used when specialized inspection methods (i.e., dimensional) are applied.

10.4 Inspection Results

Inspection results shall be recorded and maintained. Inspection records must, at minimum, identify the inspector, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

11 TEST CONTROL

11.1 Purpose

This section establishes requirements to ensure that necessary tests are performed and executed and test results are documented and evaluated. Tests associated with scientific investigations are addressed in QAM Section 3.

11.2 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. Procedures shall identify test prerequisites, measuring and test equipment requirements, and environmental conditions necessary to properly perform the test. Scientific notebooks can be used in place of test procedures provided they contain information equivalent to test procedures.

11.3 Test Records

Test records shall identify the type of test, item tested, date of test, tester or data recorder, and any observations and test results. Test records, certifications, reports, scientific notebooks, and any other quality records shall be maintained.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Purpose

This section establishes requirements for control, calibration, adjustment, repair, and records for measuring and test equipment used for quality-affecting data collection. Controls shall address the applicable elements of NQA–1–1986, Supplement 12S–1.

12.2 Selection of Measuring and Test Equipment

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. Procedures, instructions, or scientific notebooks shall identify the type of measuring and test equipment required based on the accuracy and precision requirements of the measurements to be taken.

12.3 Calibration Categories

12.3.1 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.

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

(1) A system of recall shall include notifying the user of calibration due dates and removing from service if the calibration interval has been exceeded.

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

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

(4) Calibrated measuring and test equipment and standards shall be tagged, labeled, or equivalently identified with a unique identifying number, the date of the last calibration, the date the next calibration is due, and the identity of the calibrating personnel or organization.

(5) A history of calibration and repair record shall be maintained for each calibrated item.

(6) Measuring and test equipment out of calibration shall be identified or segregated to prevent use until recalibrated.

12.3.2 Equipment Calibrated Before Use

(1) 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 or standardized before use and verified periodically throughout its use.

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

12.3.3 Equipment Not Requiring Calibration

(1) Equipment for which normal commercial practices provide sufficient accuracy does not require calibration. Appropriate care shall be exercised to verify that accuracy has not been degraded through breakage, lack of maintenance, 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 performing measurements or for equipment used for making qualitative performance checks or evaluations.

12.4 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 used as analytical standards shall be selected based on the purity and concentration accuracy requirements of the analysis to be performed. Chemical and reagent grades shall meet industry practices for purity and concentration accuracy.

12.5 Calibration Procedures

(1) Equipment and standards shall be calibrated in accordance with documented instructions. Manufacturer and industry standard methods may be used as long as sufficient details are provided in 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.

12.6 Out-of-Tolerance Evaluations

(1) Measuring or test equipment found out of tolerance upon recalibration shall be reported and dispositioned in accordance with Section 15. The out-of-tolerance condition shall be evaluated to determine whether measurements made since the last valid calibration were adversely affected.

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

12.7 Procurement of Calibration Work

Services for calibration and control of measuring and test equipment under scheduled recalibration may be obtained from SwRI or supplier calibration facilities having calibration systems accredited to ISO17025, General Requirements for the Compliance of Calibration and Testing Laboratories.

12.8 References

International Organization for Standardization, ISO17025, General Requirements for the Compliance of Calibration and Testing Laboratories.

13 HANDLING, STORAGE, AND SHIPPING

13.1 Purpose

This section establishes requirements for handling, storing, and shipping quality-affecting samples, materials, and equipment that are susceptible to damage or degradation. Controls shall address applicable elements of NQA–1–1986, Supplement 13S–1.

13.2 Determination of Requirement

Materials, samples, and equipment used in scientific investigations shall be controlled if susceptible to damage or degradation that may adversely affect the scientific investigation results. The PI shall identify potentially affected materials, samples, and equipment and specify appropriate controls.

13.3 Personnel Qualifications

Operators of special handling and lifting equipment shall be trained and qualified in use of the equipment whenever necessary for safety or to prevent damages.

13.4 Handling, Storage, and Shipping Procedures

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

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

14 INSPECTION AND TEST STATUS

14.1 Purpose

This section establishes requirements for identifying inspected or tested items to ensure required actions have been performed and preventing inadvertent use of items that have not passed required inspections or tests.

14.2 Status Identification

Quality-affecting items having been inspected or tested shall be identified in regard to their inspection or test status, either on the items or in documents traceable to the items. The status of the inspections or tests shall be identified to prevent the use of items that have not satisfactorily met the requirements.

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

Tags identifying nonconforming items shall be removed upon proper disposition of any nonconformance in accordance with Section 15.

15 NONCONFORMANCE CONTROL

15.1 Purpose

This section establishes requirements for identifying, segregating, reporting, dispositioning, and controlling the nonconformances of items, materials, software, and activities to specified requirements. Controls shall address the applicable elements of NQA–1–1986, Supplement 15S–1.

15.2 Identification

Methods shall be developed for legible and easily recognizable marking, tagging, or other means of identifying nonconforming items, materials, and software (items) in a manner that will not adversely affect their end use.

When identifying the item itself is impractical, suitable identification shall be applied, as appropriate, to the container, package, or a clearly identified segregated storage area may be used.

15.3 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.

15.4 Disposition

Controls for the review and disposition of nonconforming conditions shall include, as a minimum

(1) Proposing and approving the disposition of nonconforming characteristics

(2) Further processing, delivery, or use pending an evaluation and approved disposition

(3) Identifying individuals having responsibility and authority for the evaluation and disposition

(4) Assuring personnel who evaluate and determine dispositions have demonstrated competence in the area of evaluation, adequate understanding of the requirements, and access to pertinent background information

(5) Notifying the client of nonconformances identified in delivered products

15.4.1 Repaired or Reworked Item Inspection

Repaired and reworked items shall be reinspected and retested, as applicable, to the same criteria required of the original item unless the disposition of the nonconforming item has established documented, approved alternate acceptance criteria.

15.4.2 Notification of Affected Organizations

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

15.5 Trend Analysis

On an annual basis, nonconformance and other relevant information shall be evaluated for adverse trends. The results of the trend analysis shall be reported to management and used to initiate additional corrective action measures, as necessary.

16 CORRECTIVE ACTION

16.1 Purpose

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

16.2 Significant Conditions Adverse to Quality

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

(1) Repetitive occurrences of nonconformances of similar type and cause

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

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

16.3 Root Cause Determination and Recurrence Control

The root cause of significant conditions adverse to quality shall be determined. Corrective action shall be taken to address the root cause to preclude recurrence of the condition adverse to quality.

16.4 Stop Work Authority

Division management, staff, consultants, and subcontractors have the authority to stop work that does not conform to established requirements. The Director of QA has the authority to prevent or stop work in situations where continued processing or activities could result in recurring conditions adverse to quality. Sufficient corrective action shall be taken to preclude recurrence of the adverse condition before resuming activities.

16.5 Documentation and Reporting

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

16.6 Corrective Action Verification

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

16.7 Trend Analysis

On an annual basis, corrective action requests and other relevant information shall be evaluated for adverse trends. The results of the trend analysis shall be reported to management and used to initiate additional corrective action measures, as necessary.

17 RECORDS CONTROL

17.1 Purpose

This section identifies the types of records subject to controls and describes methods for collecting, storing, retaining, and retrieving records. Controls shall address the applicable elements of NQA–1–1986, Supplement 17S–1.

17.2 Identification and Validation of Records

Two classes of records providing evidence of activities affecting quality and subject to controls are generated as a result of Division activities: technical records, including supporting documentation for technical activities, and QA programmatic records. Developed procedures shall identify records and records categories. Prior to becoming records, documents shall be validated by authorized individuals attesting to their authenticity and completeness.

17.3 Control of Documents Prior to Becoming Records

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

17.4 Electronic Messages as Quality Records

The Division uses electronic systems to convey important messages or directions. Electronic messages that meet the criteria for QA records shall be in “hard paper copy” form. These e-mail QA records do not have to be “signed” because the security controls on individual staff computers preclude issuing e-mail with someone else’s user identification.

17.5 Quality Assurance Record Corrections

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.

17.6 Records Processing

(1) Validated records shall be controlled to ensure proper identification and retrieval.
(2) Records shall be examined upon receipt to confirm their reproducibility.
(3) Each record shall be assigned a unique records control number.
(4) A record index system shall be maintained to ensure timely retrieval.

17.7 Records Classification

(1) Permanent and nonpermanent records shall be maintained in accordance with developed procedures. Permanent records are those that

- 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.

(3) Certain types of records will be delivered to the Licensing Support Network (LSN), an HLW repository program records management system. Requirements related to the LSN are established in 10 CFR Part 2, Subpart J, and in applicable Division procedures.

17.8 Records Storage

Records facilities shall have restricted access and shall be constructed to minimize the risk of damage from winds, fires, floods, temperature and humidity extremes, and by insects, molds, or rodents. Developed procedures shall establish requirements regarding record retention, including location, and assigned responsibility.

18 AUDITS

18.1 Purpose

This section establishes requirements for preparing, scheduling, performing, reporting, and following up on completed audits. Controls shall address applicable elements of NQA–1–1986, Supplement 18S–1 and should follow the guidance of NQA–1–1986, Appendix 18A–1.

18.2 Audit Program

Developed procedures shall specify the methods by which planned and periodic audits are performed to verify compliance with all aspects of the QA program and determine its effectiveness. Surveillances shall be planned and performed in accordance with developed procedures.

18.3 Audit Schedules

Schedules shall be developed for internal (and supplier audits, when necessary) to provide adequate coverage and coordination with the QA activities being conducted. Schedules shall be revised as necessary to ensure coverage is maintained current.

The frequency of audits of activities shall be specified and shall be commensurate with the status and importance of the activity. At a minimum, the Division shall be audited on an annual basis.

Supplemental audits of specific subjects shall be performed when necessary.

18.4 Auditor Qualification

The qualification requirements of auditors shall be in accordance with NQA–1–1986, Supplement 2S–3. Lead auditor education and experience should follow the guidance of NQA–1–1986, Appendix 2A–3. Audit team members shall not have direct responsibilities in the areas being audited.

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.

For internal audits, the personnel responsible for the activity being audited shall not be involved in selecting the audit team. The audit team leader shall be responsible for verifying the qualifications of technical specialists used in the audit.

18.6 Audit Performance

Audit checklists shall be prepared for each audit and shall be used in performing the audit. Objective evidence shall be examined to an extent necessary to determine whether the elements of the quality program QAM are being implemented effectively.

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

18.7 Audit Reports

Audit reports shall be prepared and reviewed by the audit team leader. Distribution of the audit internal reports shall include, at a minimum, management of the audited activity and Division management.

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, as described in Section 16 of this QAM.

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

18.9 Followup Action

Followup action, including verifying the implementation of corrective action as scheduled and reauditing deficient areas, shall be taken.

18.10 Audit Records

Audit records shall include audit plans, reports, responses to findings, and records of completed corrective actions (See Section 16).

APPENDIX

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

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.

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.

Condition Adverse to Quality

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

Confirmatory Analysis/Testing

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

Controlled Document

A document that is prepared, reviewed, and approved in accordance with established implementing documents; subject to controlled distribution; and subject to a defined change process because of the importance to quality of the associated activities.

Corrective Action

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

DEMPS

Department of Earth, Material, and Planetary Sciences

Division

Geosciences and Engineering Division

Deviation

Departure from specified requirements.

Document

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

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 (i.e., an audit of a supplier).

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

(1) Irradiated reactor fuel.

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

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

Important to Licensing

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

Important to Safety

Those engineered structures, systems, components, and products essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body or any organ, exceeding the limits of 10 CFR Part 20, as defined in 10 CFR Part 63, Part 70, Part 71, Part 72, or in other applicable NRC regulations.

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 that are relied on for demonstrating that regulatory performance objectives will be met, as defined in 10 CFR Part 63.

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.

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 acquire data to verify conformance to specified requirements.

Nonconformance

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

Objective Evidence

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

Operating Procedures

Technical Operating Procedures (TOPs), Quality Assurance Procedures (QAPs), and Administrative Procedures (APs) that provide detailed methods and acceptance criteria necessary to accomplish an activity. Operating procedures are controlled documents.

Operations Plan

A document that describes the objectives; scope; technical approach; and management, fiscal, and general QA requirements for a contracted activity. Operations Plans are controlled documents.

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

ensure the work is impartially reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work.

Principal Investigator

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

Procedure

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

Procurement Document

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

Proposal

An offer for consideration or acceptance that describes the objectives; scope; technical approach; and management, fiscal, and general QA requirements.

Purchaser

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

Quality Assurance (QA)

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 product will comply with client requirements.

Quality Assurance Record

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

Qualification (Personnel)

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

Quality Planning

A process of identifying the implementing procedures and other requirements applicable to a specific task. Quality planning is performed for each new task and for significant revisions to tasks.

Qualified Procedure

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

Radioactive Material, Radioactive Waste, or "Waste"

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

Receiving

Taking delivery of an item at a designated location.

Repair

The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item 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

Those investigations or experimentation activities (planned and unplanned) 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 observation, identification, description, experimental study, or analysis of natural or man-made phenomena. NRC-related examples of scientific investigations include investigating the natural barriers or 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 facility

and the waste package. Non-NRC related examples include laboratory and site investigations, numerical analysis, technical assistance, and software and numerical model development.

Scientific Notebook

A document that may be used to provide a written record of the methods used and results of scientific investigations. These notebooks may be used when procedures have not been developed or are not appropriate, or where the exploratory nature of the work goes beyond what is addressed by established procedures or methods.

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—neither a requirement, recommendation, nor guideline. The words "is, are, will, must," and so on 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.

SwRI

Southwest Research Institute

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, materials, or data that require technical verification and 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 track, follow, or monitor 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 (Software)

The test and evaluation of completed software to ensure compliance with software requirements.

Verification

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