

U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

SOURCE MATRIX OF NRC REVIEW PLAN

VS

QUALITY ASSURANCE REQUIREMENTS DOCUMENT, REVISION 0


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NRC CRITERIA

1. The organization elements responsible for the QA Program are acceptable if:
 - 1.1 The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.
 - 1.2 DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.
 - 1.3 DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE Headquarters and the field office should be addressed.

QAR Introduction: Responsibility:

The PROGRAM Director retains responsibility for the total quality assurance program; ensures its development, implementation, and verification; and retains ultimate review and approval authority on matters pertaining to the implementation of quality assurance program requirements.

2 RESPONSIBILITY

2.1 Purpose

The organizational structure and the responsibility assignments shall be such that:

- (a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and
- (b) quality achievement is verified by persons or organizations not directly responsible for performing the work.

NQA-1 Supplement 1S-1

2.2 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefor.

3 MULTIPLE ORGANIZATIONS

3.1 Responsibility

Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.

QAR Introduction - Responsibility:

The PROGRAM Director retains responsibility for the total quality assurance program; ensures its development, implementation, and verification; and retains ultimate review and approval authority on matters pertaining to the implementation of quality assurance program requirements.

1.3 (continued)

QAR Section 1:

1.1 Quality Assurance Program Management

Each PROGRAM participant shall identify the quality assurance management position within their organization responsible for the establishment and implementation of their respective quality assurance programs. This quality assurance management position shall have the following characteristics:

- (a) An organizational position at the same or higher organizational level as the highest equivalent manager responsible for performing activities affecting quality
- (b) Knowledge and experience in the areas of quality assurance and management
- (c) The authority and responsibility to verify the adequacy and implementation effectiveness of the organizations and subtier organizations' quality assurance program
- (d) No other duties or responsibilities that are unrelated to quality assurance and that could prevent full attention to quality assurance matters
- (e) Sufficient freedom from cost and schedule considerations when opposed to quality considerations
- (f) Access to management at the next higher PROGRAM organizational level to identify, and obtain resolution to, unresolved quality concerns
- (g) Review and approval recommendation authority for quality assurance programs

1.2 Delegation of Work

When OCRWM or a Project Office delegates work to other PROGRAM participants, a qualified individual or organization from within the delegating office shall be designated as responsible for the quality of the delegated work.

1.4 DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.

1.5 Qualified individual(s) or organization element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.

1.6 Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.

NQA-1 Supplement 7S-1

5 SUPPLIER PERFORMANCE EVALUATION

The Purchaser of items and services shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f) below:

- (a) establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents;
- (b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements;
- (c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements;
- (d) identifying and processing necessary change information;
- (e) establishing method of document information exchange between Purchaser and Supplier;
- (f) establishing the extent of source surveillance and inspection activities.

These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for verification of quality achievement.

5.1 Extent of Activities

The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of Suppliers.

QAR Section 1

1.2 Delegation of Work

When OCRWM or a Project Office delegates work to other PROGRAM participants, a qualified individual or organization from within the delegating office shall be designated as responsible for the quality of the delegated work.

NQA-1 Supplement 1S-1

3 MULTIPLE ORGANIZATIONS

3.1 Responsibility

Where more than one organization is involved in the execution of

1.7 Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA Program and the lines of responsibility.

1.8 The QA organization is involved in the aspects of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.

activities covered by this Standard, the responsibilities and authority of each organization shall be clearly established and documented.

3.2 Interface Control

3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

3.2.2 Interface responsibilities shall be defined and documented.

MQA-1 Basic Requirement 1

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.

Note: Organization Charts are presented in the QAPD - none are included in QAR.

MQA-1 Basic Requirement 2

A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof. The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality. The program shall provide control over activities affecting quality to an extent consistent with their importance.

QAR Section 2

2.2 Planning

Participant's QA PROGRAMS shall include provisions for quality assurance program planning to be integrated and coordinated among participating organizations to provide consistency and completeness and to avoid duplication of effort. Quality assurance program planning is to include as a minimum the following elements:

- (a) Definition of activities
- (b) Assignment of quality levels to items and activities based on their importance to radiological safety, waste isolation, or other PROGRAM objectives
- (c) Selective application of appropriate quality assurance requirements and procedural controls within each quality level (that is, a graded approach) to items and activities

1.9 DOE and its prime contractors describe the QA responsibilities of each of the organizational elements noted on the organization charts.

1.10 DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position occupied by an individual with appropriate management and QA knowledge and experience, has the following characteristics:

- a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design engineering, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
- b. Has effective communication channels with other senior management positions.
- c. Has responsibility for approval of QA Manual(s), changes to, and interpretations thereof.

2.2 (continued)

- (d) Assignment of responsibilities for quality assurance program control and verification activities
- (e) Identification of the specific scientific or technical information to be collected, analyzed, or used for design, performance assessment, or site characterization
- (f) Identification of applicable technical and quality assurance program management control and verification activities
- (g) Identification of field, laboratory, and engineering procedures for sampling, testing, and analysis activities
- (h) Provisions for the identification of required quality assurance records

MQA-1 Basic Requirement 1

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.

MQA-1 Supplement 1S-1

3 MULTIPLE ORGANIZATIONS

3.1 Responsibility

Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.

Note: Organization charts are presented in the QAPD, not the QAR

MQA-1 Basic Requirement 1

Persons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

- (1) identify quality problems;
- (2) initiate, recommend, or provide solutions to quality problems through designated channels;
- (3) verify implementation of solutions; and
- (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that

1.10 (continued)

- d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

1.11 Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for: design, item 3.7; inspections, item 10.2; and test data evaluation, item 11.3 are outlined in these sections.

required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.

QAR Section 1

1.1 QUALITY ASSURANCE PROGRAM MANAGEMENT

Each PROGRAM participant shall identify the quality assurance management position within their organization responsible for the establishment and implementation of their respective quality assurance programs. This quality assurance management position shall have the following characteristics:

- (a) An organizational position at the same or higher organizational level as the highest equivalent manager responsible for performing activities affecting quality
- (b) Knowledge and experience in the areas of quality assurance and management
- (c) The authority and responsibility to verify the adequacy and implementation effectiveness of the organizations and subtier organizations' quality assurance program
- (d) No other duties or responsibilities that are unrelated to quality assurance and that could prevent full attention to quality assurance matters
- (e) Sufficient freedom from cost and schedule considerations when opposed to quality considerations
- (f) Access to management at the next higher PROGRAM organizational level to identify, and obtain resolution to, unresolved quality concerns
- (g) Review and approval recommendation authority for quality assurance programs

NOA-1 Basic Requirement 10

Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

NOA-1 Supplement 10S-1

2.1 Inspection personnel shall not report directly to the immediate

1.12 Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

- a. Identify quality problems.
- b. Initiate, recommend, or provide solutions through designated channels.
- c. Verify implementation of solutions.
- d. Stop unsatisfactory work.

Those persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

1.13 Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

1.14 Policies regarding the implementation of the QA program are documented and made mandatory.

supervisors who are responsible for performing the work being inspected.

NQA-1 Basic Requirement 1

Persons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

- (1) identify quality problems;
- (2) initiate, recommend, or provide solutions to quality problems through designated channels;
- (3) verify implementation of solutions; and
- (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

QAR Section 1

1.5 Stop Work Provisions

Provisions for issuing and lifting stop work orders shall be developed and implemented. The provisions shall include the following factors:

- (a) Criteria for stopping work and for lifting stop work orders
- (b) Authorities and responsibilities
- (c) Methodology for lifting stop work orders

QAR Section 1

1.3 Dispute Resolution

Provisions shall be made for the resolution of disputes involving quality arising from a difference of opinion at a given organizational level. These provisions shall include progressively elevating the dispute to the level of the PROGRAM Director if necessary.

QAR Introduction - General:

Well-defined quality assurance (QA) programs describing the set of management controls needed to achieve PROGRAM objectives are to be established and effectively implemented by all PROGRAM participants.

1.15 The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.

QAR Section 1

1.1 Quality Assurance Program Management

Each PROGRAM participant shall identify the quality assurance management position within their organization responsible for the establishment and implementation of their respective quality assurance programs. This quality assurance management position shall have the following characteristics:

- (a) An organizational position at the same or higher organizational level as the highest equivalent manager responsible for performing activities affecting quality
- (b) Knowledge and experience in the areas of quality assurance and management
- (c) The authority and responsibility to verify the adequacy and implementation effectiveness of the organizations and subtier organizations' quality assurance program
- (d) No other duties or responsibilities that are unrelated to quality assurance and that could prevent full attention to quality assurance matters
- (e) Sufficient freedom from cost and schedule considerations when opposed to quality considerations
- (f) Access to management at the next higher PROGRAM organizational level to identify, and obtain resolution to, unresolved quality concerns
- (g) Review and approval recommendation authority for quality assurance programs

2. Activities related to the QA program are acceptable if:

2.1 The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.

QAR Section 2

2.4 Quality Levels and Graded Quality Assurance

2.4.1 Classification of Quality Levels

A three-tier quality classification system shall be used as an aid in the decision process for selecting and applying appropriate quality assurance requirements. Methodologies for the classification of items and activities into the three quality levels shall be developed. The rationale for the classifications shall be documented. Wherever possible, the classification methodologies shall be technically based and shall include appropriate supporting failure analyses and risk assessments. Items and activities shall be identified and categorized as one of the following quality level classifications:

(a) Quality Level 1 (QL1). QL1 is the classification to be assigned to PROGRAM items and activities requiring application of the most stringent quality assurance requirements and procedural controls because of their importance to radiological health and safety or waste isolation. The assignment of QL1 imposes without allowance for deviation the applicable quality assurance requirements of 10 CFR 60, Subpart G; and ANSI/ASME NQA-1-1986b. OCRUM and each Project Office shall establish a Q-List and a Quality Activities List.

2.1 (continued)

QAR Section 2.4.1 (continued):

- (b) **Quality Level 2 (QL2).** QL2 is the classification to be assigned to PROGRAM items and activities requiring application of additional quality assurance requirements and procedural controls because of their importance to the success of the PROGRAM. The assignment to QL2 imposes the appropriate quality assurance requirements of ANSI/ASME NQA-1-1986b. QL2 will be assigned as a minimum to the following categories:
- (1) **Items and activities designed to minimize nonradiological health and safety hazards to the public and PROGRAM workers**
 - (2) **Items and activities designed to protect workers from radiological hazards exceeding the limits of 10 CFR 20**
 - (3) **Items whose failure, omission, or degradation could affect the operational reliability, maintainability, and performance of engineered structures, systems, and components**
 - (4) **Items and activities of special programmatic importance designated as such by the appropriate director or program manager**
- (c) **Quality Level 3 (QL3).** QL3 is the classification to be assigned to PROGRAM items and activities requiring routine quality assurance requirements and procedural controls to assure proper performance or service. The assignment of QL3 imposes the use of routine managerial, administrative, scientific, engineering, industry, and laboratory practices.

2.2 The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High Level Waste Management."

QAR Section 3:

3.2 Computer Software Control

Computer software used to calculate or develop data in support of a license application shall be verified, validated, and documented.

For the purpose of this document, computer software verification is defined as the process that demonstrates that the computer software correctly performs its stated capabilities and functions, whereas computer software validation is defined as the process that demonstrates that the mathematical model embodied in the computer software is a correct representation of the process or system for which it is intended.

3.2.1 Each PROGRAM participant shall control computer software development, testing, maintenance, and configuration management. The description shall include:

- (a) Criteria for application of the requirements of this document
- (b) Methods to be used to develop functional performance requirements, to translate those requirements into a detailed design, and to implement that design in computer software
- (c) Documentation to be prepared, reviewed, and maintained during computer software design, development, implementation, test, and use
- (d) Methodology for establishing computer software baselines and baseline changes and for tracking changes throughout the life of the computer software
- (e) Process to be used for verification and validation of computer software
- (f) Procedure for reporting and documenting computer software discrepancies, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action

3.2.2 Computer software shall be placed under configuration control as each baseline element is approved. Baseline elements shall be uniquely identified to assure positive control of revisions and to provide traceability between the documentation and the computer software version.

2.2 (continued)

- 3.2.3** Changes to computer software shall be systematically evaluated, coordinated and approved to assure that the impact of change is carefully assessed prior to updating the baseline. Information concerning approved changes shall be transmitted to all users or affected organizations. Changes to computer software shall be subjected to the same level of approval, verification, and validation as the original computer software.
- 3.2.4** As applicable, computer software documentation shall include the following elements:
 - (a)** A description of the computer software development history that identifies specific computer software versions and other basic information about the evolution of the computer software.
 - (b)** An explanation of the mathematical model(s) and derivation of the numerical methods used in the computer software design. Physical and mathematical assumptions on which the computer software is based shall be listed along with an explanation of the capabilities and limitations inherent in the computer software.
 - (c)** Instructions enabling users to run the computer software and a description of anticipated errors with user responses.
 - (d)** A description of formal reviews and verification and validation testing.
- 3.2.5** Computer software testing shall be performed for those inputs and conditions necessary to exercise the computer software to assure that unintended functions that would degrade the computer software will not be performed. The documentation shall include test boundary conditions and provide suitable benchmarks or sample problems.
- 3.2.6** If parameters that control experiments are too poorly defined to allow for validation, an independent assessment shall be performed to determine the degree of computer software validation achievable.
- 3.2.7** Computer software that was not developed under a documented quality assurance program meeting the requirements of Subsection 3.2.1 may be qualified for use provided that the computer software is verified and validated, a baseline is established and controlled, and applicable documentation is prepared to support its use.

2.3 Provisions are established to assure that technical and quality assurance procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official.

2.4. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements. (Quality related refers to quality of items "important to safety" or "important to waste isolation.")

2.5 The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities. This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR Part 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

QAR Section 2

2.1 Quality Assurance Program

PROGRAM participants shall develop quality assurance program documents that address quality assurance requirements applicable to their respective PROGRAM scope of work. Quality assurance program documents (hereafter referred to as the QA PROGRAM) consist of a description of the quality assurance program and detailed technical and quality assurance administrative procedures. The QA PROGRAM shall meet the requirements established by the document. The quality assurance program descriptions (or QA Plans) shall be reviewed and approved by line management of the next higher PROGRAM organizational level in a timely manner. PROGRAM-participant QA organizations shall review and make recommendations to line management concerning the approval of lower-tier quality assurance program descriptions (or QA Plans).

Also refer to DIRECTOR, OCRWM's QA Policy Statement

QAR Section 2

2.1 Quality Assurance Program

PROGRAM participants shall develop quality assurance program documents that address quality assurance requirements applicable to their respective PROGRAM scope of work. Quality assurance program documents (hereafter referred to as the QA PROGRAM) consist of a description of the quality assurance program and detailed technical and quality assurance administrative procedures. The QA PROGRAM shall meet the requirements established by the document. The quality assurance program descriptions (or QA Plans) shall be reviewed and approved by line management of the next higher PROGRAM organizational level in a timely manner. PROGRAM-participant QA organizations shall review and make recommendations to line management concerning the approval of lower-tier quality assurance program descriptions (or QA Plans).

WQA-1 Basic Requirement 2

The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

2.5 (continued)**QAR Section 2****2.4 QUALITY LEVELS AND GRADED QUALITY ASSURANCE****2.4.1 Classification of Quality Levels**

A three-tier quality classification system shall be used as an aid in the decision process for selecting and applying appropriate quality assurance requirements. Methodologies for the classification of items and activities into the three quality levels shall be developed. The rationale for the classifications shall be documented. Wherever possible, the classification methodologies shall be technically based and shall include appropriate supporting failure analyses and risk assessments. Items and activities shall be identified and categorized as one of the following quality level classifications:

- (a) Quality Level 1 (QL1). QL1 is the classification to be assigned to PROGRAM items and activities requiring application of the most stringent quality assurance requirements and procedural controls because of their importance to radiological health and safety or waste isolation. The assignment of QL1 imposes without allowance for deviation the applicable quality assurance requirements of 10 CFR 60, Subpart G; and ANSI/ASME NQA-1-1986b. OCRWM and each Project Office shall establish a Q-List and a Quality Activities List.
- (b) Quality Level 2 (QL2). QL2 is the classification to be assigned to PROGRAM items and activities requiring application of additional quality assurance requirements and procedural controls because of their importance to the success of the PROGRAM. The assignment to QL2 imposes the appropriate quality assurance requirements of ANSI/ASME NQA-1-1986b. QL2 will be assigned as a minimum to the following categories:
 - (1) Items and activities designed to minimize nonradiological health and safety hazards to the public and PROGRAM workers
 - (2) Items and activities designed to protect workers from radiological hazards exceeding the limits of 10 CFR 20
 - (3) Items whose failure, omission, or degradation could affect the operational reliability, maintainability, and performance of engineered structures, systems, and

components

- (4) Items and activities of special programmatic importance designated as such by the appropriate director or program manager

(c) Quality Level 3 (QL3). QL3 is the classification to be assigned to PROGRAM items and activities requiring routine quality assurance requirements and procedural controls to assure proper performance or service. The assignment of QL3 imposes the use of routine managerial, administrative, scientific, engineering, industry, and laboratory practices.

2.4.2 Graded Quality Assurance

Management controls shall be selectively applied. The selective application and the degree of application of the quality assurance requirements assigned to each item and activity shall be commensurate with the following factors:

- (a) Consequence of failure
- (b) Importance of data
- (c) Complexity of function
- (d) Reliability of process
- (e) Reproducibility of results
- (f) Uniqueness of product
- (g) Degree of functional product demonstration
- (h) Degree of standardization
- (i) History of quality
- (j) Impact on schedule or cost or both
- (k) Necessity of special controls or processes
- (l) Significance to licensing process

2.6 Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities will be met.

2.7 A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

- a. Frequent contact with program status through reports, meetings, and/or audits.
- b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.

QAR Introduction: Purpose and Applicability

This document incorporates and supplements applicable quality assurance program requirements from 10 CFR 60; 10 CFR 71; 10 CFR 72; 10 CFR 50, Appendix B; NQA-1; and DOE Orders. As such, only this document and the documents referenced specifically within 18 sections of this document need be referenced for all OCRWM's quality assurance programmatic requirements. However, this document has not incorporated the technical implementation requirements of DOE Orders and applicable NUREGs that are to be followed when implementing the OCRWM quality assurance program.

NQA-1 has been chosen as the basic document for the OCRWM quality assurance program requirements because DOE Order 5700.6B, Quality Assurance has endorsed NQA-1 as the preferred standard for quality assurance requirements for the nuclear area and the Nuclear Regulatory Commission (NRC) in Regulatory Guide 1.28 has found that the requirements of NQA-1 are acceptable for use in quality assurance programs for reactor design and construction.

QAR Section 2

2.1 Quality Assurance Program

PROGRAM participants shall develop quality assurance program documents that address quality assurance requirements applicable to their respective PROGRAM scope of work. Quality assurance program documents (hereafter referred to as the QA PROGRAM) consist of a description of the quality assurance program and detailed technical and quality assurance administrative procedures. The QA PROGRAM shall meet the requirements established by the document.

NQA-1 Basic Requirement 2

Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation. QAR Section 2

QAR Section 2

2.7 Management Assessment

Independent management assessments by persons above or outside the quality assurance organization shall be conducted at least annually by, or at the direction of, the highest management position identified in each PROGRAM-participant's organization. These management assessments shall evaluate as a minimum the following program aspects:

- (a) Effectiveness of the quality assurance program
- (b) Adequacy of planning and procedural controls

2.7 (Continued)

- (d) Adequacy of organizational structure and staffing to implement the quality assurance program
- (e) Adequacy of the indoctrination and training program
- (f) Adequacy of the quality assurance management information tracking, evaluation, and reporting system

2.8 Quality Assurance Management-Information Reporting and Tracking

2.8.1 PROGRAM participants shall report, disseminate, and track the following types of quality-related.

- (a) Status of development and implementation of the quality assurance program
- (b) Status of resolution of significant conditions adverse to quality, issues, and trends
- (c) Summary of management overview results (Exemplary practices shall be reported but need not be tracked).

2.8.2 Quality assurance management information shall be reported to the appropriate level of management and the next higher PROGRAM organizational level at least quarterly.

2.8 Indoctrination, training, and qualification programs are established such that:

- a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.
- b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.
- c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.
- d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.
- e. Qualified personnel are certified in accordance with applicable codes and standards.

NOA-1 Basic Requirement 2

The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

QAR Section 2

2.5.1 Supplement 2S-1 shall only apply to personnel who conduct inspections and testing activities to verify conformance of an item to specified requirements for the purpose of acceptance and to demonstrate that items will perform satisfactorily in service.

2.5.2 Supplement 2S-4 to NOA-1 shall apply except that Paragraph 2 is amplified with the following requirements:

- (a) Management of each PROGRAM-participant organization shall analyze each job position to determine the quality-affecting task responsibilities of the position. The analysis shall document education and experience prerequisites for each position involved in the performance or verification of activities affecting quality.

2.8 (continued)

- (b) Personnel selected to perform or verify activities affecting quality shall have education, experience, and training commensurate with the minimum requirements specified. Relevant education and experience shall be verified. The capabilities of an individual shall be based upon an evaluation of education and experience and compared to those qualification requirements established for the position. Management shall monitor the performance of personnel doing work affecting quality and, at least annually, determine the need for retraining or reassignment.

Note: The following NQA-1 Supplements are also applicable to this requirement.

NQA-1-Supplement 2S-1	Qualification of Inspection and Test Personnel
NQA-1-Supplement 2S-2	Qualification of Nondestructive Examination Personnel
NQA-1-Supplement 2S-3	Qualification of Quality Assurance Audit Personnel
NQA-1-Supplement 2S-4	Personnel Indoctrination and Training

3. Activities related to design control are acceptable if:

3.1 The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and

NQA-1 Supplement S-1:

Design Input. Those criteria, parameters, bases, or other design requirements upon which detailed final design is based.

Design Output. Documents, such as drawings, specifications, and other documents, defining technical requirements of structures, systems, and components.

Design Process. Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Design Change. Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Final Design. Approved design output documents and approved changes thereto.

analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954.

3.2 The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities as described in 3.1. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.

QAR Glossary:

Design - (noun) The totality of the design outputs for a structure, system, or component. (verb) The act of defining technical requirements for a structure, system, or component.

Design Activities - Activities related to the design process including data collection and analyses activities that are used in supporting design development and verification.

MQA-1 Basic Requirement 3

The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled.

MQA-1 Supplement 3S-1**2 DESIGN INPUT**

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.

3 DESIGN PROCESS

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented and controlled.

NQA-1 Supplement 3S-1

Section 3 (continued):

Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall:

- (a) be relatable to the design input by documentation in sufficient detail to permit design verification; and
- (b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.2 (continued):

Performance requirements are specified for repository system components to support:

- (a) identification of which items are important to waste isolation

QAR Section 2

2.4.1 Classification of Quality Levels

A three-tier quality classification system shall be used as an aid in the decision process for selecting and applying appropriate quality assurance requirements. Methodologies for the classification of items and activities into the three quality levels shall be developed. The rationale for the classifications shall be documented. Wherever possible, the classification methodologies shall be technically based and shall include appropriate supporting failure analyses and risk assessments. Items and activities shall be identified and categorized as one of the following quality level classifications:

- (a) Quality Level 1 (QL1). QL1 is the classification to be assigned to PROGRAM items and activities requiring application of the most stringent quality assurance requirements and procedural controls because of their importance to radiological health and safety or waste isolation. The assignment of QL1 imposes without allowance for deviation the applicable quality assurance

requirements of 10 CFR 60, Subpart G; and ANSI/ASME NQA-1986b. OCRWM each Project Office shall establish a Q-List and a Quality Activities List.

3.2 (continued):

Performance requirements are specified for repository system components to support:

- (b) establishment of a graded QA approach

QAR Section 2

2.4.2 Graded Quality Assurance

Management controls shall be selectively applied. The selective application and the degree of application of the quality assurance requirements assigned to each item and activity shall be commensurate with the following factors:

- (a) Consequence of failure
- (b) Importance of data
- (c) Complexity of function
- (d) Reliability of process
- (e) Reproducibility of results
- (f) Uniqueness of product
- (g) Degree of functional product demonstration
- (h) Degree of standardization
- (i) History of quality
- (j) Impact on schedule or cost or both
- (k) Necessity of special controls or processes
- (l) Significance to licensing process

3.2 (continued):

Performance requirements are specified for repository system components to support:

- (c) establishment of data gathering and analysis needs.

QAR Section 3

3.5.1 Control of Scientific Investigations

Scientific investigations shall be defined, controlled, and verified. Process variables affecting scientific investigations shall be measured and controlled. Variables that affect interrelated scientific investigations shall be identified, documented, and controlled in each investigation.

The scientific notebook system and the technical procedures system are two approaches that may be used to control scientific investigations activities. The scientific notebook system may be used by qualified individuals who are required to use a high degree of professional judgement or trial and error methods for the task.

The technical procedures system shall be used by qualified personnel to perform repetitive work that does not include the use of professional judgement nor trial and error methods. Technical procedures are required when it is not possible to deviate from a strict sequence of actions without endangering the validity of the results. Technical procedures shall be reviewed for technical adequacy and approved by qualified persons other than those who prepared the procedures. Changes to technical procedures for conducting scientific investigations shall be reviewed and approved by qualified persons familiar with the procedures and the purposes of the investigations to ensure that the objectives of the investigations are fulfilled. Activities to develop new methods or procedures for conducting scientific investigations or critical processes shall be documented. Results shall be reviewed for adequacy and approved by qualified persons prior to use of the procedures to collect data.

3.5.2 Planning

The intended use of data shall be documented as part of the planning for scientific investigations. Any alternate use of the data shall be evaluated for appropriateness and the justification documented. Planning shall assure the compatibility of scientific investigations with any conceptual or mathematical models used at each applicable stage. Planning shall establish provisions for the evaluation of data quality to assure that data generated is valid comparable, complete, representative, precise, and accurate. Known sources of error and uncertainty and input data that is suspect or whose quality is beyond the control of the performing organizations shall be identified. These measures shall include or reference provisions for assuring that prerequisites for the given scientific investigation have been met, that adequate instrumentation is available and used, that necessary monitoring including witness or hold points is performed, and that suitable environmental conditions are maintained.

3.2 (Continued):

3.5.2 Planning (continued):

The following prerequisites shall be considered: calibrated instrumentation; appropriate equipment; trained personnel; readiness of facilities, equipment, supplies, and items or samples; suitable environmental conditions; provision for acquisitions and recordings of data; and disposition of facilities after completion of scientific investigation activities.

The range, accuracy, and precision of equipment used for scientific investigations shall be specified in order to be commensurate with requirements. In developing quality assurance requirements for equipment, consideration shall be given to whether proper performance of a scientific investigation can be determined during or after the scientific investigation (that is, whether failure or malfunction of equipment can be detected). Where requirements are found to be necessary, special quality or performance verification requirements shall be established and described to govern the use of the equipment.

Scientific investigations shall be performed in accordance with nationally recognized standards (for example, ASTM) where available. Standards used without modification require documentation by reference only. If deviation from standards or establishment of specially prepared procedures is deemed appropriate, the modifications or new methods shall be documented in sufficient detail to be repeatable and shall be evaluated, justified, and approved.

3.5.3 Data Collection and Analysis

Equipments and methods used to obtain and analyze data shall be verified to assure technical soundness and proper selection. Data collection and analysis shall be controlled by measures that provide sufficient detail to allow the processes to be repeated by an individual of comparable education or training to the person originally conducting the task. Where appropriate, verifications shall be performed using recognized methods.

Data transfer and reduction controls shall be established to assure data transfer is error free or within a prescribed permissible error rate, to assure that information is not lost in transfer and that the input is completely recoverable from the output. All processes that change either the form or expression or quantity of data, values, or number of data items (data reduction) shall be controlled by prescribed methods that allow verification of the conversion process.

3.3 Organizational responsibilities are described for preparing, reviewing, approving, verifying and validating design and design information documents.

3.5.4 Use of Data

Data collection and analysis shall be technically reviewed by qualified individuals other than those who performed the scientific investigation. Questions shall be resolved before the results are used as a baseline. Unreviewed data and data with unresolved questions shall be clearly identified when used or reported. Uncertainty limits shall be assigned to the data prior to use. Data collected should be reported so as to relate it to information needs and issue resolution.

3.5.5 Data Identification and Traceability

All data shall be recorded so as to be clearly identifiable and traceable to the source from which it was generated. Identification and traceability shall be maintained throughout the needed lifetime of the data.

Data found to be erroneous, rejected, superseded, or otherwise unsuitable for the intended use shall be controlled and dispositioned. Controls shall include the identification and segregation of unsuitable data to avoid inadvertent use. The disposition of unsuitable data shall be justified and documented.

MQA-1 Supplement 3S-1

3. Design Process

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.

4. Design Verification

The responsible design organization shall identify and document the particular design verification method(s) used. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification.

3.3 (Continued):

3.4 Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

QAR Section 3

3.3.3 Technical reviews shall be performed by individuals with sufficient technical knowledge of the area under review to be able to render an opinion. Individuals shall be independent of those who performed the work.

3.4.4 Peer reviews shall be performed by personnel having an appropriate spectrum of technical skills in the subject matter to be reviewed. Peer reviewers shall have comparable knowledge in the subject matter to the person who conducted the original work. Peer reviewers shall have no direct involvement as a performer, supervisor, technical reviewer, or advisor in the work being reviewed. Peer reviewers shall have sufficient freedom from outside influences to ensure the work is impartially reviewed.

QAR Section 3

3.1 Design Error and Deficiency Control

Errors and deficiencies in approved design and design information documents shall be documented and corrective action shall be taken in accordance with Section 16 or Section 18 as appropriate.

QAR Section 3

3.5.5 Data found to be erroneous, rejected, superseded, or otherwise unsuitable for the intended use shall be controlled and dispositioned. Controls shall include the identification and segregation of unsuitable data to avoid inadvertent use. The disposition of unsuitable data shall be justified and documented.

3.5 Interface controls among organizations or groups involved in design development and other design activities are described.

3.6 Procedures require that design drawings, specifications, criteria and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.

NOA-1 Supplement 3S-1

6 INTERFACE CONTROL

Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

QAR Glossary:

Document - (noun) Any written, printed, recorded, pictorial, or processed information describing, defining, specifying, prescribing, reporting, or certifying activities, requirements, procedures, data, or results.

NOA-1 Basic Requirement 6

Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

Note: QAR does not require design documents to be reviewed by QA controlled document.

3.7 Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design, (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform verification, provided: (a) the supervisor is the only technically qualified individual; (b) the need is individually documented and approved in advance with the concurrence of the quality assurance managers. It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.

MOA-1 Supplement 3S-1

Section 4

Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification.

QAR Section 3

3.3.3 Technical reviews shall be performed by individuals with sufficient technical knowledge of the area under review to be able to render an opinion. Individuals shall be independent of those who performed the work.

3.4.4 Peer reviews shall be performed by personnel having an appropriate spectrum of technical skills in the subject matter to be reviewed. Peer reviewers shall have comparable knowledge in the subject matter to the person who conducted the original work. Peer reviewers shall have no direct involvement as a performer, supervisor, technical reviewer, or advisor in the work being reviewed. Peer reviewers shall have sufficient freedom from outside influences to ensure the work is impartially reviewed.

NOTE: Approval by the QA manager to allow the use of a designer's supervisor to perform design verification is not required by the QAR.

3.8 For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review, should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.

OAR Section 3**3.4 PEER REVIEWS**

3.4.1 A peer review shall be performed when the adequacy of information or the suitability of procedures and methods cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices. A peer review shall be considered when:

- (a) Critical interpretations or decisions will be made in the face of significant uncertainty including the planning for data collection, research or exploratory testing
- (b) Decisions or interpretations will be made having significant impact on performance assessment conclusions
- (c) Novel or beyond the state-of-the-art testing, methods, procedures, or analyses are, or will be used
- (d) Detailed technical criteria or standard industry procedures do not exist or are being developed
- (e) Results of tests are not reproducible or repeatable
- (f) Data or interpretations are ambiguous
- (g) Data adequacy is questionable (for example, data may not have been collected in conformance with an established quality assurance program)

3.4.2 A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

3.4.3 A peer review plan shall be prepared prior to initiating a peer review. The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce the peer review report.

3.4.4 Peer reviews shall be performed by personnel having an appropriate spectrum of technical skills in the subject matter to be reviewed. Peer reviewers shall have comparable knowledge in the subject matter to the person who conducted the original work. Peer reviewers shall have no direct involvement as a performer, supervisor, technical reviewer, or advisor in the work being reviewed. Peer reviewers shall have sufficient freedom from outside influences to ensure the work is impartially reviewed.

3.4.5 The results of peer reviews shall be documented and, as a minimum, shall address the suitability of the work being reviewed for intended purpose and for conformance to specified requirements. Minority positions shall be documented. The peer review report shall identify the reviewers and document their qualifications and experience in a manner that provides sufficient information to demonstrate the requirements for technical coverage and independence have been met. The investigators performing the work under review shall document their disposition of, and justify any departures from the peer review group's conclusions and recommendations. When appropriate, peer review reports shall address the following subjects:

- (a) Validity of assumptions**
- (b) Alternate interpretations**
- (c) Uncertainty of results and consequences if wrong**
- (d) Appropriateness and limitations of methodology and procedures**
- (e) Adequacy of application**
- (f) Accuracy of calculations**
- (g) Validity of conclusions**
- (h) Adequacy of requirements**

3.9 The responsibilities of the verifier(s), the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

NQA-1 Supplement 3S-1

4 DESIGN VERIFICATION

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this Standard.

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release of procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.

4.1 Extent of Design Verification

The extent of the design verification required is a function of the importance to the safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

3.9 (continued)

NQA-1 Supplement 3S-1

4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

4.2.1 Design Reviews. These are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable, (a) through (f) below will be addressed.

- (a) Were the design inputs correctly selected?
- (b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- (c) Was an appropriate design method used?
- (d) Were the design inputs correctly incorporated into the design?
- (e) Is the design output reasonable compared to design inputs?
- (f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

4.2.2 Alternate Calculations. These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

4.2.3 Qualification Tests. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.

3.10 Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affect groups or individuals.

4. Activities related to procurement document control are acceptable if:

4.1 Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors, and consultants to provide an acceptable quality assurance program.

MQA-1 Supplement 3S-1

5 CHANGE CONTROL

Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the structure, system, or component are still valid. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization which could be the Owner's engineering organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

QAR Section 4

4.1 Review

Procurement documents shall be reviewed by PROGRAM-participant QA representatives to assure that applicable quality assurance requirements are included.

MQA-1 Supplement 4S-1

2.3 Quality Assurance Program Requirements

Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard. The extent of the program required shall depend upon the type and use of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtler procurement documents.

4.2 Organizational responsibilities are described for 1) procurement planning, 2) the preparation, review, approval, and control of procurement documents, 3) supplier selection, 4) bid evaluations, and 5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

NOA-1 Supplement 7S-1

2. PROCUREMENT PLANNING

Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. Planning shall determine the following:

- (a) what is to be accomplished;
- (b) who is to accomplish it;
- (c) how it is to be accomplished;
- (d) when it is to be accomplished.

3. SUPPLIER SELECTION

Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability.

4. BID EVALUATION

Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

- (a) technical considerations
- (b) quality assurance requirements
- (c) Supplier's personnel
- (d) Supplier's production capability
- (e) Supplier's past performance
- (f) alternates
- (g) exceptions

Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation.

QAR Section 2.1

The quality assurance program descriptions (or QA Plans) shall be reviewed and approved by line management of the next higher PROGRAM organizational level in a timely manner. PROGRAM-participant QA organizations shall review and make recommendations to line management concerning the approval of lower-tier quality assurance program descriptions (or QA Plans).

QAR Section 4.1

Procurement documents shall be reviewed by PROGRAM-participant QA representatives to assure that applicable quality assurance requirements

5. Activities related to instructions, procedures, and drawings are acceptable if:

5.1 Organizational responsibilities are described for assuring that quality-related activities are 1) prescribed specified in instructions, procedures, and drawings, and 2) accomplished through implementation of these documents. The documents should be verified and approved as described in Section 3.

5.2 Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality-related activities have been satisfactorily accomplished.

6. Activities related to document control are acceptable if:

6.1 The scope of the document is described, and the types of controlled documents are identified.

are included.

NQA-1 Basic Requirement 1

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.

NQA-1 Basic Requirement 5

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances.

NQA-1 Supplement 6S-1

2. Document Preparation, Review, Approval, and Issuance

The control system shall be documented and shall provide for identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.

NQA-1 Basic Requirement 5

These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

NQA-1 Basic Requirement 6

The preparation, issue and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed.

NQA-1 Supplement 6S-1

Section 1

The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings.

The term document control used throughout this Supplement is defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

6.2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality-related aspects.

6.3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.

Section 2(a)

The control system shall be documented and shall provide for identification of documents to be controlled and their specific distribution.

NOA-1 Basic Requirement 6

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

NOA-1 Supplement 6S-1

2 DOCUMENTATION PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

The control system shall be documented and shall provide for (a) through (c) below:

- (a) identification of documents to be controlled and their specified distribution;
- (b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;
- (c) review of documents for adequacy, completeness, and correctness prior to approval and issuance.

QAR Section 2.1

PROGRAM-participant QA organizations shall review and make recommendations to line management concerning the approval of lower-tier quality assurance program descriptions (or QA Plans).

QAR Section 6

6.1 Control

Each PROGRAM participant shall assure that correct and applicable documents are available at the location where PROGRAM work activities will be performed prior to commencing the work.

6.4 Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revision at work areas in a timely manner.

6.5 A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.

6.6 When documents which require verification are released prior to verification, they are so identified and controlled.

QAR Section 6

6.1 Control

Each PROGRAM-participant shall assure correct and applicable documents are available at the location where PROGRAM work activities will be performed prior to commencing work.

6.3 Controlled Documents

Certain documents within the quality assurance program shall be identified as controlled documents. Control measures shall be established for controlled documents that are in addition to the normal controls of Section 6. These additional control measures include the development of a controlled documents list, the establishment of a receipt acknowledgement system, and the development of an objective, obsolete- or suspended- document control system.

NOA-1 Supplement 6S-1

Section 2(a)

The control system shall be documented and shall provide for identification of documents to be controlled and their specified distribution.

6.3 Controlled Documents

Certain documents within the quality assurance program shall be identified as controlled documents. Control measures shall be established for controlled documents that are in addition to the normal controls of Section 6. These additional control measures include the development of a controlled documents list, the establishment of a receipt acknowledgement system, and the development of an objective, obsolete- or suspended- document control system.

NOA-1 Supplement 3S-1

Section 4

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.

7. Activities related to control of purchased material, equipment, and services are acceptable if:

7.1 Organizational responsibilities are described for the control of purchased material, equipment, and services.

7.2 Procedures governing procurement of items or services including appropriate QA organization participation provide for:

- a) Evaluation and selection of suppliers**
- b) Verification of supplier's activities**
- c) Receiving inspections**

NOA-1 SUPPLEMENT 7S-1

Section 2

Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities.

NOA-1 SUPPLEMENT 7S-1

3.1 Source Evaluation and Selection

The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.

Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability.

Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more of (a) through (c) below:

(a) evaluation of the Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The Supplier's history shall reflect current capability.

(b) Supplier's current quality records supported by documented qualitative information which can be objectively evaluated;

(c) Supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.

7.2 (continued)

NOA-1 SUPPLEMENT 75-1

5. SUPPLIER PERFORMANCE EVALUATION

The Purchaser of items and services shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f) below:

(a) Establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents;

(b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements;

(c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements;

(d) identifying and processing necessary change information;

(e) establishing method of document information exchange between Purchaser and Supplier;

(f) establishing the extent of source surveillance and inspection activities.

These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for verification of quality achievement.

5.1 EXTENT OF ACTIVITIES

The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of Suppliers.

7.3 The organization providing materials, equipment, or services furnishes the following records to the purchaser:

- a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.
- b. Documentation identifying any procurement requirements that have not been met.
- c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

The procedure for review and acceptance of these documents should be described in the purchaser's QA program.

NQA-1 SUPPLEMENT 7S-1**8.2.3 Receiving Inspection**

When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall be performed in accordance with established procedures and inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanness. Receiving and cleanness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

NQA-1 SUPPLEMENT 7S-1**8.2.1 Certificate of Conformance.**

When a Certificate of Conformance is used, the minimum criteria of (a) through (f) below shall be met.

(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.

(b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.

(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.

7.3 (continued)

(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

9 CONTROL OF SUPPLIER NONCONFORMANCES

The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement documentation requirements.

These methods shall contain provision for (a) through (e) below:

(a) evaluation of nonconforming items;

(b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification.

QA-1 Supplement 7S-1

Section 9 (continued):

Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:

- (1) technical or material requirement
 - (2) requirement in Supplier documents, which has been approved by the Purchaser, is violated;
 - (3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework;
 - (4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired;
- (c) Purchaser disposition of Supplier recommendation;
(d) verification of the implementation of the disposition;
(e) maintenance of records of Supplier-submitted nonconformances.

7.4 Supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

7.5 In developing quality assurance requirements for data collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment.

NOA-1 Supplement 7S-1

Section 8.2.1 (f)

Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

QAR Section 3

3.5.2 Planning

The range, accuracy, and precision of equipment used for scientific investigations shall be specified in order to be commensurate with requirements. In developing quality assurance requirements for equipment, consideration shall be given to whether proper performance of a scientific investigation can be determined during or after the scientific investigation (that is, whether failure or malfunction of equipment can be detected). Where requirements are found to be necessary, special quality or performance verification requirements shall be established and described to govern the use of the equipment.

8. Activities related to sample and hardware identification and control are acceptable if:

8.1 Controls are established and described to identify and control samples. The description should include organizational responsibilities.

8.2 Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.

8.3 Identification of samples and hardware can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.

8.4 Correct identification of samples is verified and documented prior to release for use or analysis.

QAR Section 8

8.1 SAMPLES

Samples shall be identified and controlled in a manner consistent with the samples' intended uses. Such controls shall define the responsibilities including interfaces between technical specialties and organizations for collection, identification, and traceability of samples (including archival samples); for test allocation; for disposition of samples; and for generation of associated records.

QAR Section 8

8.1.1 Sample Identification

Samples shall be identified by placing identification directly on the samples when possible, on the samples' containers, or on labels or tags attached to the samples or the samples' containers. Sample identification shall be verified and documented prior to release for testing or analysis.

8.1.2 Sample Traceability

Identification systems shall assure traceability of samples to the appropriate source, requirement, or use document. Traceability of samples from initial acquisition through final disposition is required. Measures shall be taken to preclude the use of samples that cannot be identified.

QAR Section 8

8.1.1 Sample Identification

Samples shall be identified by placing identification directly on the samples when possible, on the samples' containers, or on labels or tags attached to the samples or the samples' containers. Sample identification shall be verified and documented prior to release for testing or analysis.

9. Activities related to control of special processes are acceptable if:

9.1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantages, is provided.

9.2 Organizational responsibilities including those for the QA organization are described for qualification of personnel.

9.3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.

9.4 Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9.5 Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.

MQA-1 Supplement S-1

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

QAR Section 9

9.2 List of Special Processes

Each PROGRAM participant shall provide a list of special processes that they will perform or be responsible for.

MQA-1 Supplement 9S-1

3.1 Responsibility

It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.

MQA-1 Supplement 9S-1

3.1.1 Qualification of personnel, procedures, and equipment shall comply with specified requirements.

QAR Section 9

9.3 QA Involvement in Qualification Activities

The QA organization shall be involved in qualification activities to help assure satisfactory performance. As a minimum, the QA organization shall overview the development and implementation of special process qualification activities through the conduct of audits and surveillances.

MQA-1 Basic Requirement 17

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained.

MQA-1 Supplement 9S-1

3.3 Records

Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

10. Activities related to inspection are acceptable if:

10.1 The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.

10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.

10.3 A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.

NQA-1 Basic Requirement 10

Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified.

NQA-1 Supplement 10S-1

4.1 Planning

Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria and shall provide for recording objective evidence of inspection results.

NQA-1 Basic Requirement 10

Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

NQA-1 Supplement 10S-1

2.1 Reporting Independence

Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

Note: QAR requires the independence of the inspection function but does not require inspection personnel to be from QA organization.

NQA-1 Supplement 10S-1

2.2 Qualification

Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.

Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.

NQA-1 Supplement 2S-1

Qualification of Inspection and Test Personnel is applicable to this NRC Review Plan item.

NRC CRITERIA

- 10.4 Inspection procedures, instructions, or checklists provide for the following:
- a. Identification of characteristics and activities to be inspected.
 - b. A description of the method of inspection
 - c. Identification of the individuals or groups responsible for performing the inspection operation.
 - d. Acceptance and rejection criteria.
 - e. Identification of required procedures, drawings, and specifications and revisions.
 - f. Recording inspector or data recorder and the results of the inspection operation.
 - g. Specifying necessary measuring and test equipment including accuracy requirements.

MQA-1 Basic Requirement 5

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances.

MQA-1 Supplement 10S-1

4.1 Planning

Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.

8 RECORDS

Records shall, as a minimum, identify (a) through (f) below:

- (a) item inspected
- (b) date of inspection
- (c) inspector
- (d) type of observation
- (e) results or acceptability
- (f) reference to information on action taken in connection with nonconformances

QAR Section 10

10.1 Records

In addition to the elements identified in Supplement 10S-1 Section 8, inspection records shall include:

- (a) Inspection procedure
- (b) Characteristics inspected
- (c) Inspection criteria or reference documents used to determine acceptance
- (d) Equipment used during the inspection
- (e) Special expertise used

10.5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

10.6 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual or group.

NQA-1 Supplement 10S-1

3 INSPECTION HOLD POINTS

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

NQA-1 Supplement 10S-1

8 RECORDS

Records shall, as a minimum, identify (a) through (f) below:

- (a) item inspected
- (b) date of inspection
- (c) inspector
- (d) type of observation
- (e) results of acceptability
- (f) reference to information on action taken in connection with nonconformances

QAR Section 10

10.1 Records

In addition to the elements identified in Supplement 10S-1 Section 8, inspection records shall include:

- (a) Inspection procedure
- (b) Characteristics inspected
- (c) Inspection criteria or reference documents used to determine acceptance
- (d) Equipment used during the inspection
- (e) Special expertise used

11. Activities related to test control are acceptable if:

- 11.1** The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed; and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.
- 11.2** Test plans and procedures are reviewed in accordance with the verification requirements in Sections 3.7, 3.8 and 3.9.
- 11.3** The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.
- 11.4** Test Procedures or instructions provide for the following:
- a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.
 - b. Instructions for performing the test.
 - c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.
 - d. Mandatory inspection hold points (as required).
 - e. Acceptance and rejection criteria, including required levels of precision and accuracy.

NQA-1 Basic Requirement 11

Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated.

Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.

QAR Section 5**5.1 Reviews**

An independent review of instructions, procedures, and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of quality requirements.

QAR Section 3**3.5.2 Planning**

Known sources of error and uncertainty and input data that is suspect or whose quality is beyond the control of the performing organizations shall be identified.

NQA-1 Supplement 11S-1**2 TEST REQUIREMENTS**

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents.

- f. Methods of documenting or recording test data and results.
- g. Provisions for assuring test prerequisites have been met.

3 TEST PROCEDURES

Tests procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.

In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.

QAR Section 3

3.5 Scientific Investigations

3.5.1 Control of Scientific Investigations

Scientific investigations shall be defined, controlled, and verified. Process variables affecting scientific investigations shall be measured and controlled. Variables that affect interrelated scientific investigations shall be identified, documented, and controlled in each investigation.

The scientific notebook system and the technical procedures system are two approaches that may be used to control scientific investigations activities. The scientific notebook system may be used by qualified individuals who are required to use a high degree of professional judgment or trial and error methods for the task.

The technical procedures system shall be used by qualified personnel to perform repetitive work that does not include the use of professional judgment nor trial and error methods. Technical procedures are required when it is not possible to deviate from a strict sequence of actions without endangering the validity of the results. Technical procedures shall be reviewed for technical adequacy and approved by qualified persons other than those who prepared the procedures. Changes to technical procedures for conducting scientific investigations shall be reviewed and approved by qualified persons familiar with the procedures and the purposes of the investigations to ensure that the objectives of the investigations are fulfilled. Activities to develop new methods or procedures for conducting scientific investigations or critical processes shall be documented. Results

shall be reviewed for adequacy and approved by qualified persons prior to use of the procedures to collect data.

3.5.2 Planning

The intended use of data shall be documented as part of the planning for scientific investigations. Any alternate use of the data shall be evaluated for appropriateness and the justification documented. Planning shall assure the compatibility of scientific investigations with any conceptual or mathematical models used at each applicable stage. Planning shall establish provisions for the evaluation of data quality to assure that data generated is valid, comparable, complete, representative, precise, and accurate. Known sources of error and uncertainty and input data that is suspect or whose quality is beyond the control of the performing organizations shall be identified. These measures shall include or reference provisions for assuring that prerequisites for the given scientific investigation have been met, that adequate instrumentation is available and used, that necessary monitoring including witness or hold points is performed, and that suitable environmental conditions are maintained. The following prerequisites shall be considered: calibrated instrumentation; appropriate equipment; trained personnel; readiness of facilities, equipment, supplies, and items or samples; suitable environmental conditions; provision for acquisitions and recordings of data; and disposition of facilities after completion of scientific investigation activities.

The range, accuracy, and precision of equipment used for scientific investigations shall be specified in order to be commensurate with requirements. In developing quality assurance requirements for equipment, consideration shall be given to whether proper performance of a scientific investigation can be determined during or after the scientific investigation (that is, whether failure or malfunction of equipment can be detected). Where requirements are found to be necessary, special quality or performance verification requirements shall be established and described to govern the use of the equipment. Scientific investigations shall be performed in accordance with nationally recognized standards (for example, ASTM) where available. Standards used without modification require documentation by reference only. If deviation from standards or establishment of specially prepared procedures is deemed appropriate, the modifications or new methods shall be documented in sufficient detail to be repeatable and shall be evaluated, justified, and approved.

11.5 Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.

MQA-1 Supplement 115-1

4 TEST RESULTS

Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied.

5 TEST RECORDS

Test records shall, as a minimum, identify (a) through (g) below:

- (a) item tested
- (b) date of test
- (c) tester or data recorder
- (d) type of observation
- (e) results and acceptability
- (f) action taken in connection with any deviations noted
- (g) person evaluating test results

QAR Section 3

3.5.6 Data Recording, Storage, and Retrievability

Original recorded data shall be considered a QA Record and shall be handled in accordance with Section 17.

Records shall, as appropriate, identify the following elements:

- (1) Scientific investigation requirements, plans, and procedures including applicable revisions
- (2) Item or sample investigated
- (3) Date of scientific investigation
- (4) Identification of the persons performing the scientific investigation and the performers' organizations
- (5) Results and acceptability for intended use
- (6) Action taken in connection with any deviations noted
- (7) Persons evaluating scientific investigation results and evaluators' organizations
- (8) Identification of equipment used

12. Activities related to control of measuring and test equipment are acceptable if:

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.

12.2 QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.

NOA-1 Basic Requirement 12

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

NOA-1 Basic Requirement 1

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities shall be documented.

NOA-1 Supplement 12S-1

2 SELECTION

Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

3 CALIBRATION AND CONTROL

3.1 Calibration

Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

3.2 Control

The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.

Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect.

12.4 Measuring and test equipment is labeled, tagged or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.

12.5 Measuring and test equipment is calibrated at specified intervals based upon required accuracy, precision, purpose, degree of usage, stability, characteristics, and other conditions which could affect the measurement.

12.6 Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.

12.7 When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.

NQA-1 Supplement 12S-1

5. RECORDS

Records shall be maintained and equipment shall be suitably marked to indicate calibration status.

NQA-1 Supplement 12S-1

3.1 Calibration

Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

3.2 Control

The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.

NQA-1 Supplement 12S-1

3.1 Calibration

Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

QAR Section 12

12.1 Accuracy of Calibration Standards

Calibration standards shall have equal or greater accuracy than the equipment being calibrated unless limited by the state of the art.

NQA-1 Supplement 12S-1

Section 3.2

When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.

13. Activities related to sample and hardware handling, storage, and shipping are acceptable if:

13.1 Sampling handling, preservation, storage, packaging and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

NQA-1 Supplement 135-1

2 INSTRUCTION

Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, or other pertinent documents or procedures specified for use in conducting the activity.

3 REQUIREMENTS

3.1 General

When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature level(s)) shall be specified, provided, and their existence verified.

3.2 Procedures

When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

3.3 Tools and Equipment

Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.

3.4 Operators

Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment.

4 MARKING

Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

MRC CRITERIA

13.2 Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

QAR Section 13

13.1 SAMPLES

Handling, storage, and shipping requirements are also applicable to samples collected for site characterization.

13.1.1 Sample Handling and Shipment

Samples shall be controlled during handling, storage, and shipment to preclude damage or loss and minimize deterioration. Controls shall be established for appropriate packaging, handling, and modes of transportation, with consideration being given to types of containers, time constraints on perishable materials (that is, shelf life), and any other environmental or safety considerations applicable to the samples. Measures shall be taken to avoid sample contamination during handling and shipment. Where multiple organizations are involved, appropriate procedures shall describe interface and custody responsibilities. Sample identification shall be verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another.

13.1.2 Sample Storage

Provisions shall be made to maintain sample characteristics, integrity, and identification while in storage. These provisions shall be consistent with the planned duration and conditions of storage and shall describe actions to be taken where samples have a maximum life expectancy while in storage. Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined environmental conditions commensurate with the samples' intended purposes. Samples shall be controlled to preclude mixing of like samples or contamination. Provisions shall be made for identification and storage of tested samples in areas physically separated from untested sample materials.

QAR Section 8

8.1.3 Archival Samples

Applicable technical specifications, procurement documents, test procedures, or other similar documents shall specify representative archival samples to be maintained from difficult-to-repeat, geologic sample collection activities and from waste-form qualification activities.

14. Activities related to inspection, test and operating status (17.1.14) are acceptable if:

14.1 Procedures are established to indicate by the use of

15. Activities related to nonconformances are acceptable if:

15.1 Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. The procedures identify individuals authorized to dispose of and close out nonconformances.

NQA-1 Basic Requirement 14

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

NQA-1 Basic Requirement 15

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affect organizations.

NQA-1 Supplement 15S-1

2 IDENTIFICATION

- (a) Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item. The identification shall be legible and easily recognizable.
- (b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified according to documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.

3 SEGREGATION

- (a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.
- (b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

NOA Supplement 155-1

4 DISPOSITION

4.1 Control

Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.

4.2 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.

4.3 Personnel

Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

4.4 Disposition

The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.

Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

4.5 Repaired or Reworked Items

Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming items disposition has established alternate acceptance criteria.

15.2 QA responsibilities related to nonconformance control are described.

NQA-1 Basic Requirement 1

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.

15.3 Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.

NQA-1 Basic Requirement 15

Controls shall provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations.

15.4 Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.

NQA-1 Supplement 15S-1

4.4 Disposition

The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.

Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

16. Activities related to corrective action are acceptable if:

QAR Section 16

16.1 Trend Analysis

Quality information, such as audit reports, surveillance reports, nonconformance reports, corrective action reports, and related documents, shall be analyzed to identify both favorable and adverse quality trends. Trend analysis shall be performed in a manner and at a frequency that shall provide for prompt identification of adverse quality trends. Adverse quality trends shall be evaluated and reported to the organization responsible for corrective action.

16.1 Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

NQA-1 Basic Requirement 16

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation.

- 16.2 Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in the documented concurrence of the adequacy of the corrective action to assure that QA requirements are satisfied.
- 16.3 Followup action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.
- 16.4 Significant conditions are adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.

17. Activities related to quality assurance records are acceptable if:

- 17.1 The scope of the records program is described. QA records include geotechnical samples and data, results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures and equipment, and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; design review reports; peer review reports; nonconformance reports; and corrective action reports.

QAR Section 16

16.3 Significant Conditions Adverse to Quality

Criteria for determining the existence of significant conditions adverse to quality shall be developed at each PROGRAM-participant organizational level. Significant conditions adverse to quality shall be identified, documented, and corrected at each PROGRAM organizational level. Corrective action shall include root cause identification and resolution of the generic implications to the PROGRAM. Copies of corrective action documentation shall be provided to appropriate management of the next higher PROGRAM organizational level and the Director, OCRWM Office of Quality Assurance. QA organizational concurrence with proposed corrective action and QA verification of corrective action implementation are required.

QAR Section 3

3.1 Design Error and Deficiency Control

Errors and deficiencies in approved design and design information documents shall be documented and corrective action shall be taken in accordance with Section 16 or Section 18 as appropriate.

NQA-1 Basic Requirement 17

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained.

NQA-1 Supplement 17S-1

2.1 Records System

A records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

QAR Section 17

17.1 Compliance With OCRWM Records Management Program

Each PROGRAM participant shall develop quality assurance records programs or procedures appropriate for their scope of work that are consistent with, and meet the requirements in DOE/RW-0194 "Records Management Policies and Requirements".

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

17.3 Inspection and test records contain the following where applicable:

- a. A description of the type of observation.
- b. The date and results of the inspection or test.
- c. Information related to conditions adverse to quality.
- d. Inspector or data recorder identification.
- e. Evidence as to the acceptability of the results.
- f. Action taken to resolve any discrepancies noted.

NQA-1 Basic Requirement 1

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.

NQA-1 Supplement 10S-1

8 RECORDS

Records shall, as a minimum, identify (a) through (f) below:

- (a) item inspected
- (b) date of inspection
- (c) inspector
- (d) type of observation
- (e) results or acceptability
- (f) reference to information on action taken in connection with nonconformances

10.1 RECORDS

In addition to the elements identified in Supplement 10S-1 Section 8, inspection records shall include:

- (a) Inspection procedure
- (b) Characteristics inspected
- (c) Inspection criteria or reference documents used to determine acceptance
- (d) Equipment used during the inspection
- (e) Special expertise used

NQA-1 Supplement 11S-1

5 TEST RECORDS

Test records shall, as a minimum, identify (a) through (g) below:

- (a) item tested
- (b) date of test
- (c) tester or data recorder
- (d) type of observation

- (e) results and acceptability
- (f) action taken in connection with any deviations noted
- (g) person evaluating test results

QAR Section 3

3.5.6 Data Recording, Storage, and Retrievability

Original recorded data shall be considered a QA Record and shall be handled in accordance with Section 17.

Records shall, as appropriate, identify the following elements:

- (1) Scientific investigation requirements, plans, and procedures including applicable revisions
- (2) Item or sample investigated
- (3) Date of scientific investigation
- (4) Identification of the persons performing the scientific investigation and the performers' organizations
- (5) Results and acceptability for intended use
- (6) Action taken in connection with any deviations noted
- (7) Persons evaluating scientific investigation results and evaluators' organizations
- (8) Identification of equipment used

17.4 Suitable facilities for storage of records are described and utilized.

NQA-1 Supplement 17S-1

4.4 Facility

Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

- (a) natural disasters such as winds, floods, or fires;
- (b) environmental conditions such as high and low temperatures and humidity;
- (c) infestation of insects, mold, or rodents.

There are two satisfactory methods of providing storage facilities, single or dual.

4.4.1 Single Facility

Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below:

- (a) reinforced concrete, concrete block, masonry, or equal construction;
- (b) floor and roof with drainage control. If a floor drain is

- provided, a check valve (or equal) shall be included;
- (c) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum of 2 hour fire rating;
 - (d) sealant applied over walls as a moisture or condensation barrier;
 - (e) surface sealant on floor providing a hard wear surface to minimize concrete dusting;
 - (f) foundation sealant and provisions for drainage;
 - (g) forced air circulation with filter system;
 - (h) fire protection system;
 - (i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampened to comply with the minimum 2 hr fire protection rating.

The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.

If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.

4.4.2 Alternate Single Facilities.

The following are acceptable alternatives to the criteria of para. 4.4.1 above for a single facility:

- (a) 2 hr fire rated vault meeting NFPA 232-1975;
- (b) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1975; or
- (c) 2 hr fire rated file room meeting the requirements of NFPA 232-1975 with the following additional provisions:
 - 1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station;
 - 2) records storage in fully enclosed metal cabinets;
 - 3) adequate access and aisle ways;
 - 4) prohibition in the room of work not directly associated with record storage or retrieval;
 - 5) prohibition in the room of smoking, eating, or drinking;
 - 6) 2 hr fire rated dampers or doors in all boundary penetrations.

4.4.3 Dual Facilities.

If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either

para.4.4.1 or para. 4.4.2 above, but shall meet the other requirements of this Standard.

18. Activities related to audits are acceptable if:

18.1 Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractor. DOE should perform audits for the prime contractor and representative subcontractors, consultants, vendors and laboratories to assess the effectiveness of the prime contractor's audit program.

18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities begin performed and are initiated early enough to assure effective QA.

NQA-1 Basic Requirement 18

Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness.

NQA-1 Supplement 18S-1

2 SCHEDULING

Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

QAR Section 18

18.2 Project Office Audits

OCRWM shall audit the Project Offices annually for the effective implementation of their QA programs.

NQA-1 Supplement 18S-1

2 SCHEDULING

Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

3 PREPARATION

3.1 Audit Plan

The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements,

18.3 Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities and items and the review of documents and records to ensure that the QA program is effective and properly implemented.

18.4 Audit data are analyzed by the QA organization and the results are reported to management for review, assessment, and appropriate action.

18.5 Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the area being audited.

18.6 A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.

audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

NQA-1 Supplement 18S-1

4 PERFORMANCE

Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

NQA-1 Supplement 18S-1

5 REPORTING

The audit shall be signed by the audit team leader and issued, and it shall include the following information, as appropriate:

- (a) description of the audit scope;
- (b) identification of the auditors;
- (c) identification of persons contacted during audit activities;
- (d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited;
- (e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

NQA-1 Basic Requirement 18

These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities audited.

NQA-1 Supplement 18S-1

7 FOLLOW-UP ACTION

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

QAR Section 16

16.1 Trend Analysis

Quality information, such as audit reports, surveillance reports, nonconformance reports, corrective action reports, and related documents, shall be analyzed to identify both favorable and adverse quality trends. Trend analysis shall be performed in a manner and at a frequency that shall provide for prompt identification of adverse quality trends. Adverse quality trends shall be evaluated and reported to the organization responsible for corrective action.

NQA-1 Supplement 18S-1

6 RESPONSE

Management of the audited organization or activity shall investigate the adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

NQA-1 Supplement 18S-1

6 RESPONSE

Management of the audited organization or activity shall investigate the adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

NQA-1 Basic Requirement 16

The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.

18.7 The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.

18.8 In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.