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QAP-X-88-NRC-01

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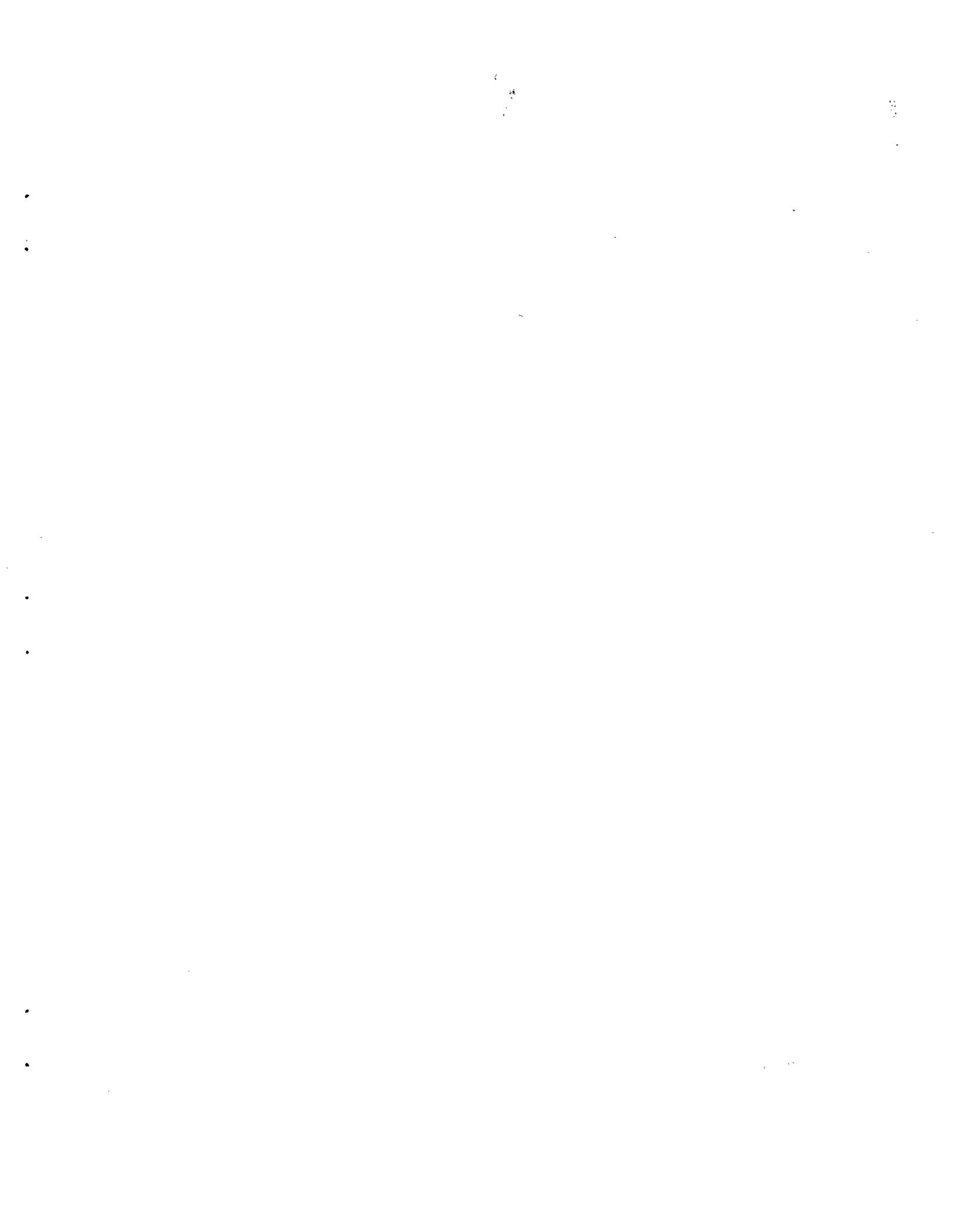
**MARTIN MARIETTA**

**NUCLEAR REGULATORY COMMISSION PROGRAM  
QUALITY ASSURANCE PROGRAM  
REQUIREMENTS**

**AUGUST 31, 1988**

OPERATED BY  
MARTIN MARIETTA ENERGY SYSTEMS, INC.  
FOR THE UNITED STATES  
DEPARTMENT OF ENERGY

[REDACTED]



QAP-X-88-NRC-01

**Nuclear Regulatory Commission Programs**  
**Quality Assurance Program**  
**Requirements**

August 31, 1988



APPROVALS



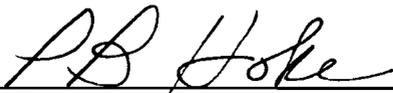
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A. P. Malinauskas, Director  
Nuclear Regulatory Commission Programs

8-31-88

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Date



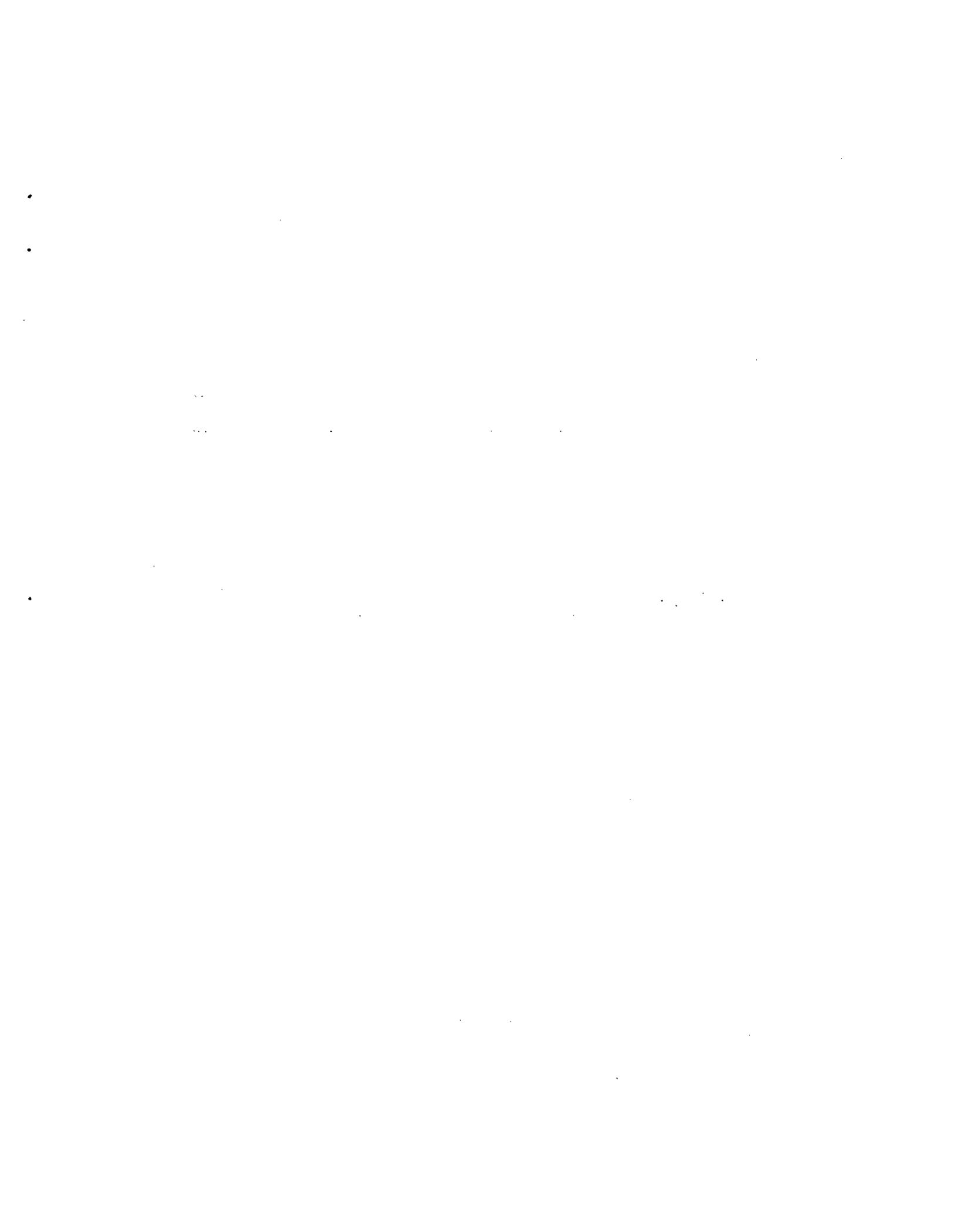
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8-31-88

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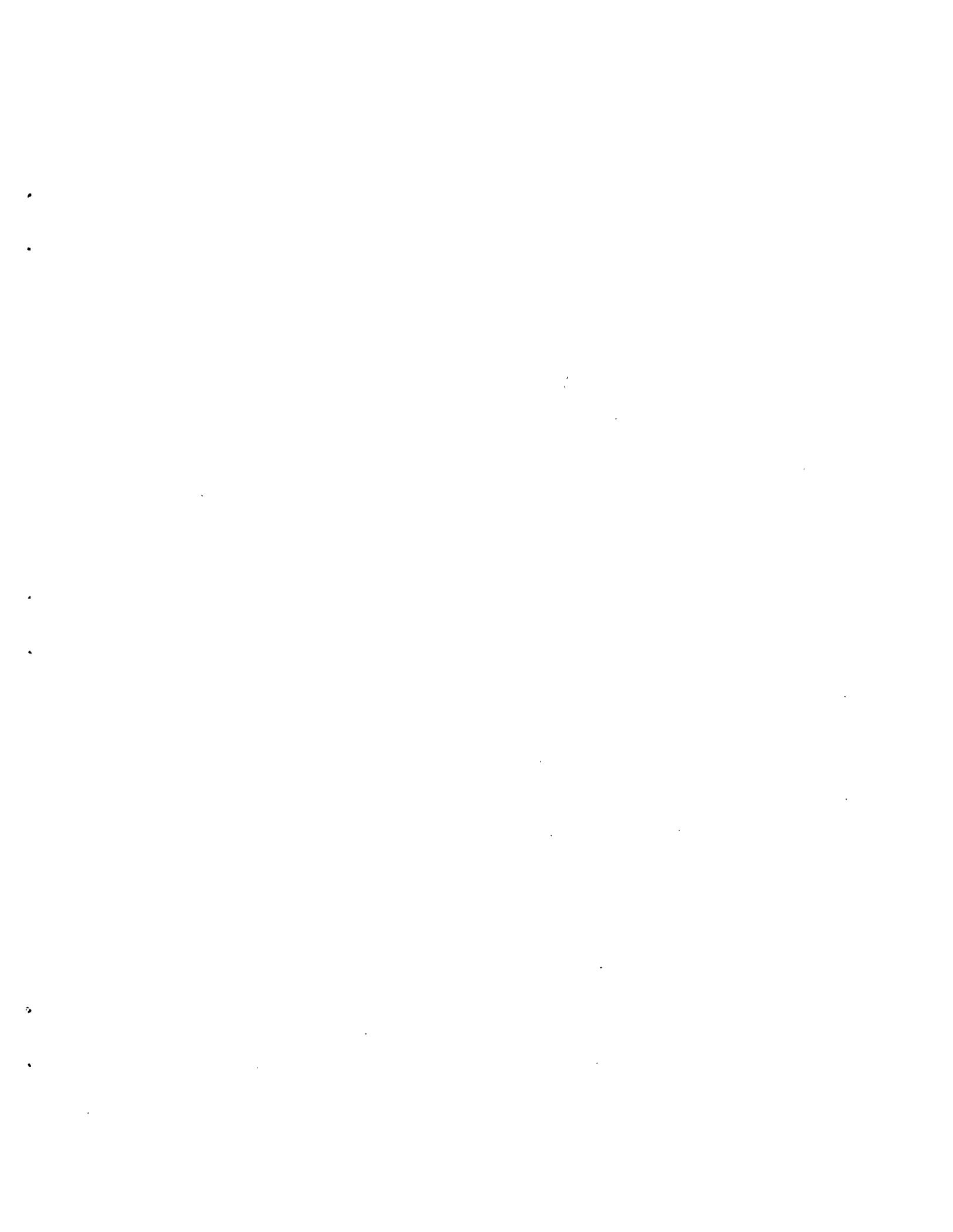


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## 1.0 INTRODUCTION

The Oak Ridge National Laboratory (ORNL) provides research and technical support to the Nuclear Regulatory Commission (NRC) in areas in which the Laboratory has demonstrated significant expertise. These areas include structural analysis, materials evaluation, fission product behavior, accident sequence analysis, advanced instrumentation and diagnostics, reliability and operating data analysis, integrated risk assessment, and radiation dose and health effects.

The success of the NRC programs is dependent upon program managers effectively implementing a management system that ensures adequate control over all aspects of the program. Quality Assurance (QA) must be integrated into the overall management system with the minimal requirements established in this document, which will lead to emphasis on performance rather than compliance.

The goal of the Quality Assurance Program is to ensure that NRC programs meet sponsor specifications and requirements, that effective testing and reviews are performed to confirm the adequacy of and conformance to the specifications and requirements, and that design of systems will function reliably and effectively so that the objectives of the program are achieved.

This document (1) establishes the Quality Assurance Program policy, (2) defines the QA requirements to be imposed on this program, and (3) provides guidance for the application of these requirements.

### 1.1 Quality Assurance Policy

It is the policy of the NRC Programs Director that a formal evaluation of program activities be completed to determine the level of QA planning required and that QA program plans are established and implemented to ensure that all activities having cost, schedule, technical, safety, and environmental impact are controlled to ensure their conformance to program requirements. The degree to which QA program requirements are applied to specific items or activities depends on the complexity of the items or activities and the effect of these items or activities on project success and safety. The level of quality assurance should be addressed at the outset of NRC program development and the cost clearly documented in program plans.

### 1.2 Implementation of the QA Program

Management direction for the QA function will flow through the ORNL NRC Programs Director's office and then to the program office that has primary responsibility for an assigned NRC program. (Note: A program office is defined as the organization, either internal to Martin Marietta Energy Systems, Inc., or a subcontractor, that has the primary responsibility for a designated NRC program.) The appropriate program office will effectively implement a management system that ensures adequate control over all aspects, including QA, of the programs. The oversight and review activities performed by the NRC Programs Office shall not relieve those performing assigned work

of their responsibility for implementing and performing QA programs and activities or for the quality of the work performed.

The QA requirements of this document are in compliance with Department of Energy (DOE) Order 5700.6, "Quality Assurance," the Martin Marietta Energy Systems, Inc., Quality Procedures Manual, and the ORNL Quality Assurance Manual. ANSI/ASME NQA-1-1986 (NQA-1), "Quality Assurance Program Requirements for Nuclear Facilities," has been selected as the basic quality assurance standard for application to the NRC programs. The organizations responsible for performing an assigned work activity have the principal responsibilities for implementation of the QA requirements established by NQA-1 and this document, including the specification of the requirements which apply to subcontractors and suppliers. A quality plan, if required following an evaluation, is to be prepared by each organization involved in this program to provide the appropriate translation and implementation of the QA document.

NRC program specific plans may not be necessary where existing division or program QA plans are in place. The responsible Program Manager/Principal Investigator and Quality Assurance Specialist shall ensure that the existing plans meet the requirements of this document. Where appropriate, an addendum may be added to existing QA plans to meet NRC program specific requirements.

### **1.3 Responsibilities**

#### **1.3.1 Director, NRC Programs**

The NRC Programs Director has overall responsibility for the success of the programs, including the responsibility of issuing and maintaining this QA requirements document. Through the QA requirements document, the director ensures that a comprehensive QA program, if required, is established and implemented, and that systematic surveillance is performed on the program participants' activities.

#### **1.3.2 Program Manager/Principal Investigator**

Program manager(s) are responsible for the planning, technical direction, monitoring of progress, and overall technical success of the assigned program(s). The program manager(s) shall ensure that a comprehensive QA program, if required, is established and implemented and that systematic surveillance is performed on program activities. Escalation of quality events and problems shall be through the program manager(s) to their respective line management (division/organization) and to the NRC Programs Director.

#### **1.3.3 Line (Administrative) Management**

The responsible program manager works within a matrix management structure which ensures that appropriate communication interfaces are controlled between line, quality assurance, and program personnel. This line management is responsible for developing and providing the facilities, equipment, and expertise necessary for completing the assigned program requirements. The

line manager has the authority and responsibility for implementing and enforcing the QA program.

#### **1.3.4 Quality Assurance Management**

The Quality Department Manager is responsible for administration and coordination of the ORNL QA Program. The Quality Assurance Specialist (QAS) assigned to the line organization having primary responsibility for a NRC Program shall administer the quality assurance program. The Quality Department Manager and the QAS are independent of cost and scheduling considerations and have access to all work areas.

The QAS has the responsibility and authority to administer the quality requirements as defined in developed QA plans. The QAS shall have stop-work authority to suspend work where a significant condition adverse to quality cannot be satisfactorily resolved. Such stop-work authority is exercised through line management.

### **2.0 Quality Assurance Requirements and Applicability**

As soon as the requirements of a program have been sufficiently defined, the program manager and QAS shall evaluate the need for developing a QA plan. The program shall be evaluated against the following criteria: involvement of nuclear fuel, waste, or reactors; complexity of system, mathematical models, or computer codes; legality aspects for licensing; uniqueness; poor quality history of similar programs; high failure impact or consequence; and customer QA requirements. The involvement of nuclear fuel, waste, or reactors or customer mandates constitutes mandatory criteria for establishing the need for a plan. A positive response to the other criteria strongly suggests the need for a plan.

This section identifies and describes QA requirements that have been established for the NRC Program activities, the applicability of these requirements to program participant activities, the requirements and procedures established for the application of these requirements on a selective basis to program activities, and guidelines for implementation. The requirements presented are from DOE Order 5700.6 and NQA-1, but are tailored to reflect specific requirements as specified by the ORNL Quality Assurance Manual.

Specific guidance and/or selective application of QA requirements is presented in Section 3.0.

#### **2.1 Organization**

##### **2.1.1 Requirements**

NQA-1 Basic Requirement 1 and Supplement 1S-1 are applicable to all participating organizations.

The organizational structure of each participating organization shall be documented. The documentation shall include the functional responsibilities of the various organizational elements, levels of authority, and lines of communication for activities affecting quality.

Implementation of this element shall include provisions for:

- a. Documented organizational charts.
- b. Identified and defined organizational interfaces.
- c. Defined responsibilities and authorities for QA program implementation in order to achieve quality objectives with emphasis on the performing (technical) functions.
- d. Identified authority and organizational independence for the quality program verification activities.

The persons or organizations responsible for ensuring that an effective QA program is established and for verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

- a. Identify quality problems.
- b. Initiate or provide solutions to quality problems.
- c. Verify implementation of solutions.

The highest level of management within each participating organization shall be involved in QA program activities and, particularly, in the periodic review of the program and the resolution of significant problems.

### **2.1.2 Guidance**

Program management documentation may be used for compliance to this quality assurance element. However, the methods of complying with this requirement, if not documented in a QA plan or manual, should be appropriately referenced. At a minimum, supplementary definitions regarding the independence and organizational freedom of persons or organizations responsible for QA functions shall be documented in the QA program plans.

## **2.2 Quality Assurance Program**

### **2.2.1 Requirements**

NQA-1 Basic Requirement 2 and Supplements 2S-1, 2S-2, and 2S-3 are applicable to all organizations that participate in this program.

When required, program participants shall establish and implement a documented QA program based on NQA-1. The selective application of requirements of the NQA-1 elements shall be identified.

NQA-1 does not address the establishment of controls over the conduct of peer or technical reviews or the qualification of personnel performing these reviews, although these reviews are important to the quality assurance of this program. The appropriate program manager shall identify where reviews are required and approve personnel performing the reviews.

DOE Order 5700.6 requires the development of risk assessments. Risk assessments shall be developed by the program manager to identify and evaluate the risks of potentially significant quality problems (failure modes) and to plan for the prevention or minimization of the consequences of the potential problems.

### **2.2.2 Guidance**

Supplement 2S-1 and 2S-2, Section 2.0, addresses the qualification and certification of inspection and test personnel. The supplementary requirements shall be applied where applicable to assure acceptability; however, these supplements may have limited application to NRC programs. The primary principles of ensuring appropriate qualifications of inspection and test personnel are necessary, but much of the NQA-1 emphasis on the organizational separation and control of "inspection and test" personnel is not always appropriate for R&D activities and may be ensured in ways other than organizational independence, such as independent and documented reviews for acceptance.

Lead Auditors shall be trained and qualified in accordance with the intent of Supplement 2S-3. Formal audits, requiring the use of auditing personnel, may not be applicable due to the short duration and types of work of many NRC programs. However, an active and continuing surveillance program to ensure compliance to quality requirements shall be conducted by program management and the responsible QAS.

Training and indoctrination shall be conducted commensurate with the responsibilities and with the experience, training, education, and position of the individuals assigned to perform their task.

## **2.3 Design Control**

### **2.3.1 Requirements**

NQA-1 Basic Requirement 3 and Supplement 3S-1 are applicable to all organizations that have design-related responsibilities.

Participants in this program shall include provisions for implementing requirements related to the control of data collection, validation, analysis, and reporting. The requirements for the collection of data to be used for the development or validation of designs shall be identified and documented in procedures, instructions, or other appropriate documents on a timely basis. Documentation shall be to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit validation that the design meets the requirements established. Data verification and reduction shall be accomplished in accordance with accepted methods.

When specified by the appropriate program manager, documents that support design information and design activities shall be subjected to independent technical or peer review, as appropriate and as discussed below.

- a. A technical review is a formally documented review of technical material performed by individuals who are independent of those responsible for the work but who may be members of the organization within which the work was done.
- b. A peer review is a formally documented review of technical material performed by individuals who are independent of the organization that performed the work and who have technical expertise at least equal to that of the performing individuals.

The use of computer codes and mathematical models may be an important element in many of the NRC programs. Thus, it is essential that the computer codes be of high quality and as free from errors as possible. Requirements are applicable to computer codes used in experiments and computer codes intended for the control of special equipment and processes.

As determined by the scope of an assigned NRC program, the QA program for adequate control of computer codes may include provisions for all or part of the following elements:

- a. Design and Development
- b. Verification/Assessment
- c. Qualification/Validation
- d. Configuration Control
- e. Documentation/Procedures

Existing computer codes that are recognized and generally accepted shall not require additional verification or validation. Computer codes developed, modified, or changed shall be subjected to review by an individual with equivalent capabilities who did not generate the original work. The reviewer shall sign a statement as to validity/nonvalidity of the code for the designated calculations or application. The program manager shall maintain a file of the record of all such reviews.

Software quality assurance for Martin Marietta Energy Systems, Inc., is specified in a manual controlled by the Computing and Telecommunications Division entitled "ADP-Systems Development Methodology" (SDM). The SDM manual defines a life-cycle approach to developing and maintaining computer-based systems. The following are definitions of three components of the SDM manual which may be in the scope of many NRC programs activities:

- a. Verification: process of reviewing, inspecting, testing, checking, or otherwise establishing and documenting whether or not items, processes, services, or documents conform to specified requirements.

- b. Validation: process of evaluating software at the end of the development process to ensure compliance with requirements (e.g., comparison with experimental results).
- c. Configuration Control: the systematic evaluation, coordination, certification, implementation, and documentation of all changes to automated data processing (ADP) software.

### 2.3.2 Guidance

Items requiring emphasis for compliance to the NQA-1 Design Control Requirement include:

- a. Identification of applicable design codes and standards (including the applicable national consensus standards, e.g., IEEE, ANSI, ASME, Military Standards) and review and approval of their selection.
- b. Documented description of the design process.
- c. Design verification.
- d. Establishment of a change control system.
- e. Identification and control of design interfaces.
- f. Requirements regarding control of proprietary items.

## 2.4 Procurement Document Control

### 2.4.1 Requirements

NQA-1 Basic Requirement 4 and Supplement 4S-1 are applicable to all program participants.

The originating organizations shall ensure that procurement documents include the applicable quality requirements that are to be imposed upon the supplier. The documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. Procurement documents shall include provisions for program participants to perform inspections and surveillance audits and to process reviews of suppliers.

### 2.4.2 Guidance

It is the responsibility of the program participants controlling procurement to identify and establish the NQA-1 requirements to be implemented by the supplier, including the selected reference to the information as program activities progress.

Information and data used as assumptions for design activities shall be documented to permit inclusion of portions of Supplement 4S-1 and the appropriate portions of all 18 NQA-1 Basic Requirements and associated supplements.

Most procurements do not require all of the control provisions described by NQA-1 Supplement 4S-1. Judicious and selective application of QA requirements should consider complexity, consequences of failure, and significance to program success. This judgment should recognize that safety, environmental protection, quality, and performance are all closely related.

Areas requiring emphasis for compliance to the NQA-1 Procurement Document Control Requirement include:

- a. Identification and incorporation of technical requirements.
- b. Establishment and identification of required supplier QA program controls.
- c. Provisions for purchaser access for inspection and monitoring.
- d. Requirements, included in procurement documents, for establishing a nonconformance control system.
- e. Requirements for establishing a change control system.

## 2.5 Instructions, Procedures, and Drawings

### 2.5.1 Requirements

NQA-1 Basic Requirement 5 is applicable to all organizations that participate in the project.

### 2.5.2 Guidance

The program participant's QA plans and associated program documentation should identify the activities requiring written procedures, instructions, or drawings.

Procedures and instructions shall be prepared to control program activities to the extent necessary for correct performance of activity. The form of these documents should be such as to provide a qualified individual with information needed for satisfactory performance of assigned tasks. For noncomplex tasks, authorized notes or instructions may suffice, while, for more critical activities, a procedure with step-by-step instructions and verifications may be required. It is not necessary to provide exhaustive detail describing routine work practices. The prime consideration is that the procedures or instructions must be written with an understanding clearly in mind of the complexity of the activities involved and the competence level of the personnel using the documents. Alternatively, sufficient training must be provided prior to application of the procedures or instructions.

Items requiring emphasis for compliance to the NQA-1 Instructions, Procedures, and Drawings Requirement include:

- a. Preparation and use of implementation procedures, instructions, and drawings for activities required to achieve quality.

- b. Inclusion of appropriate acceptance criteria.
- c. Control of documents (e.g., drawings, procedures, instructions).

## **2.6 Document Control**

### **2.6.1 Requirements**

NQA-1 Basic Requirement 6 and Supplement 6S-1 are applicable to all program participants.

Program participants shall establish and implement document control systems that ensure that correct documents are used for all activities affecting QA. The document control system and the records control system shall be fully integrated to the extent possible.

### **2.6.2 Guidance**

Items requiring emphasis for compliance to the NQA-1 Document Control Requirement include:

- a. Identification of a defined system for administrative control and distribution of documents.
- b. Identification of approval authorities for procedures.
- c. Establishment of a change control system and authority for authorizing changes.
- d. Identification of documents to be controlled.

## **2.7 Control of Purchased Items and Services**

### **2.7.1 Requirements**

NQA-1 Basic Requirement 7 and Supplement 7S-1 are applicable to all program participants.

The requirements of this element address actions required of the purchaser to ensure an appropriate and systematic approach to the procurement process and to ensure that items comply with the requirements established. The extent of the control actions established and implemented shall reflect the relative importance and risks associated with items or services being procured. These actions shall also be consistent with the requirements imposed upon the supplier by procurement documents.

### **2.7.2 Guidance**

Items requiring emphasis for compliance to the NQA-1 Control of Purchased Items and Services Requirements include:

- a. Documented procurement planning methods and responsibilities.
- b. Supplier evaluation and selection.
- c. Verification of supplier's compliance to contract technical requirements (e.g., source and receiving inspection).
- d. Verification of supplier's compliance to specified quality assurance requirements (audits and surveillance).

## 2.8 Identification and Control of Items

### 2.8.1 Requirements

NQA-1 Basic Requirements 8 and Supplement 8S-1 are applicable to all organizations that have hardware specifications and/or handling responsibilities.

The application of this requirement ensures that only correct, appropriately traceable, and accepted items are used or installed.

Chain-of-custody for samples and other controlled materials shall be established to include provisions for the control of archive samples and other controlled materials.

### 2.8.2 Guidance

Items requiring emphasis for compliance to the NQA-1 Identification and Control of Items Requirement include:

- a. Defining and establishing physical identification and appropriate segregation of items.
- b. Ensuring traceability of items.
- c. Identifying items using techniques designed to prevent the loss or damage of identification.
- d. Relating items to appropriate documents.

## 2.9 Control of Processes

### 2.9.1 Requirements

NQA-1 Basic Requirement 9 and Supplement 9S-1 are applicable to all organizations that are responsible for activities related to special processes.

### **2.9.2 Guidance**

The application of this NQA-1 element is typically associated with the fabrication and construction activity. However, this requirement is also applicable to processes used for the acquisition of research and technology data. This interpretation reflects the NQA-1 definition of a special process (i.e., 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).

Items requiring emphasis for compliance to the NQA-1 Control of Processes Requirement include:

- a. Identification and use of qualified and approved procedures.
- b. Training and qualification of personnel.
- c. Control of process parameters, environment, and equipment.

## **2.10 Inspection**

### **2.10.1 Requirements**

NQA-1 Basic Requirement 10 and Supplement 10S-1 are applicable to all program participants responsible for inspection activities. The associated requirements from Supplement 2S-1 and Supplement 2S-2 shall also be applied.

### **2.10.2 Guidance**

As discussed in Section 2.1.2, the application of Supplement 2S-1 should be carefully considered in relation to research and development activities. The same is true for Supplement 10S-1. Independence of the inspection personnel must be ensured, but strict organizational independence may not be required.

Items requiring emphasis for compliance to the NQA-1 Inspection Requirements include:

- a. Documented planning of inspections.
- b. Documentation and reporting of inspection results.
- c. Reporting independence of acceptance inspection.
- d. Training and qualification of inspection personnel.

## 2.11 Test Control

### 2.11.1 Requirements

NQA-1 Basic Requirement 11 and Supplement 11S-1 are applicable to all program participants responsible for controlling test activities.

### 2.11.2 Guidance

Items requiring emphasis for compliance to the NQA-1 Test Control Requirements include:

- a. Test planning.
- b. Identification and documentation of test objectives.
- c. Use of written and approved test procedures with defined acceptance criteria.
- d. Evaluation of test results.
- e. Documentation and reporting of test results.

## 2.12 Control of Measuring and Test Equipment

### 2.12.1 Requirements

NQA-1 Basic Requirement 12 and Supplement 12S-1 are applicable to all participants utilizing measuring and test equipment.

### 2.12.2 Guidance

When applicable, measuring and test equipment (M&TE) should be calibrated to standards traceable to the U.S. National Bureau of Standards (NBS).

Items requiring emphasis for compliance to the NQA-1 Control of Measuring and Test Equipment Requirements include:

- a. Identification of equipment requiring control.
- b. Established calibration frequency.
- c. Established recall system.
- d. Identification of calibration standards.
- e. Establishment of acceptance and rejection criteria.
- f. Provisions for calibration status and record control.

## **2.13 Handling, Storage, and Shipping**

### **2.13.1 Requirements**

NQA-1 Basic Requirement 13 and Supplement 13S-1 are applicable to all program participants involved in material or equipment handling activities.

### **2.13.2 Guidance**

Items requiring emphasis for compliance to the NQA-1 Handling, Storage, and Shipping Requirements include:

- a. Use of written instructions and/or procedures.
- b. Special control related to safety and environmental protection.
- c. Marking and labeling instructions.
- d. Identification of items requiring special handling, storage, and shipping provisions.

## **2.14 Inspection, Test, and Operating Status**

### **2.14.1 Requirements**

NQA-1 Basic Requirement 14 is applicable to all program participants involved in equipment or system fabrication, testing, or operation.

Readiness reviews shall be conducted, where appropriate, prior to operation to verify that specified prerequisites have been satisfied, that procedures are available and adequate, that personnel have been trained and qualified, and that operation and tests have been planned in consonance with established objectives and process or facility capabilities.

### **2.14.2 Guidance**

Items requiring emphasis for compliance to the NQA-1 Inspection, Test, and Operating Status Requirements include:

- a. Identification of inspection and test status.
- b. Identification of nonconforming items and appropriate segregation of nonconforming items.
- c. Provisions for the use and control of status indicators.

## 2.15 Control of Nonconforming Items

### 2.15.1 Requirements

NQA-1 Basic Requirement 15 and Supplement 15S-1 are applicable to all program participants.

Nonconforming items shall be controlled to prevent inadvertent installation or use. Program participants shall establish programs to ensure the prompt identification, control, and disposition of items which do not conform to specifications or drawings. The Quality program plans for each participant are to identify and describe the controls and associated responsibilities for the classification and disposition of nonconforming items.

When material or components are supplied by program participants to another, any nonconformances, and associated documentation of the disposition, related to the material or component shall be included in the data package that is transmitted with the component or material.

The centralized Nonconformance and Problem/Failure Reporting System (Energy Systems Quality Information System - ESQIS) shall be utilized by QA personnel for the documentation of analysis and correction of nonconformances related to failures. Each program participant shall establish written instructions to submit all nonconformances to the appropriate manager within a reasonable period of time following the initial identification and documentation of the nonconformance, problem, or failure.

### 2.15.2 Guidance

NQA-1 Basic Requirement 15 and Supplement 15S-1 are applicable to the control of equipment materials, components, and other physical plant items. The basic and supplementary requirements are also applicable to nonconforming design drawings, specifications, analytical data, computer software, and other items or activities that may affect the success of this program.

Items requiring emphasis for compliance to the NQA-1 Control of Nonconforming Items Requirements include:

- a. Identification, classification, and documentation of nonconformances.
- b. Control of nonconformances prior to disposition.
- c. Controlled and approved disposition of nonconformances, resolution, and provisions for escalation of significant nonconformances in accordance with established corrective action system controls (see Section 2.16).
- d. Defined responsibilities and authorities, including provisions for stop-work authority.

## 2.16 Corrective Action

### 2.16.1 Requirements

NQA-1 Basic Requirement 16 is applicable to all program participants.

NQA-1, Section II-16, requires that all significant quality problems shall be investigated and documented for management review and, when appropriate, corrective actions taken.

Appropriate program managers, upon determining that an unusual or unplanned event has occurred during design, manufacture, procurement, installation, testing, or operation of NRC programs, shall notify their line manager and the NRC Programs Director. The programs director shall determine if the event is reportable to DOE. Events reported to DOE shall be reported as unusual occurrences through the ORNL Office of Operational Safety.

Unusual or unplanned events judged as not being unusual occurrences shall be evaluated by the appropriate division director to determine if they are quality problems. Quality Event Reports, Non-Conformance Reports, or Quality Investigation Reports shall be used to document the quality event, findings, and required actions.

The centralized Nonconformance and Problem/Failure Reporting System (Energy Systems Quality Information System - ESQIS) shall be utilized by QA personnel for documentation of analysis and correction of quality problems and unusual occurrences.

### 2.16.2 Guidance

Items requiring emphasis for compliance to the NQA-1 Corrective Action Requirements include:

- a. Defined responsibilities and authorities.
- b. Prompt identification of conditions adverse to quality.
- c. Determination of cause(s).
- d. Timely implementation of corrective action.
- e. Follow-up to verify correction.
- f. Periodic evaluation of corrective action system, including review of documented deficiencies for trends.

## 2.17 Quality Assurance Records

### 2.17.1 Requirements

NQA-1 Basic Requirement 17 and Supplement 17S-1 are applicable to all organizations that participate in this program.

Provisions shall be established to ensure that sufficient documentary evidence of quality assurance be specified, prepared, and maintained. Types of records shall be identified and listed at the beginning of each program, and additional records will be identified and added to the records index system during the program duration. The indexing system shall include, at a minimum, sufficient information for retrieval, records retention times, and the location of the record within the record system. Records shall be classified as "lifetime" or "nonpermanent" as defined by NQA-1 Supplement 17S-1.

The need for Quality Assurance records shall be evaluated in order to assure the availability of needed information, while avoiding over-documentation. The degree to which Quality Assurance records are reviewed for procedural compliance should vary depending upon the situations presented.

### 2.17.2 Guidance

Items requiring emphasis for compliance to the NQA-1 Records Control Requirements include:

- a. Establishment of a documented records management system.
- b. Provisions for prompt identification, classification, indexing, and validation.
- c. Identification of responsibilities for receipt, handling, storage, and preservation.
- d. Provisions for records retrievability.

## 2.18 Audits

### 2.18.1 Requirements

NQA-1 Basic Requirement 18 and Supplement 18S-1 are applicable to all program participants.

### 2.18.2 Guidance

The appropriate program manager and QAS shall establish an auditing and/or surveillance schedule. Formal audits for some NRC programs may not be appropriate due to short duration or type of program. However, an active and continuing surveillance program to ensure compliance to quality requirements shall be conducted by program management. A surveillance activities list shall be maintained by the program manager.

Readiness reviews shall be conducted, where appropriate, prior to operation to verify that specified prerequisites have been satisfied, that procedures are available and adequate, that personnel have been trained and qualified, and that operation and tests have been planned in consonance with established objectives and process or facility capabilities.

### **3.0 Application of the Quality Requirements**

The quality requirements presented in this document shall be applied on a selective basis, commensurate with the importance and complexity of the work activity conducted. The purpose of this selective application is to cost effectively focus on activities needed to assure conformance to requirements and on those items and activities which, if they failed to perform or were not performed satisfactorily, would have an adverse impact on program success and safety.

#### **3.1 Selection of Applicable Quality Requirements**

Although the basis for the quality requirements is ANSI/ASME NQA-1, the NRC programs may impose QA requirements that are additional to those in NQA-1. NQA-1 is organized around 18 basic requirements, and each of these basic requirements is greatly amplified by the supplements and nonmandatory appendices. The requirements of the supplements and nonmandatory appendices may be applied with different levels of intensity. The determination of which Quality Assurance elements are applicable to a specific organization is dependent on two considerations: (1) importance of that work activity on program success or safety and (2) whether or not the work activity to which the Quality Assurance element is to be applied is indeed being performed by the specific organization.

#### **3.2 Implementation of Selected Quality Requirements**

If required, program participants shall have documented Quality Assurance Program Plans which will indicate those NQA-1 elements to be imposed, any additions or clarifications to those elements, referenced Quality Assurance Procedures, and any additions or clarifications to those procedures. For each NQA-1 element, an evaluation is made to determine its applicability to the program. For instance, if there is no design required for a program, then "Design Control" would be marked as "not applicable." If design was involved, then specific procedures or instructions to be used for controlling design activities to ensure success of the program would be identified. The procedures or instructions cited are not necessarily limited to Quality Assurance procedures and may include documents from other disciplines. For some programs, existing procedures or instructions may not provide adequate control of the processes involved. For those programs it may be necessary to provide for addition to or clarification of those documents. These additions or clarifications shall be provided as attachments to the plan. For each project there are also unique supporting documents such as organization charts, functional responsibility matrixes or descriptions, controlled document lists, QA records lists, and surveillance activities plans. These documents shall be provided as attachments to the quality assurance plan. Existing QA programs of organizations providing services or materials to the NRC programs may be used to provide a response to the QA planning criteria. Participant Quality Program Plans shall be approved by program management and the ORNL Quality Assurance Program Manager.

