Quality Assurance Manual

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Franklin Research Center
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20th and Race Streets. Phila., Pa. 19103 (215) 448-1000

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QUALITY ASSURANCE MANUAL

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2	2-8-80	2	Addition of Paragraphs 3 and 4		
2	2-8-80	5	Organization Chart		
2	2-8-80	7	Parts C and D		
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Approved By	A.D. Saggiomo, QA Manager		
Concurred By	Dr. T.S. Hermann, President		

SECTION 1. INTRODUCTION

A. Content

1. This Quality Assurance Manual contains policy statements, and describes the framework for the main elements of the Franklin Quality Assurance Program. A second level-type procedure known as Quality Assurance Systems Document (QASD) is used to support those elements that require interdepartmental coordination. A third level-type document known as a Quality Assurance Procedure (QAP) is used to support those elements where single organizational units are involved. The generation, control and maintenance of these documents is described in the Quality Assurance Administrative Instruction No. 1-1.

B. Purpose

The purpose of this Quality Assurance Program is to meet the applicable regulations of:

-ANSI N45.2- 1977
-10CFR50 Appendix B
-ASME Boiler and Pressure Vessel Code -
Section III - Article NCA-4000

C. Issuing Authority

1. The Franklin Manager of Quality Assurance is responsible for issuance of all new or revised procedures or documents contained in this Manual, as well as for providing instructions for interpretation of its content or intent, and for deletion of obsolete subject material.

D. Approvals

1. All initial issues, subsequent additions and revisions to this Manual shall be approved by the Manager of Quality Assurance and concurred by the President of FRC.

QA. 1. Introduction

E. Control of Copies

1. All copies of the Manual are issued by the:
Quality Assurance Office
The Franklin Research Center
Philadelphia, PA 19103

Copies of this Manual are issued in one of the following categories:

a. Working Copies - Copies, which are required for use by project personnel, are issued to individuals on a record-of-issue sheet. Record-of-issue sheets and an authorized distribution list of Manual holders are maintained and controlled at the above location. Each of these copies is numbered to assure strict control of copies and follow-up distribution of additions and revisions to this Manual. Only those Manual holders listed on the authorized distribution list receive additions and revisions automatically. Clients who receive copies of the Manual will be asked to return them upon completion of their projects at the Research Center.

b. Reference Copies - Copies which are required for use during audits, surveys, etc. are issued on a "one-time" basis and are not numbered, controlled, or updated. Such copies shall only be used for reference purposes. Reference copies are prefaced with a cover sheet stating: "This is an uncontrolled copy of the Franklin Quality Assurance Manual. For reference use only." The holder shall be responsible for verifying that the contents of a reference copy are current prior to each use of the copy. Reference copies shall normally be returned immediately after use unless otherwise authorized by the Manager of Quality Assurance or his designee.

F. Transmittal of Working Copy and Revisions

1. After initial issue, all copy holders are responsible for the complete, orderly filing and up-to-date maintenance of their own copy.

2. When a revision of this Manual is distributed, a record of revision page accompanies the revisions. The transmittal sheet also provides for acknowledgement of receipt by the holder and a statement that the designated Manual copy has been updated by the addition of the revised pages. The acknowledgement must be returned to the Franklin Quality Assurance Office within 10 days of the date of transmittal.

3. All copies which are no longer required by the individual holder shall be returned to the Quality Assurance Office as soon as possible. Upon

receipt of the returned Manual, this Office will delete the individual's name from the authorized distribution list.

G. Additions or Revisions

1. Tentative revisions, additions, or extensions consistent with the objectives of this Manual may be proposed to the Manager of Quality Assurance for review and possible incorporation. All such requests from Franklin personnel shall be submitted in writing through the applicable Laboratory manager.

2. Revisions to correct misspelled words, minor typing errors, and other editorial improvements which do not change the technical content are made on the next revision for the procedure involved, or annually, whichever method is the most practical at the time of change.

3. At the time of incorporation of revisions, the revision number, date, portion revised, and approval initials by the Manager of Quality Assurance and the President of FRC are added to the record-of-revision page. A vertical line in the right hand margin is placed on each affected page to indicate the location of the latest revision, except when an entire section has been revised.

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Concurred By		Dr. T.S. Hermann, President	

SECTION 2. STATEMENT OF POLICY

Franklin has the responsibility to assure that engineering services are provided in accordance with applicable codes and specifications. Accordingly, Franklin has established a comprehensive Quality Assurance Program which begins with initial design and stress analysis and carries through all phases of development, qualification testing, engineering, fabrication when applicable, and preservation of records. This Program provides for review of specifications and/or associated purchase documents to assure that any necessary quality control requirements are included. Quality Assurance surveillance and audits are performed to ensure that these specified requirements are met.

The Quality Assurance Program has been established and is implemented under the direction of the Franklin Manager of Quality Assurance. The Manager of Quality Assurance has the responsibility for establishing the program and auditing for compliance. The Director of each Operating Department has the responsibility for implementing the Quality Assurance Program for his Department through coordination and direction of all necessary quality control requirements and procedures, and assuring that these requirements and procedures are followed throughout the project.

The Manager of Quality Assurance shall report each year at a meeting of the President's staff on the state of the Quality Assurance Program.

Effective February 15, 1982 Andrew J. Saggiomo is appointed Quality Assurance Manager.

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	Approved By	A.J. Saggiomo, QA Manager
SECTION 3. ABBREVIATIONS, TERMS, AND DEFINITIONS	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To define the abbreviations, terms, and definitions commonly used in connection with Franklin's Quality Assurance effort.

B. Scope

1. The abbreviations below are given in the sense in which they are used or related to Quality Assurance. Additional abbreviations will be added to this procedure when the need arises.

2. The terms and definitions given in this section are described in the sense in which they are used or related to Quality Assurance. This listing is not meant to be complete; some sections contain definitions of key terms used therein. Additional terms and definitions will be added to this section when the need arises.

C. Abbreviations

ANSI	American National Standards Institute
DOE	Department of Energy
Franklin	Franklin Research Center (not-for-profit division of The Franklin Institute)
FRC	Franklin Research Center
FIRL	Franklin Institute Research Laboratories (for-profit subsidiary of The Franklin Institute)
NRC	Nuclear Regulatory Commission
PA	Project Administrator
PE	Professional Engineer

QA. 3. Abbreviations, Terms and Definitions

QA	Quality Assurance
QC	Quality Control

D. Definitions

Term	Definition
Audit	A periodic check of an organization's quality system, methods, effort and/or performance to contractual requirements.
Corrective Action	Any action initiated to change, correct, add, or delete engineering data or to implement changes in engineering, design, analysis, test, documentation, or quality control procedures, in order to prevent a recurrence of a nonconformance.
Documented Instruction	A method or manner of describing work or effort to be accomplished when it is defined in writing by procedures, drawings, technique sheets, industry standards, codes, etc.
Equipment	A combination of parts or materials in subassembly or completed form.
Inspection	Steps such as machine and gage measurements, visual and dimensional, etc., performed to verify that material, equipment, systems, or processes are in accordance with the specifications, drawings, or procedures.
Material	Items used to create other items; includes raw materials such as weld rod, plate, castings, forgings.
Procedure	A form of descriptive, documented instruction which is generally written in step-by-step format (as described in Quality Assurance Administrative Instruction No. 1-1 on QAPs).
Quality Administration	The management and documentation which assure that the specified Quality Assurance is carried out.
Quality Assurance	Comprises all those planned and systematic actions necessary to provide adequate confidence that all components, parts, or appurtenances are designed, tested, computed, manufactured, or installed (as applicable) in

	accordance with the contract requirements and applicable codes.
Quality Control	Comprises the examination of the physical characteristics of a material, component, part, or appurtenance and the acceptance standards associated with those examinations.
Sponsor	The client (agency, company, or individual) who pays for Franklin's services.

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SECTION 4. OUTLINE OF FRANKLIN QUALITY ASSURANCE PROGRAM	Concurred By	Dr. T.S. Hermann, President

A. General

1. The Franklin Quality Assurance Program is based on a system designed to effectively control, evaluate, and assure satisfactory control of quality and product integrity throughout all areas of project performance.

2. Particular emphasis is placed on controlling the quality of all structures, systems and components which could through product malfunction or failure, inadequate quality or accident cause undue harm and risk to the project or the health and safety of the public.

B. Applicability

1. This Program is applicable to all phases of engineering effort including coverage for:

   a. Incorporation of all necessary Quality Assurance requirements during design, stress analysis, fabrication, performance testing, development , and related effort.

   b. Evaluations of the Quality Assurance capabilities of any prospective consultant or subcontractor, and surveillance of any outside work performed.

   c. Assuring identification of and compliance with requirements of appropriate engineering codes and standards consistent with good engineering practice and consistent with contractual requirements of the sponsor. This shall include compilation of all pertinent Quality Assurance documents, as required.

QA. 4. Outline of Franklin Quality Assurance Program

C. Applicable Regulations

1. ANSI N45.2 - 1977 - Quality Assurance Program Requirements for Nuclear Power Plants.

2. 10CFR50 Appendix B - Quality Assurance Criteria for Nuclear Power Plants.

3. ASME Boiler and Pressure Vessel Code - Section III - Article NCA-4000 - Quality Assurance.

D. Program Responsibilities

1. Franklin is responsible for compliance with all applicable quality control requirements established by the sponsor.

2. In addition, Franklin is responsible for establishing, implementing and maintaining a Quality Program which assures that all supplies and services furnished under the project (whether manufactured or performed) are controlled at all points necessary to ensure conformance to project quality requirements.

3. In the event that Franklin procures services from a consultant or subcontractor, Franklin will apply and impose similar techniques, concepts, and requirements for quality as those used in managing its own Quality Assurance system.

4. The Manager of Quality Assurance is responsible for ensuring that individuals assigned to Quality Assurance activities possess the needed experience or training for carrying out the required functions.

E. Program Implementation

1. Specific elements of Franklin's Quality Assurance Program are described in Sections 5 through 20 of this Manual.

2. Quality Assurance System Documents are referenced for those elements that require inter-departmental standardization and coordination. They are generated, controlled and maintained by a top level Quality Assurance Administrative Instruction No. 1-1.

3. Quality Assurance Procedure documents are referenced for those elements where typically a single organizational unit is involved. They are generated, controlled and maintained by a top level Quality Assurance Administrative Instruction No. 1-1.

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Concurred By	Dr. T.S. Hermann, President

SECTION 5. CORPORATE ORGANIZATION

A. Purpose

To define the organizational structure, functional responsibilities, level of authority, and lines of internal and external communication for the management, direction and execution of the Quality Assurance Program as dictated by good business practices, and/or contractually required by sponsors of Test Lab/Engineering Evaluation service-type projects.

B. Applicability

1. Sponsor

2. Franklin Research Center

3. Consultants and Subcontractors

4. This section is applicable to those projects which contractually require the implementation of Criterion I of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Organization

In structuring the organization and assigning responsibility, Quality Assurance is recognized as an interdisciplinary function involving many organizational components. Quality Assurance is not the sole domain of a single Quality Assurance group. The achievement of our quality objectives is attained by each competent individual performing his assigned task in strict compliance with the approved applicable requirements and procedures defined in the Quality Assurance Program.

The FRC Quality Organization is illustrated by the organizational charts in Figures 1 and 2 of this section.

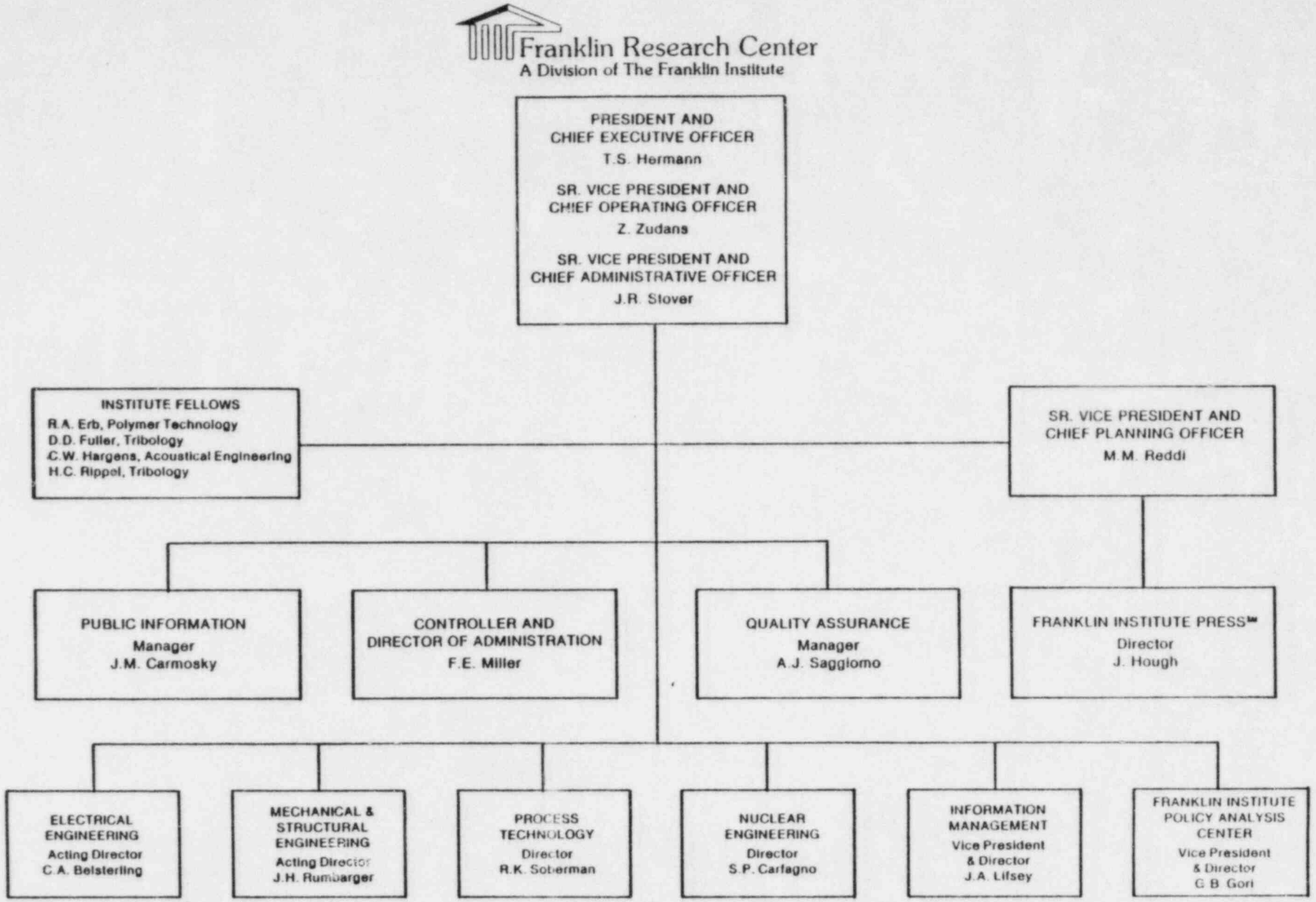

Figure 1. FRC Organization (Dec. 1)

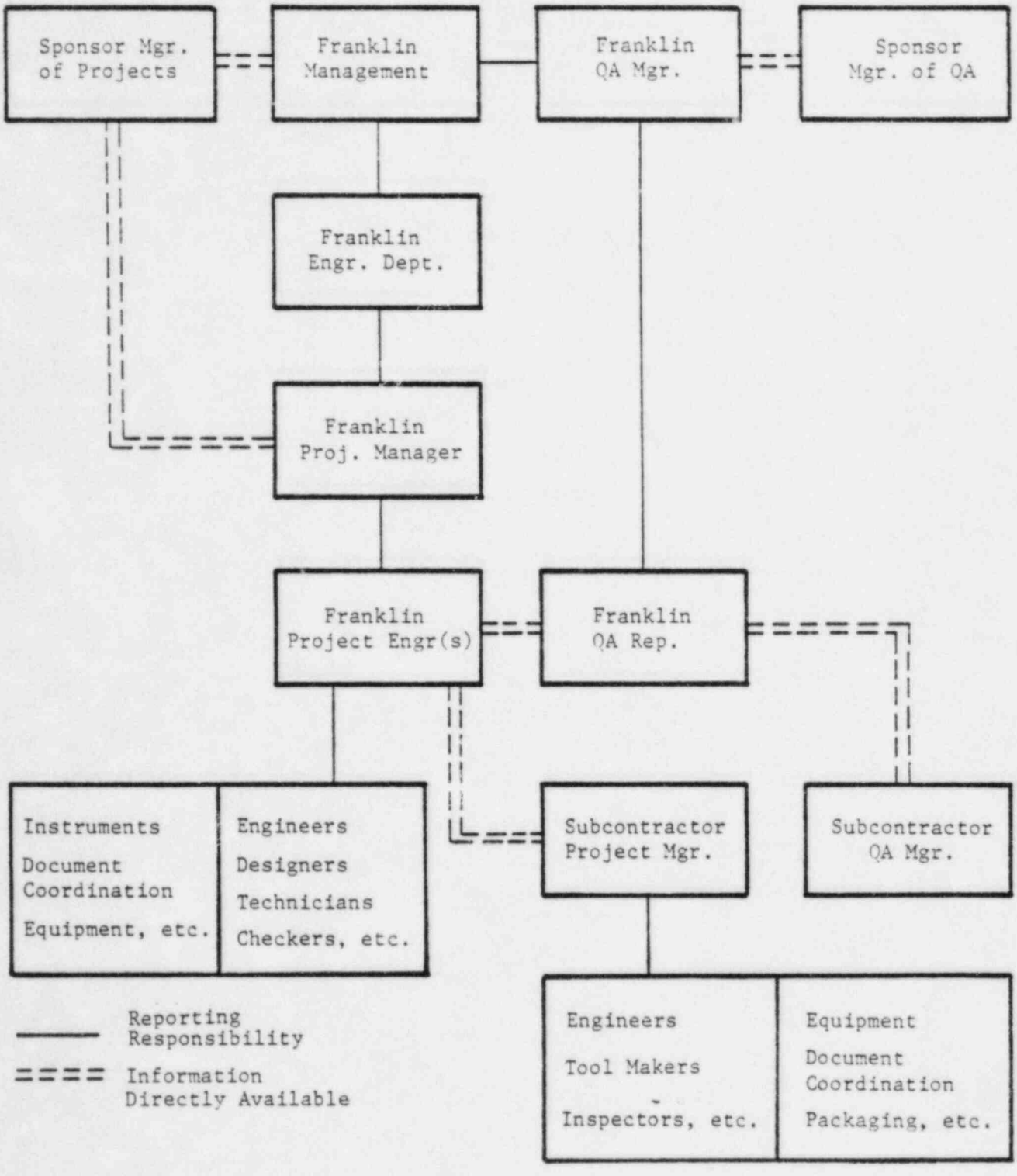

Figure 2. Franklin/Sponsor Project Organization

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SECTION 6. DESIGN CONTROL	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To define the product quality characteristics and quality standards (acceptance criteria) as found on drawings and/or sponsor designated contractual documents; to assure that changes or deviations from these defined requirements and quality standards are identified, documented and controlled.

2. To define requirements for establishing suitability of materials of construction, parts, and processes for a given project.

3. To establish the need for identification and control of Design or Test Lab/Engineering Evaluation service-type project interfaces.

4. To define requirements for implementation of design reviews, alternate methods of calculation, or testing to verify the adequacy of designs, and/or adequacy of Test Lab/Engineering Evaluation service-type projects (see QASD No. 6-1).

5. To define the necessary change control methods which would be implemented on projects of a design nature as well as Test Lab/ Engineering Evaluation service-type projects.

B. Scope

1. All projects involving Design and Test Lab/Engineering Evaluation service-type activities. This section is applicable to those projects which contractually require the implementation of Criterion III of 10CFR50, Appendix B, and its equivalent ANSI section.

QA. 6. Design Control

C. Responsibility/Action

1. The Project Manager shall identify the engineering interfaces that are involved and implement QASD No. 6-1, to the extent necessary.

2. The Project Manager shall determine whether design reviews, alternate methods of calculation or testing shall be used to verify design activities or Test Lab/Engineering Evaluation service activities. He shall implement QASD No. 6-1, to the extent necessary.

3. The Project Manager shall ensure that all defined requirements and quality standard changes are covered by design change control measures. These control measures shall provide for the same degree of control over changes as was exercised for the original design. The Project Manager shall implement QASD No. 9-1, to the extent necessary.

4. The Project Manager shall ensure that materials, parts and processes are suitable for a given use.

5. The Project Manager shall ensure that drawings and specifications prepared under his cognizance include Quality Assurance standards.

6. The Quality Assurance Manager or his designated alternate shall audit projects for compliance to the requirements of this section and any supporting QASD.

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Concurred By	Dr. T.S. Hermann, President

SECTION 7. CONTROL OF PROCUREMENT

A. Purpose

1. To ensure that applicable requirements (codes, standards, regulatory requirements, quality control plans, etc.) are included or referenced in the purchase order or contract documentation.

2. To ensure that materials, equipment and services comply with purchase order documentation.

3. To ensure that vendors or subcontractors are required to provide a Quality Assurance Program responsive to 10CFR50, Appendix B, to the extent necessary to assure that the quality of product is consistent with the safety-related function to be performed, both directly and indirectly implied.

B. Scope

1. This section of the Quality Assurance Program applies to the procurement of all materials, equipment and services, to the extent necessary, as defined above in para. A.2. It is applicable to those projects which contractually require the implementation of Criteria IV and VII of 10CFR50, Appendix B, and its equivalent ANSI sections.

C. Responsibility

1. The Project Manager or his designee shall be responsible for defining the elements (vendor quality requirements) for an approved Quality Assurance Procedure to the extent necessary, and for assuring that it is included or referenced in the purchase order or contract documentation.

2. The Project Manager or his designee shall be responsible to define the elements (FRC Test and Inspection Requirements) for an approved Quality Assurance Procedure, to the extent necessary.

QA. 7. Control of Procurement

3. The Quality Assurance Manager shall be responsible for qualifying prospective vendors or subcontractors, based on audits of their Quality Assurance Program, past quality performance record and/or other quality-related rationale, to the extent necessary. In addition the Manager of Quality Assurance is responsible for review/approval of quality-related procurement documentation.

D. Action

1. The Project Manager or his designee shall prepare the necessary Quality Assurance Procedure which shall include one or more of the following. (See QASD No. 7-1).

   a. Vendor performed in-process and/or final inspection activity

   b. Franklin performed source inspection activity

   c. Franklin performed receiving inspection activity

   d. Franklin performed vendor qualification inspection activity. The Manager of Quality Assurance shall possess documentation showing justification rationale for the qualified status of the vendor.

2. The Project Manager shall assure that the applicable vendor requirements, defined in the form of approved QAPs, are included or referenced in the purchase order or contract documentation.

3. The Manager of Quality Assurance shall qualify, to the extent necessary, prospective vendors or subcontractors. This shall be done based on audits of their Quality Assurance Program, past quality performance record and/or other substantive quality-related rationale.

4. The Project Manager or his designee, with the approval of the Manager of Quality Assurance, shall implement the Quality Assurance Procedure which calls for in-house test or inspection of in-coming pruchased material or equipment.

5. The Project Manager shall file all quality-related documents including material traceability records, to the extent necessary. The filing and control of Quality Assurance records shall be done in accordance with QASD No. 19-1.

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SECTION 8. INSTRUCTIONS, PROCEDURES AND DRAWINGS	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To ensure that quality-related activities are documented in instructions, procedures, and drawings and that these activities are determined objectively to be implemented as documented.

B. Scope

1. This section is applicable to those projects which contractually require the implementation of Criterion V of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibility

1. The Project Manager is responsible for assuring that all applicable quality requirements are included in appropriate drawings, procedures or instructions. Further, this documentation shall include appropriate quantitative or qualitative criteria for determining that important and relevant activities have been satisfactorily accomplished.

2. The Quality Assurance Manager is responsible for assisting the Project Manager in defining the acceptance criteria/methods and in approving all documentation.

D. Action

1. The Project Manager or his designee shall prepare adequate documentation of quality-related activities and this documentation shall include appropriate quantitative or qualitative criteria for determining that important and relevant activities have been satisfactorily accomplished. This documentation will normally take the form of an approved QAP.

2. The Quality Assurance Manager shall approve all documentation and shall audit to ensure a compliance with the requirements of this section.

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	Approved By	A.J. Saggiomo, QA Manager
SECTION 9. DOCUMENT CONTROL	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To ensure that measures are taken to establish a "Document Control System" for both design and Quality Assurance documents which prescribe activities affecting quality (see QASD No. 9-1 and QAAI No. 1-1, respectively).

B. Scope

1. All design documentation such as drawings, specifications, instructions and Quality Assurance documents such as QASDs and QAPs that prescribe activities affecting quality, whether such documents are generated internally or externally. This section is applicable to those projects which contractually require the implementation of Criterion VI of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibility/Action

1. The Project Manager is responsible for assuring that:

   a. The proper document is used, such as proper revision etc.

   b. The document is used at the right place, such as where the quality-related activity is performed.

   c. All elements of generation, control and maintenance of documents described in QAAI No. 1-1 and QASD No. 9-1 are implemented.

2. The Quality Assurance Manager is responsible for establishing measures to control the issuance of documents and for performing periodic audits to ensure compliance. (See QASD No. 9-1 and QAAI No. 1-1).

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SECTION 10. CONTROL OF SPECIAL PROCESSES	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To ensure that special processes such as heat treating, welding, and nondestructive testing are carried out under controlled conditions, by qualified personnel and procedures in accordance with applicable codes, standards, and specifications.

B. Scope

1. All special processes involving pertinent quality requirements as specifically defined by the sponsor and which contractually require the implementation of Criterion IX of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibilities

1. The Project Manager is responsible for assuring that all activities on his project which are classed as special processes shall conform to the requirements of this section, to the extent necessary.

2. The Quality Assurance Manager is responsible for assisting the Project Manager in establishing a documented system appropriate for the project, approving the QASD that may be developed, and auditing for compliance.

D. Action

1. The Project Manager shall review project requirements to determine any special processes that have been specified for a given project.

2. The Project Manager shall provide qualified procedures and personnel which will include workmanship and/or skill training, to the extent necessary, for special process operations defined and/or approved by the sponsor.

QA. 10. Control of Special Processes

3. The Project Manager shall maintain qualification documentation for personnel, processes and equipment as required contractually by the sponsor and in accordance with applicable Quality Assurance codes and standards.

4. The Quality Assurance Manager or his designated alternate shall audit projects for compliance to the requirements of this section and any supporting QASD or QAP.

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Approved By	A.J. Saggiomo, QA Manager		
Concurred By	Dr. T.S. Hermann, President		

SECTION 11. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

A. Purpose

1. To ensure that appropriate materials, parts or components that are fabricated or tested at the Research Center are properly identified and controlled throughout their period of processing.

B. Scope

1. All appropriate materials, parts or components that are fabricated or tested at the Research Center. The identification system will be in the form of a QASD or QAP as defined in QAAI No. 1-1. The identification may be either on the item or on records traceable to the item. This section is applicable to those projects which contractually require the implementation of Criterion VIII of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibility

1. The Project Manager is responsible for establishing a system of identifying and controlling all appropriate materials, parts or components that are fabricated or tested for a specific project.

2. The Quality Assurance Manager is responsible for giving guidance to the Project Manager on this issue, approving the appropriately documented system (QASD or QAP), and auditing to ensure compliance with the requirements of this section.

D. Action

1. The Project Manager shall review the contractual details of the project, and using the guidance of the Quality Assurance Manager, determine the extent to which an identification and control system for materials, parts or components will apply. Further, he shall provide adequate measures for those safety-related, code-covered items which require traceability.

2. The Manager of Quality Assurance or his designated alternate shall audit to ensure compliance to the requirements of this section.

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Approved By	A.J. Saggiomo, QA Manager		
Concurred By	Dr. T.S. Hermann, President		

SECTION 12. INSPECTION

A. Purpose

1. To ensure that fabrication and/or assembly operations which generate important quality characteristics are properly controlled through a formally documented inspection program. This program shall inspect both the activities affecting quality and the generated product quality characteristics in order to verify conformance with the documented instructions, procedures and drawings for accomplishing the activity.

B. Scope

1. All fabrications, operations and tests that are performed on projects which contractually require the implementation of Criterion X of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibility

1. The Project Manager is responsible for determining the product attributes and/or process parameters which must be measured at various process points to assure proper quality; establishing the proper tests that are to be done; and documenting this into an inspection program.

2. The Project Manager is responsible for ensuring that the inspection program contains sponsor designated hold points which require witness or inspection by the sponsor. These specific hold points shall be indicated in appropriate documents.

3. The Quality Assurance Manager is responsible for approving the inspection program plan and periodically auditing for compliance.

D. Action

1. The Project Manager or his designee shall prepare adequate documentation of the quality-related activities (i.e. inspection program) that are involved in the fabrication and/or assembly

operations. This documentation will normally take the form of an approved QAP.

2. The Quality Assurance Manager shall:

   a. Aid the Project Manager in the determination of the proper product attributes and/or process parameters that must be measured.

   b. Aid the Project Manager in establishing the proper tests that are to be done.

   c. Aid the Project Manager in assuring that final inspection and verification are performed by individuals other than those who carried out the work being inspected.

3. The Quality Assurance Manager shall audit to ensure compliance with the requirements of this section.

A. Purpose

1. To ensure that the inspection, test and operating status of parts or components fabricated or tested at the Research Center are known at all times.

B. Scope

1. All materials, parts or components that are in process at the Research Center and that are related to a specific project which contractually requires the implementation of Criterion XIV of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibility/Action

1. The Project Manager is responsible for assuring that inspection, test and operating status of parts or components are known at all times. This may be accomplished by defining the method as part of the documented test and inspection requirements for the quality-related activities of a specific project.

2. The Manager of Quality Assurance is responsible for review and approval of all Quality Assurance Documents (QASDs and QAPs), and for auditing the documented system in order to assure compliance to the requirements of this section.

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	Approved By	A.J. Saggiomo, QA Manager
SECTION 14. TEST CONTROL	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To ensure that a controlled testing service program is conducted for demonstrating the proper performance and/or safety of equipment and materials. A documented test program shall be implemented to assure that the contractual requirements of the sponsor are satisfied.

B. Scope

1. Performance qualification tests encompass all of the physical evaluations of the performance of materials, equipment, and devices used in industrial plants, transportation systems, commercial establishments, and homes. The tests include, but are not limited to, performance measurements; accelerated thermal, operational and radiation aging (simulation of the degradation that occurs during normal installed life); seismic and other vibrations; fire and overheating exposures; and simulation of design-basis accident conditions, such as those in nuclear power plants. This section is applicable to those projects which contractually require the implementation of Criterion XI of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Definitions

1. Performance Qualification Testing - The independent physical evaluation of the performance of materials and mechanical, electrical, and other equipment when subjected to both normal and abnormal conditions.

2. In-Date calibration is the same as Active Status referred to in QASD No. 15-1, titled "Periodic Calibration System". This status is assigned to any measuring and testing device which has been calibrated and has a recorded calibration due data that is beyond the current date.

QA. 14. Test Control

D. Responsibility

1. The Project Manager is responsible for documenting the necessary test program which will assure that the contractual requirements (applicable design documents, standards, codes etc.) are satisfactorily implemented.

2. The Project Manager is responsible for assuring that the necessary procedures for the tests are prepared and approved before testing begins. This shall include the completion of all prerequisites for the test including availability of calibrated test instrumentation.

3. The Manager of Quality Assurance or his designated alternate is responsible for approving all test program documentation which addresses quality-related activities and for auditing to assure compliance with the various requirements of this section.

E. Action

1. The Project Manager or his designee shall prepare the test plan and procedure which will assure that the contractual requirements (applicable design documents, standards, codes etc.) are satisfactorily implemented. He shall sign all approved test plans, procedures and documentation. He shall review all purchase requisitions to ensure that applicable codes and specifications are referenced. Typically, quality-related activities will be documented by a QAP and will be approved by the Manager of Quality Assurance.

2. The Project Manager or his designee shall prepare a list of all calibrated instruments to be used in the test program and check the in-calibration (active status) of each instrument before testing begins.

3. The Project Manager shall review all test results and conclusions to certify their correctness and to assure that the test plan has been satisfied. He shall sign all paperwork which contains project reportable data.

4. The Project Manager shall include provision for assuring that all test prerequisites are satisfied, and that tests are performed under suitable environmental conditions as dictated by contractual requirements and good engineering practice.

5. The Manager of Quality Assurance shall audit the testing program at periodic intervals to ensure compliance with the requirements of this section.

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Approved By	A.J. Saggiomo, QA Manager		
Concurred By	Dr. T.S. Hermann, President		

SECTION 15. CONTROL OF MEASURING AND TEST EQUIPMENT

A. Purpose

1. To ensure that measures are taken to identify, control and maintain measuring and testing devices. This shall include the establishment of a "Periodic Calibration System" for tools, gages and instruments.

B. Scope

1. All tools, gages and instruments which are used to acquire project reportable data shall be identified, controlled and maintained by the "Periodic Calibration System." This section is applicable to those projects which contractually require the implementation of Criterion XII of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibilities/Action

1. The Quality Assurance Manager is responsible for establishing the necessary "Periodic Calibration System" and for performing periodic audits to ensure compliance. (See QASD No. 15-1).

2. The Project Manager is responsible for assuring that the tools, gages, instruments or other measuring and testing devices, which he intends to use to acquire project reportable data, are calibrated to within the accuracy tolerance specified. To accomplish this he shall rely on the output information from the "Periodic Calibration System."

3. The Project Manager is responsible for delivering to the instrument engineer all newly acquired measuring and testing devices which he intends to use to acquire project reportable data. This shall include all supporting paperwork, operating and calibration instructions. Newly acquired means measuring and testing devices which have either been bought, borrowed or rented and are currently not on the gage calibration master list.

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SECTION 16. HANDLING, STORAGE, AND SHIPPING

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Approved By		A.J. Saggiomo, QA Manager	
Concurred By		Dr. T.S. Hermann, President	

A. Purpose

1. To ensure that proper controls are established on the methods of handling, storage and shipping, (including cleaning, packaging and preservation of material and equipment) on which quality requirements apply.

2. To ensure that when special protective environments are necessary to prevent damage or deterioration, the special requirements are documented in appropriate instructions.

B. Scope

1. All items that are in process at the Research Center, and all equipment that is used in such processing on projects which contractually require the implementation of Criterion XIII of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibility

1. The Director of each Department shall ensure that permanent equipment in his area of cognizance is properly housed, preserved, and maintained.

2. The Project Manager shall ensure that drawings, procedures, or instructions are prepared for the proper handling, storage, or shipment of items in fabrication or test at the Research Center.

D. Action

1. The Director of each Department shall have a housekeeping committee to review, and if necessary, improve the methods for protection of permanent equipment.

QA. 16. Handling, Storage, and Shipping

2. The Project Manager shall provide a system that includes a review of drawings and work procedures to ensure that handling, storage and shipping (including cleaning, packaging and preservation of material and equipment) are accomplished by suitably trained individuals in accordance with escablished instructions, procedures or drawings to prevent damage, deterioration and loss. In particular, when special protective environments are necessary to prevent damage or deterioration, the special requirements shall be documented in an appropriate procedure (QASD or QAP).

3. The Manager of Quality Assurance shall audit applicable projects at periodic intervals to review the adequacy of handling, storage, and shipping requirements of this section.

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SECTION 17. CONTROL OF NONCONFORMING MATERIALS, PARTS OR COMPONENTS

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Approved By	A.J. Saggiomo, QA Manager		
Concurred By	Dr. T.S. Hermann, President		

A. Purpose

1. To establish a system to control nonconforming materials, parts or components and thereby prevent the inadvertent use of such items. This system shall include the documentation, segregation and disposition of nonconforming material, and the notification to affected organizations.

B. Scope

1. All materials, parts or components that are present at the Research Center for fabrication, testing and/or engineering evaluation. This section is applicable to those projects which contractually require the implementation of Criterion XV of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibilities/Action

1. The Manager of Quality Assurance is responsible for establishing, documenting, and maintaining a nonconforming material control system. (See QASD No. 17-1)

2. The Project Manager is responsible for assuring that the requirements of this section and those of supporting document, QASD No. 17-1, are implemented.

3. The Manager of Quality Assurance or his designated alternate is responsible to audit for compliance to the requirements of this section and its supporting documents.

D. Action

1. The Manager of Quality Assurance shall take measures to establish a control system for nonconforming materials, parts or components. This shall include, as appropriate, the writing of procedures for the identification, documentation, segregation, disposition and notification to affected organizations of discrepant items. In addition, nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. (See QASD No. 17-1)

QA. 17. Control of Nonconforming Materials, Parts or Components

2. The Manager of Quality Assurance shall provide and designate an enclosed area for quarantine of discrepant items.

3. The Manager of Quality Assurance shall provide tags to be used to identify items that are discrepant.

4. The Manager of Quality Assurance shall audit the system at periodic intervals to determine compliance with the requirements of this section.

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	Approved By	A.J. Saggiomo, QA Manager
SECTION 18. CORRECTIVE ACTION	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To establish a documented corrective action system which shall assure that conditions adverse to quality will be properly defined, controlled and actively corrected in a timely way.

B. Scope

1. The Corrective Action System shall be implemented to assure that nonconformances (as determined by engineering reviews, independent in-house audits, or simply, individual awareness of what is right/wrong relative to the Franklin Quality Assurance Program) are identified, the proper cause defined and corrective action taken to preclude repetition. (See QASD No. 17-1). This section is applicable to those projects which contractually require the implementation of Criterion XVI of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Responsibilities/Action

1. Any individual who discovers a nonconformance is responsible for initiating a corrective action request and having it reviewed for approval by the Manager of Quality Assurance.

2. The Project Manager is responsible for the initiation and implementation of corrective action requests (CAR) appropriate to his area of responsibility. This shall include filing all approved CARs in the project file.

3. The Project Manager in whose area a major deficiency has occurred is responsible for defining the cause and implementing the corrective action to preclude repetition.

4. The Manager of Quality Assurance is responsible for approving all corrective action requests; for filing all "Corrective Action Request" forms; and for establishing a follow-up system to assure implementation of the corrective action. He shall audit to ensure compliance with the requirements of this section.

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	Revision Number 3	Date 4/5/82
	Approved By	A.J. Saggiomo, QA Manager
SECTION 19. QUALITY ASSURANCE RECORDS	Concurred By	Dr. T.S. Hermann, President

A. Purpose

1. To ensure that a system is established for defining the identification, retention, retrieval and maintenance requirements involved in the collection, handling and/or storage of significant records that furnish evidence of the quality of items and/or activities affecting quality.

B. Scope

1. Typically all Quality Assurance records which the Sponsor has defined as significant/retainable, or those records which are specified in applicable codes, standards and regulations and defined contractually for a project.

C. Responsibility

1. The Sponsor of the project is responsible for clearly defining all applicable codes, standards and regulations concerning record requirements, so that the subcontractor (FRC/FIRL) knows the appropriate record generation, transmittal and maintenance requirements both during and subsequent to completion of work.

2. The Project Manager is responsible for defining Quality Assurance records which need to be generated, handled and/or stored per the supporting Quality Assurance Systems Document (QASD No. 19-1) by reviewing the project's contractual requirements.

3. The Nuclear Engineering Department Librarian is responsible for implementing the record receipt, indexing, filing and retrieval aspects of the system described in QASD No. 19-1.

4. The Quality Assurance Manager is responsible for giving guidance to the Project Manager in defining the Quality Assurance records which need to be generated, handled and/or stored; in defining the location and storage facility configuration per the requirements of ANSI N45.2.9; and for auditing to ensure compliance with the requirements of this section and the supporting QASD No. 19-1.

D. Action

1. The Project Manager shall ensure that all appropriate Quality Assurance records for his project are collected, handled and/or stored according to the established system (QASD No. 19-1).

   a. For example, such records as Calibration Test Reports, Corrective Action Requests, Project Audit Results, Design Verification Reviews, Product Inspection Results, Material Analyses Reports, Personnel Qualification Data, Procedure and Equipment Qualification Data. These records shall be copied, handled/stored in the project file folder, if required contractually.

2. The Quality Assurance Manager or his designated alternate shall audit for compliance to the requirements of this section.

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Approved By	A.J. Saggiomo, QA Manager		
Concurred By	Dr. T.S. Hermann, President		

SECTION 20. AUDITS

A. Purpose

1. To provide a system of periodic audits of all quality activities to verify compliance with the Franklin Quality Assurance Program.

B. Scope

1. The Manager of Quality Assurance is responsible for the planning and performance of audits either by himself or by a designated alternate. This section is applicable to those projects which contractually require the implementation of Criterion XVIII of 10CFR50, Appendix B, and its equivalent ANSI section.

C. Action

1. The Manager of Quality Assurance shall have a documented audit plan encompassing the total Quality Assurance Program. (See QASD No. 20-1)

2. The Manager of Quality Assurance or his designated alternate shall conduct a random audit in accordance with a documented audit plan (checklist) at least once a year.

3. The Manager of Quality Assurance or his alternate shall verify the completion of planned corrective actions called for as the result of a CAR (Section 18) generated from an internal or other special audits.

4. The Manager of Quality Assurance shall submit a report of audit results to the President of FRC and to the Manager(s) having responsibility for the activity audited.

5. Those performing audits shall be individuals with appropriate education, training and/or experience who have no direct responsibilities for activities in the area audited.

A P P E N D I X

QUALITY ASSURANCE ADMINISTRATIVE INSTRUCTION

Franklin Research Center A Division of The Franklin Institute The Benjamin Franklin Parkway, Phila., Pa. 19103 (215) 448-1000 QUALITY ASSURANCE	QAAI NO. 1-1	Page 1 of 7
	Date Issued 4-5-82	Effective Date 4-5-82
	Revision Number 0	Review Date 4-5-84
	☒ Prepared [signature]	
	☒ Approved [signature] QA Manager	
TITLE DOCUMENT CONTROL SYSTEM FOR QASD AND QAP PROCEDURES	Concurred By [signature] Dr. T.S. Hermann, President	

1.0 PURPOSE

1.1 This top level Quality Assurance Administrative Instruction (QAAI) describes the Quality Assurance documents used by Franklin to support the various work elements described in the Quality Assurance Manual. This Instruction is designed to define the generation, control and maintenance of second and third level-type Quality Assurance documents.

2.0 GENERAL REQUIREMENTS

2.1 Projects which contractually call for the implementation of the FRC Quality Assurance Manual shall adhere to the requirements of this Instruction. Regulatory requirements and business needs dictate that activities affecting quality be prescribed by documented systems and procedures of a type appropriate to the circumstances, and which are distributed to and used at the location where the prescribed activity is performed.

3.0 RESPONSIBILITIES

3.1 The Manager of Quality Assurance is responsible for ensuring full implementation of this document control system. He is responsible for review and approval of all QASD and QAP documents.

4.0 DEFINITIONS

4.1 Quality Assurance Systems Document (QASD) is a second level QA document. In general, this document addresses those quality-related work elements that require interdepartmental standardization and coordination.

4.2 Quality Assurance Procedure (QAP) is a third level type QA document. In general, this document is used where a single organizational unit is involved.

5.0 INSTRUCTIONS

The following instructions shall apply for both QASD and QAP documents:

5.1 Generation

5.1.1 Use document format as illustrated in Exhibit I and II for a QASD and QAP, respectively.

5.1.2 Use document format as illustrated in Exhibit III and IV for additional pages to a QASD or QAP, respectively.

5.1.3 For a QASD or QAP use the following sequence of sections:

1.0 PURPOSE

2.0 RESPONSIBILITIES

3.0 DEFINITIONS

4.0 INSTRUCTIONS

5.0 CROSS REFERENCES

6.0 COUNSEL AND REVIEW CONTACT

7.0 DISTRIBUTION

5.1.4 The requisite procedures shall be determined by the responsible Program Manager or Project Engineer in accordance with the needs of the program. Procedures shall be prepared by any competent individual possessing an adequate familiarity with the subject matter.

5.1.5 In general, the instruction portion of the document should contain such things as:

- Procedural steps in proper sequence
- Safety cautions, if appropriate
- Inspection hold points, if appropriate
- Reference to appended forms or data sheets
- Identification of supporting facilities, tools and instruments necessary to implement the procedure.

5.2 Control

5.2.1 A unique document control number shall be assigned by the Manager of Quality Assurance.

5.2.2 The Manager of Quality Assurance shall review and approve all documents. The Manager of the affected organizational unit shall review and approve all documents which apply in any way to the operation of his unit.

5.2.3 Concurrence by the President of FRC is required for all QASD documents. This concurrence is optional for QAP documents.

5.3 MAINTENANCE

5.3.1 The Manager of Quality Assurance shall maintain adequate records to assure proper assignment of document control numbers.

5.3.2 The Manager of Quality Assurance shall maintain adequate records to assure control of revisions to all documents. This shall include the requirement that all changes must be approved by the same organization that performed the original review and approval.

5.3.3 At the time of initial issuance of the document, the review date(not to exceed 2 years) shall be assigned. A new review date is assigned each time the document undergoes revision. If no revision occurs before the review date, the document will be reviewed by the original organization to assure that it remains fully applicable relative to the most current codes and standards.

6.0 CROSS REFERENCE

6.1 FRC Quality Assurance Manual

7.0 COUNSEL AND REVIEW CONTACT

7.1 Manager - Quality Assurance

8.0 DISTRIBUTION

8.1 Manager - Quality Assurance

8.2 Manager(s) - Affected organizational units

8.3 FRC President

8.4 Project Managers

QUALITY ASSURANCE SYSTEMS DOCUMENT

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QUALITY ASSURANCE SYSTEMS

QASD No.	Page 1 of
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☐ Prepared

☐ Approved — QA Manager

TITLE

Concurred By — Dr. T.S. Hermann, President

EXHIBIT I

QUALITY ASSURANCE PROCEDURE

Franklin Research Center A Division of The Franklin Institute 20th and Race Streets. Phila., Pa. 19103 (215) 448-1000 QUALITY ASSURANCE PROCEDURE	QAP No.	Page 1 of
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TITLE	Concurred By	

EXHIBIT II

EXHIBIT III

EXHIBIT IV

QUALITY ASSURANCE SYSTEMS DOCUMENT

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QUALITY ASSURANCE SYSTEMS

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Date Issued 3-8-82	Effective Date 3-8-82
Revision Number 0	Review Date 3-8-84

☒ Prepared Robert M. Graff QA Manager

☒ Approved Richard Spagnolo QA Manager

Concurred By T.S. Hermann
Dr. T.S. Hermann, President

TITLE: TECHNICAL VERIFICATION AND CONTROL OF TEST LAB/ENGINEERING EVALUATION SERVICE ACTIVITIES

1.0 Purpose

1.1 This document is designed to implement Section 6 of the FRC Quality Assurance Manual which in turn was designed to implement the intent of the requirements of 10CFR50 Appendix B, criterion III, titled "Design Control".

1.2 The purpose of this document is to prescribe how engineering evaluation service activities - especially those technical activities affecting the quality of engineering results - are to be generated, controlled, maintained and ultimately presented in a final report. Specifically this document shall cover three areas:

Requirements for:

1. Identification and control of engineering evaluation service type project interfaces (Document Control).

2. Implementation of the design review method for verification of engineering evaluation service type project activities.

3. The implementation of the necessary document change control method that will be implemented on engineering evaluation service type projects.

2.0 Responsibilities

2.1 The Project Manager is responsible for reviewing the contractual requirements of the project in light of the instructional requirements given below and implementing them to the extent necessary.

2.2 The Quality Assurance Manager is responsible for assisting the Project Manager in implementing the instructional requirements of this document and periodically auditing for compliance.

3.0 Definitions

3.1 Sponsor is the client who has a contractual agreement with FRC/FIRL.

3.2 Design Documents are those drawings, specifications, memoranda, instructions, etc. which relate to the technical matter of the program.

3.3 Design Inputs are those inputs to a project which take the form of design bases, performance requirements, codes, standards, design conditions such as pressure temperature, voltage, seismic loads etc.

3.4 Engineering Analysis Control/Verification Record - This record provides for engineering analysis revision control and design (engineering analysis) review verification control. (See Exhibit I).

3.5 Report Review Verification Record - This record provides for documenting on a project bases an overall summary of the reviews, approvals and verifications. (See Exhibit II).

3.6 FIRL Engineering Analyses Sheet - This sheet is used to document the details of the engineering analyses. Use form CS-FIRL-81, see Exhibit III.

4.0 Instructions

4.1 Requirements for identification and control of engineering evaluation service type project interfaces.

4.1.1 There is one engineering interface unless otherwise defined by Project Manager.

4.1.2 The engineering interface is between the sponsor and the FRC/FIRL organization. The flow of design documents (see definition) across this interface will be documented/ controlled by implementing QASD No. 9-1.

4.1.2.1 The Project Manager is responsible for assuring that QASD No. 9-1 is properly implemented.

4.1.2.2 Where it is necessary to initially transmit technical information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

4.2 Requirements for implementation of the design review method for verification of engineering evaluation service type project activities.

4.2.1 Background - "Design Control", criterion III of 10CFR50 Appendix B requires that design analysis (engineering evaluation service type project activities) be performed in a planned, controlled and documented manner.

4.2.2 Engineering analysis documents shall be legible and be in a form suitable for reproduction, filing and retrieval.

4.2.3 Engineering analysis documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

4.2.4 The Project Manager/Leader is responsible for assigning a competent individual to do the engineering analyses for the various major technical areas of the project.

4.2.5 The Project Manager/Leader is responsible for assigning a competent individual to verify the adequacy of the original engineering analyses for each of the major technical areas.

4.2.5.1 In the selection of a competent individual the Project Manager/Leader shall be guided by the following; verification shall be performed by any competent individual(s) other than those who performed the original analyses 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 analyses approach or rule out certain design considerations and did not establish the analyses inputs used in the design or provided the supervisor is the only individual in the organization competent to perform the verification.

4.2.5.2 Further the Project Manager/Leader shall be guided by the fact that the extent of analyses verification required is a function of the importance to safety of the item under consideration, the complexity of the analyses, the degree of standardization, the state of the art, and the similarity with previously proven analyses.

4.2.6 The Project Manager/Leader is responsible for determining which verification method shall be used. Acceptable verification methods include any one or a combination of the following: design reviews, alternate calculations, and

qualification testing. Typically for engineering evaluation service type projects an independent design (engineering analyses) review will be required.

4.2.6.1 The Project Manager/Leader is responsible for assuring that the assigned verifier is adequately familiar with the importance of his review. For example a design (engineering analyses) review should assure the technical integrity of the analyses by answering in a positive way the following types of questions.

1. Were the design inputs identified and traceable to referenced documents?

2. Were the design inputs correctly selected?

3. Were the design inputs correctly applied?

4. Are assumptions and problem formulation adequately described and reasonable?

5. Was the appropriate analytical/calculational method used, including computer programs?

6. Is the design output reasonable compared to design inputs?

4.3 Requirements for the implementation of the necessary document change control method on engineering evaluation service type projects.

4.3.1 Changes to Engineering Analyses are the result of two cases: (I) originator made errors in the analyses and it was found by the verifier during his independent design review or, (II) the design inputs changed.

4.3.1.1 Case (I) - For Case I the change control method is an obvious and integral part of the Engineering Analysis Control/Verification Record, see Exhibit I.

4.3.1.2 Case (II) - For Case II the change control method is an obvious and integral part of the QASD No. 9-1 titled "Document Control".

4.4 The Program Manager/Leader is responsible for assuring that the design analyses (Engineering Evaluation Service Type Project Activities) are performed in a planned, controlled and documented manner. It is therefore required that he develop a set of Work Plan Guidelines which will address the question of analysis format that will be used, and a

Qualification Test Plan Outline or procedure which will address such questions as methodology to be employed, components involved, major technical areas of analyses, qualification methods to be employed etc. Typically, the development of the Qualification Test Plan is a requirement of the contract and requires sponsors approval before implementation. The Project Manager/Leader can find excellent guidance on how to develop these two items by reviewing such documents as:

(a) Draft IEEE Std. 323-198X titled "Qualifying Class IE Equipment for Nuclear Power Generating Stations".

(b) ANSI N42.7 - 1972, Section 4.4, titled "Equipment Qualification"

(c) IEEE Std. 308-1980, "Criteria for Class IE Power Systems for Nuclear Power Generating Stations," Section 5.9, "Equipment Qualification".

5.0 Cross References

5.1 Quality Assurance Manual - Sections 6 and 9

6.0 Counsel and Review Contact

6.1 Manager - Quality Assurance

7.0 Distribution

7.1 Manager - Quality Assurance

7.2 Managers of the Performing Departments

Franklin Institute Research Laboratory, Inc.
A Subsidiary of The Franklin Institute
The Benjamin Franklin Parkway, Philadelphia, Pa. 19103

PROJECT NO.

IDENTIFIER

PROJECT TITLE

PAGE 1 OF

SUBJECT

ENGINEERING ANALYSIS CONTROL/VERIFICATION RECORD

REVISION	0	1	2
ITEM(S) REVISED			
ORIGINATOR			
DATE			
VERIFIER			
DATE			
THE DESIGN REVIEW OF THE ANALYSIS INCLUDED EVALUATION AGAINST THE FOLLOWING QUESTIONS:	REMARKS	REMARKS	REMARKS
ARE INPUTS, INCLUDING CODES, STANDARDS, AND REGULATORY REQUIREMENTS, CORRECTLY SELECTED AND APPLIED?			
ARE ASSUMPTIONS AND PROBLEM FORMULATION ADEQUATELY DESCRIBED AND REASONABLE?			
ARE ANALYSIS INPUTS IDENTIFIED AND TRACEABLE TO REFERENCED DOCUMENTS?			
WAS THE APPROPRIATE ANALYTICAL/ CALCULATIONAL METHOD USED, INCLUDING COMPUTER PROGRAMS?			
IS THE OUTPUT REASONABLE COMPARED TO THE INPUT?			

THIS IS A PERMANENT DESIGN RECORD *DO NOT DESTROY*

Franklin Institute Research Laboratory, Inc.
A Subsidiary of The Franklin Institute
The Benjamin Franklin Parkway, Philadelphia, Pa. 19103

REPORT REVIEW VERIFICATION RECORD

OJECT NO.	REVISION: DATE:	PAGE OF
OJECT TITLE		DATE:

COMPUTER PROGRAMS

_____ NOT USED _____ USED CERTIFIED PROGRAM PER _____

_____ USED, PROGRAM NOT CERTIFIED BUT VERIFIED PER _____

_____ _____
PROGRAMMER OF RECORD DATE

VERIFICATION METHOD

☐ DESIGN REVIEWS ☐ USE OF ALTERNATE CALCULATIONS ☐ PERFORMANCE OF QUALIFICATION TESTS

_____ _____
PROJECT LEADER DATE

PROFESSIONAL ENGINEER'S APPROVAL (IF REQUIRED)

_____ _____
PROFESSIONAL ENGINEER DATE

☐ APPROVAL OF VERIFICATION METHOD

☐ APPROVAL OF ENGINEERING ANALYSIS CONTROL/VERIFICATION RECORD(S)

☐ BASED ON THE RESULTS OF MY TECHNICAL REVIEW THE TECHNICAL INFORMATION PRESENTED IS SOUND, MEETS THE INTENT OF THE PROJECT OBJECTIVE AND CONFORMS TO THE CONTRACT REQUIREMENTS.

COMMENT: _____

_____

_____

PROJECT MANAGER _____ DATE: _____

☐ APPROVAL OF PROJECT FINAL REPORT

COMMENT: _____

LAB MANAGER _____ DATE: _____

Franklin Institute Research Laboratory, Inc. A Subsidiary of The Franklin Institute The Benjamin Franklin Parkway, Philadelphia, Pa. 19103	Project			Page
	By Date	Ch'k'd Date		Rev. Date
Title				

FORM CS-FIRL-81

QASD No. 6-1
Revision 0 Exhibit III

QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center
A Division of The Franklin Institute
20th and Race Streets, Phila., Pa. 19103 (215) 448-1000

QUALITY ASSURANCE SYSTEMS

	QASD No. 7-1	Page 1 of 5
	Date Issued 4-5-82	Effective Date 4-5-82
	Revision Number 2	Review Date 4-5-84
	☒ Prepared	
	☒ Approved	QA Manager
TITLE PROCUREMENT SYSTEM FOR PURCHASE OF MATERIALS AND SERVICES	Concurred By	Dr. T.S. Hermann, President

1.0 PURPOSE

1.1 This second level document establishes the systems necessary for implementing the requirements of Criteria IV and VII in 10CFR50, Appendix B, and equivalent ANSI sections. The purpose of this document is threefold:

1.1.1 To ensure that applicable quality-related requirements (codes, standards, regulatory requirements, quality control inspection planning, etc.) are included in purchase order documentation and/or contract documentation.

1.1.2 To ensure that materials, equipment and services comply with purchase order documentation.

1.1.3 To ensure that vendors and subcontractors are adequately qualified prior to supplying materials, equipment and services.

2.0 RESPONSIBILITIES

2.1 The Project Manager is responsible for reviewing the contractual scope of work and identifying the material, equipment and service resources that will be needed from outside vendors or sub-contractors.

2.2 The Project Manager is responsible for initiating appropriate procurement documentation.

2.3 The Project Manager is responsible for determining if the prospective vendor or subcontractor is on the Qualified Vendors List, and notifying the Manager of Quality Assurance on a timely basis that the vendor needs to be qualified.

2.4 The Manager of Quality Assurance is responsible for review/ approval of quality-related procurement documentation and for the qualification of outside vendors or subcontractors.

3.0 DEFINITIONS

3.1 Right of Access - the right of a Purchaser to access the vendor's or subcontractor's facilities for the purpose of inspection or quality audit.

4.0 INSTRUCTIONS

4.1 To ensure that applicable quality-related requirements are included in purchase order documentation, the following system is established.

4.1.1 Project Manager shall review the contractual Scope of Work in order to identify item and/or service requirements that will be needed.

4.1.2 Project Manager shall initiate appropriate procurement documentation. The proper content of a procurement document, as deemed necessary by the Purchaser (FRC), may include provisions for the following:

1. Scope of Work

2. Technical requirements specified by reference to applicable codes, standards, regulatory requirements, specific drawings, etc. that describe the items or services to be furnished.

3. Identification of test, inspection and acceptance requirements for monitoring the vendor's performance. A Quality Control Inspection Plan will typically be in the format of a QAP which will be referenced.

4. Quality Assurance Program requirements - the extent of the program requirement shall depend upon the type and use of the item or service being procured.

5. Right of Access

6. Vendor documentation needed for information, review or approval by the purchaser. This shall include retention times and disposition requirements when maintenance of specific Quality Assurance records is required.

7. Requirements for reporting and approving disposition of nonconformances.

4.1.3 Quality Assurance Manager or his delegated alternate shall review/approve the procurement documentation. Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. Objective evidence indicating satisfactory accomplishment of this review shall be by signature and date.

4.1.4 Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.

4.2 To ensure that materials, equipment and services comply with purchase order documentation, the following system is established.

4.2.1 Project Manager shall document in the form of a QAP a detailed Quality Control Inspection Plan. As a minimum, the Quality Control inspection activity shall focus on one of the following:

1. Vendor performed in-process and/or final inspection activity.

2. Franklin performed source inspection activity.

3. Franklin performed receiving inspection activity.

4. Franklin performed vendor qualification inspection activity. The Manager of Quality Assurance shall possess documentaion showing justification rationale for the qualified status of the vendor.

4.2.1.1 The Quality Control Inspection Plan shall adequately detail the who, what, when, where and how of the inspection activity.

4.2.2 Manager of Quality Assurance or his delegated alternate shall review/approve the QAP.

4.2.3 Project Manager shall assure that the Quality Control Inspection Plan is carried out in a timely way, unless otherwise defined in the approved QAP.

4.2.4 Manager of Quality Assurance or his delegated alternate shall assure that personnel are adequately trained/ indoctrinated to perform the Quality Control inspection activity described in the QAP.

4.3 To ensure that vendors and subcontractors are adequately qualified prior to supplying materials, equipment and services, the following guidelines are given.

4.3.1 Project Manager shall determine if a prospective vendor is qualified by reviewing the latest "Qualified Vendors List" and notifying the Manager of Quality Assurance on a timely basis that the vendor needs to be qualified.

4.3.2 Manager of Quality Assurance shall generate satisfactory documentary evidence for justifying the qualified status of a vendor or subcontractor. The following statements shall guide his decision making process:

4.3.2.1 Vendors or subcontractors shall be required to provide a Quality Assurance Program responsive to 10CFR50, Appendix B, to the extent necessary to assure quality of products consistent with the safety-related function to be performed, both directly and indirectly implied. All aspects of Appendix B do not have to be "passed on" to vendors; only those deemed necessary to provide adequate assurance that systems and components important to safety will perform their safety-related functions.

4.3.2.2 Vendors shall be evaluated on their capability to provide items or services in accordance with the requirements of the procurement documents.

4.3.2.3 Vendors shall be evaluated on their history of adequately providing an identical or similar item or service.

4.3.2.4 Vendors shall be evaluated on current records supported by documented qualitative and quantitative information which can be objectively evaluated.

4.3.2.5 Vendors shall be evaluated on their technical and quality capabilities as determined by a direct evaluation of their facilities and personnel and the implementation of their Quality Assurance Program.

4.3.3 Manager of Quality Assurance shall up-date and distribute a "Vendor Qualification Status Report" (VQSR) on a timely basis. The minimum distribution list shall be Manager of Purchasing and Department Heads.

5.0 CROSS REFERENCES

5.1 Quality Assurance Manual - Section 7

6.0 COUNSEL AND REVIEW CONTACT

6.1 Manager of Quality Assurance

7.0 DISTRIBUTION

7.1 Manager of Quality Assurance

7.2 Department Heads

7.3 Manager of Purchasing

QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center
A Division of The Franklin Institute
20th and Race Streets. Phila., Pa. 19103 (215) 448-1000

QUALITY ASSURANCE SYSTEMS

QASD No. 9-1	Page 1 of 5
Date Issued 3-8-82	Effective Date 3-8-82
Revision Number 2	Review Date 3-8-84

Prepared Robert N. Graff QA Manager

Approved Andrew D. Jagiello QA Manager

Concurred By T. S. Hermann Dr. T.S. Hermann, President

TITLE DOCUMENT CONTROL SYSTEM FOR DESIGN DOCUMENTS

1.0 Purpose

1.1 This document is designed to describe the system for the control of documents related to design or test Lab/Engineering evaluation service type projects which flow between FRC/FIRL and the sponsor on programs contractually requiring the implementation of Section 9 in the FRC Quality Assurance Manual.

2.0 Responsibilities

2.1 The Project Manager is responsible for reviewing the contractual requirements of the project in light of the instructional requirements given below and implementing them to the extent necessary.

2.2 The Quality Assurance Manager is responsible for assisting the Project Manager in implementing the instructional requirements of this document and periodically auditing for compliance.

3.0 Definitions

3.1 Sponsor is the client who has a contractual agreement with FRC/FIRL.

3.2 Design Documents are those drawings, specifications, memoranda and instructions related to the technical matter of the program that require quality assurance controls.

3.3 Document Transmittal Log (DTL) is a form used to control the transmittal of design documents from FRC/FIRL to the sponsor.

3.4 Document Receipt Log (DRL) is a form used to control the receipt of design documents.

3.5 Document Transmittal Sheet (DTS) is a form used to control design documents by accompanying the document being sent to the sponsor.

4.0 Instructions

4.1 The Project Manager shall review the contractual requirements of the project and determine, to the extent necessary, which documents (design & others) will flow between FRC/FIRL and the sponsor.

4.2 The Project Manager shall use the DRL upon receipt of design documents from the sponsor (see Exhibit I). He shall log-in the information as required.

4.3 The Project Manager shall use the DTL when design documents, originating at FRC/FIRL, are sent to the sponsor by assigning a unique project transmittal number for each document. (See Exhibit II). He shall log-in the additional information, as required.

4.3.1 The DTS shall be filled out as required and accompany the document being sent to the sponsor. (See Exhibit III).

4.3.2 When a return of the transmittal sheet from the sponsor is required, as in the case of document approval, the receipt of the transmittal sheet will be recorded on the Document Transmittal Log.

4.4 The Project Manager shall establish measures to assure that:

a.) Document changes are reviewed and approved by authorized personnel.

b.) The right document is used at the right place, such as where the quality-related design activity is performed.

4.5 The Quality Assurance Manager or his designated alternate shall periodically audit for compliance to this document.

5.0 Cross References

5.1 Quality Assurance Manual - Section 9

6.0 Counsel and Review Contact

6.1 Manager - Quality Assurance

7.0 Distribution

7.1 Manager - Quality Assurance

7.2 Managers of the Performing Departments

Documents Received Log

Project No. _____

Sponsor _____

Date Received	Description	Acknowledgement Required		Recipient	Notes
		Yes	No		
		If Applic. Initial if Done			

Document Transmittal Log

Project No. _____

Transmittal No.	Description	Return Receipt Required		Return Receipt Received Date (If Applicable)	Comments
		Yes	No		

Document No. _____

Date _____

Document Transmittal Sheet

To:

Contract No. _____

Transmitted by: _____

Form of Documents

Prints _____

Memorandum _____

Reproducibles _____

Instructions or Procedures _____

Data Sheets _____

Purpose

For Approval ☐

For Comments ☐

For Information ☐

For Distribution ☐

Description of Transmittal

Comments by Recipient

If applicable: Approved _____

Not Approved _____

Signature of Recipient _____

Date: _____

QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center
A Division of The Franklin Institute
20th and Race Streets, Phila., Pa. 19103 (215) 448-1000

QUALITY ASSURANCE SYSTEMS

QASD No. 15-1	Page 1 of 8
Date Issued 4-5-82	Effective Date 4-5-82
Revision Number 2	Review Date 4-5-84
☒ Prepared [signature]	
☒ Approved [signature] QA Manager	
Concurred By [signature] Dr. T.S. Hermann, President	

TITLE PERIODIC CALIBRATION SYSTEM

1.0 PURPOSE

1.1 This document is designed to describe the system for the identification, control and maintenance of tools, gages, instruments or other measuring and testing devices which are used to acquire project reportable data.

2.0 RESPONSIBILITIES

2.1 The Technical Associate is responsible for implementing Para. 4.1 of this "Periodic Calibration System".

2.2 The Quality Assurance Manager or his designated alternate is responsible for performing periodic audits to ensure that the system is maintained according to the instructional section of this document, particularly Para. 4.2.

2.3 The Project Manager is responsible for delivering to the Technical Associate all newly acquired measuring and testing devices which he intends to use to obtain project reportable data. This shall include the supporting paperwork, operating and calibration instructions. Newly acquired refers to measuring and testing devices which have either been bought, borrowed or rented, and which are currently not on the Gage Calibration Master List.

3.0 DEFINITIONS

3.1 Calibration Index File is the manual, 3"x5" calibration file card compilation of all measuring and testing devices which potentially may be used to acquire project reportable data. One 3"x5" calibration file card (Exhibit I) is used for each device.

3.2 Active Status is the status assigned to any measuring and testing device which has been calibrated and has a recorded calibration due date beyond the current date.

3.3 Inactive Status is the status assigned to any measuring and testing device which may or may not have a history of calibration, but which currently has not had a calibration since the recorded calibration due date.

3.4 Gage Calibration Master List is a computer generated listing of all tools, gages, instruments or other measuring and testing devices which are used to acquire project reportable data. (See Exhibit III.)

4.0 INSTRUCTIONS

4.1 The Technical Associate shall do the following:

4.1.1 Receive from the Project Manager all newly acquired measuring and testing devices including the supporting paperwork, operating and calibration instructions.

4.1.2 Prepare a 3"x5" Calibration File Card for placement into the manual Calibration Index File. (See Exhibit I for the preparation of a Calibration File Card).

4.1.3 File paperwork, operating and calibration instructions for easy retrieval using a single folder identified by item number.

4.1.4 Prepare a Gage Calibration Master List Input Record and deliver it to the computer keypunch operation for entry into the program. Place a copy of this record in a file for easy retrieval. (See Exhibit II for the preparation of the Gage Calibration Master List Input Record).

4.1.5 Provide for calibration of the measuring and testing device by an in-house procedure or by an appropriate subcontractor, as required.

4.1.5.1 Up-date the Gage Calibration Master List, as required.

4.1.5.2 Fill out and place a calibration sticker on the measuring and testing device.

4.1.6 Maintain the manual Calibration Index File by:

4.1.6.1 Sorting Active Status devices by calibration due date, i.e. sequential months.

4.1.6.2 Sorting Inactive Status devices by Item No.

4.1.6.3 Assuring that as each month's compliment of devices comes due for calibration, the 3"x5" Calibration File Card is placed in the active or inactive category based on whether the device is recalibrated or not. Note: If the device is not recalibrated a Gage Calibration Master List Input Record is not required. The Gage Calibration Master List output report has been programmed to check current date (i.e. report date) against calibration due date, and define the device's status automatically.

4.1.6.4 Adding new information to the 3"x5" Calibration File Card as it becomes available.

4.1.7 Maintain the Gage Calibration Master List by:

4.1.7.1 Cross-checking the Active Status devices as found in the manual Calibration Index File with those appearing on the Gage Calibration Master List. Process a Computer Master List Input Record as required.

4.1.7.2 Processing a Computer Master List Input Record as soon as new information becomes available.

4.1.8 Calibrate devices using QA approved procedures, typically QAPs.

4.2 The Quality Assurance Manager shall do the following:

4.2.1 Have documentation on file that demonstrates all calibration service subcontractors are qualified, to the extent necessary, as required by 10CFR50, Appendix B.

4.2.2 Have documentation on file that all standards (both in-house and subcontractors) used in the calibration of devices are traceable to the National Bureau of Standards. This shall include a certification or an approved rationale document.

4.2.3 Have documentation on file describing the procedure used to calibrate devices. Typically, this will be in the form of a QAP for in-house procedures, and shall include such items as:

4.2.3.1 Instructions for what to do when the device is found to be inaccurate, i.e. exceed its accuracy tolerance.

4.2.3.2 Instructions on the importance of using only NBS certified standards or equipment.

4.2.3.3 Instructions for preparing and filing a Calibration Test Report (Exhibit IV).

4.2.4 Have audit documentation on file indicating implementation of this QASD.

5.0 CROSS REFERENCE

5.1 Quality Assurance Manual - Section 15

6.0 COUNSEL AND REVIEW CONTACT

6.1 Manager - Quality Assurance

7.0 DISTRIBUTION

7.1 Manager - Quality Assurance

7.2 Managers of Performing Departments

EXHIBIT I
CALIBRATION FILE CARD

ITEM NO. (1) | INSTR: (2)

(3)

TYPE OR MODEL: (4)

SERIAL NO: (5)

DATE PURCHASED: (6)

MEASM'T RANGE & FEATURES: :: (7) | ACCURACY TOLERANCE: (8)

SEE CALIBRATION NOTEBOOK FOR CALIBRATION DATA.
SEE OVER FOR CALIBRATION DATES.

RECOM'D FREQ. OF CALIB: (9)

CALIBRATED	NEXT CAL DUE	INITIAL
(10)	(11)	(12)

(1) Assign a FRC No. 18 xx: by taking the next avai sequence number. This number may become the permanent item number. If Accounting considers the item as capital equ ment, a 421-xxx number will be assigned. The Technical Associate shc at that point add to hi records the 421-xxx ass Item No.

(2) Instrument name

(3) Name of instrument manu facturer

(4) Type or model of the instrument

(5) Serial No. of the instrument

(6) Date the instrument is originally received at FRC

(7) Define such things as:
a) Scale range
b) Scale units of measure
c) Smallest incremental unit of measure
d) Any scale nonlinearity

(8) Define the accuracy tolerance as follows:
a) Review manufacturer's literature for recommendations, or call if necessary.
b) Define the smallest increment of measure that is readable from the scale.
c) Review the above information with the responsible Project Manager, and jointly decide on the proper accuracy tolerance based on any unique requirements of the project, etc.

(9) Define the frequency for calibration. It should be at least once per year unless historical performance should suggest otherwise.

(10) Specify the exact date that the instrument was calibrated.

EXHIBIT I
CALIBRATION FILE CARD

(11) Specify the exact date that the instrument is due to be recalibrated. Simply add the frequency time period to the calibration date.

(12) The individual who completes the manual 3"x5" calibration file card shall affix his initials here. Subsequent initialling, if by the same individual, shall be properly performed. Ditto marks shall not be used.

EXHIBIT II

GAGE CALIBRATION MASTER LIST INPUT RECORD

GAGE CALIBRATION MASTER LIST INPUT RECORD

ITEM NO. (1) | INSTR: (2)

EXACT NAME & MFG: (3)

TYPE OR MODEL: (4)

SERIAL NO: (5)

DATE PURCHASED: (6)

CALIB. DATE (7) | ACCURACY TOLERANCE:

FREQ. OF CALIB. (8) | (10)

NEXT CALIB. DUE (9) | (11)

TECH. ASSOC : (12)

DATE: (13)

• TO KEY PUNCH •

(1) Assign a FRC No. 18xxx by taking the next available sequence number. If Accounting considers the item as capital equipment a 421-xxx number will be assigned. The Technical Associate should at that point add to his records the 421-xxx assigned Item No.

(2) Instrument name

(3) Name of instrument manufacturer

(4) Type or model of the instrument

(5) Serial No. of the instrument

(6) Date the instrument is originally received at FRC.

(7) Define the precise date that the instrument was calibrated.

(8) Define the frequency for calibration. It should be at least once per year, unless historical performance should suggest otherwise.

(9) Specify the precise date that the instrument is due to be recalibrated. Simply add the frequency time period to the calibration date.

(10) (11) Define the accuracy tolerance as follows:

a) Review manufacturer's literature for recommendations, or call if necessary.

b) Define the smallest increment of measure that is readable from the scale.

c) Review the above information with the responsible Project Manager, and jointly decide on the proper accuracy tolerance based on any unique requirements of the project,etc.

(12) Authorize the input record by signing your name.

(13) Record the date that you signed your name and send the input record to key punch operator.

EXHIBIT III
GAGE CALIBRATION MASTER LIST

INVENTORY REPORT

JUN 29, 1981 PAGE NO. 1

ITEM NO.	EQUIP. NOMENCLTURE	MANUFACT. NAME	MANUFACT. MODEL NO.	SERIAL NO.	DATE OF PURCHASE	PURCHASE ORDER NO	COST	USER/ GROUP	ACCURACY TOLERANCE	FREQ. OF CAL.	CALIBTD	NEXT-CAL DUE	[illegible] STAT
421-7748	AMMETER A	WEST.H	PA-161	56433	01/01/73			NOT AVA	LAB 33 0.5 % FS	1 YEAR	07/05/77	07/05/[illegible]	[illegible]
18037	PRES GAGE	NORDEN KEY	NOT AVAIL	A6	********			NOT AVA	LAB 33 1 % F.S.	1 YEAR	08/29/80	08/29/[illegible]	[illegible]
421-7567	INSUL GD	BECKMAN IN	1000AC/GC	77146	********			NOT AVA	LAB 33 3 % F.S.	1 YEAR	04/20/81	04/20/[illegible]	[illegible]
18300	COPPER XF	WESTON	461	11880	********			NOT AVA	LAB 33 0.4% RATI	NOT REQD	********	********	INACTIVE
16266	VT. SCALE	FAIRBANKS	NOT AVAIL	G151424	********			NOT AVA	LAB 33 NOT AVAIL	1 YEAR	10/20/80	10/20/[illegible]	[illegible]
19131	RECORDER	LEEDS&NORT	524-	E72-54507-	********			NOT AVA	LAB 33 0.25% F.S	6 MONTHS	04/22/81	10/22/[illegible]	[illegible]
18291	DIFF PRES	ITI/BARTON	227	89431	10/01/74			NOT AVA	LAB 33 0.75% F.S	1 YEAR	03/07/80	03/07/[illegible]	[illegible]
421-8030	MEGOHMMET	GEN.RADIO	1864	3137	06/01/79			NOT AVA	LAB 33 5% OR LES	6 MONTHS	11/06/80	05/06/[illegible]	[illegible]
18253	MILLIAMME	MULTI-AMP	165	2104	11/04/74			NOT AVA	LAB 33 0.5% F.S	1 YEAR	03/19/81	03/19/[illegible]	[illegible]
19251	VOLTMETER	STHPSON	PANE	SS1 7192	********			NOT AVA	LAB 33 NOT AVAIL	1 YEAR	10/22/74	10/22/[illegible]	[illegible]
18172	2 PEN REC	ESTERLINE	L11025	908424	********			NOT AV	LAB 33 0.25% FS	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
421-7802	MEGOHMMET	GEN.RADIO	1864	4368-1075	12/01/73			NOT AVA	LAB 33 5% OR LES	1 YEAR	04/01/81	04/01/[illegible]	[illegible]
16297	DIG.MULTI	JOHN FLUKE	8600A	36076	04/01/76			NOT AVA	LAB 33 .02% RETI	1 YEAR	04/13/81	04/13/[illegible]	[illegible]
18290	TRI/MULT/	TAKEDA RIK	6355	54721122	07/01/75			NOT AVA	LAB 33 0.5%+1DIG	1 YEAR	06/09/81	06/09/[illegible]	[illegible]
16254	AC MILLIA	MULTI AMP	165	2102	11/04/74			NOT AVA	LAB 33 0.5% F.S.	1 YEAR	06/22/81	06/22/[illegible]	[illegible]
421-7927	PRESS/GAU	WEISE PRES	CMM	CMM-23725	05/01/78			NOT AVA	LAB 33 0.1% F.S.	1 YEAR	07/17/80	07/17/[illegible]	[illegible]
421-3554	2 PEN REC	HONEYWELL	Y153X	726612	********			NOT AVA	LAB 33 0.25% F.S	6 MONTHS	03/20/81	09/20/[illegible]	[illegible]
421-6023	MULTI./RE	HONEYWELL	15305644-2	4363730300	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	03/20/81	09/20/[illegible]	[illegible]
421-6016	SIN.PE./R	HONEYWELL	153X11V-X-	785870	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	03/20/81	09/20/[illegible]	[illegible]
421-7601	MUL.PT/RE	HONEYWELL	NONE	665217	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	03/20/81	09/20/[illegible]	[illegible]
421-7779	REC./TEMP	HONEYWELL	16303856	S0355 7790	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	03/20/81	09/20/[illegible]	[illegible]
421-6072	MULTPT/RE	HONEYWELL	15305840-1	4365670900	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	11/07/80	05/07/[illegible]	[illegible]
***					********						********	********	
16181	OHAUS BAL	OHAUS HVY	1119	2355	10/15/73			NOT AVA	LAB 33 1 GRAM	1 YEAR	10/20/80	10/20/[illegible]	[illegible]
18130	OHAUS TRI	OHAUS	NONE	1732612	********			NOT AVA	LAB 33 0.1 GRAM	1 YEAR	10/20/80	10/20/[illegible]	[illegible]
16221	2 PEN/REC	ESTERLINE	L11025	906001	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
16220	2 PEN/REC	ESTERLINE	L11025	908621	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
16234	MULPT./PE	ESTERLINE	E1124E	941628	05/01/74			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
16267	2 PEN/REC	ESTERLINE	L11025	908859	********			NOT AVA	LAB 33 0.25% F.S	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
18266	2 PEN/REC	ESTERLINE	L11025	908893	********			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
18345	MULPT/REC	ESTERLINE	L11245	950436	12/01/77			NOT AVA	LAB 33 0.25% SPA	6 MONTHS	04/16/81	10/16/[illegible]	[illegible]
421-7639	ELEC/VOLT	SENSITIVE	ESH	90821	********			NOT AVA	LAB 33 1% SPAN	6 MONTHS	04/01/81	10/01/[illegible]	[illegible]
1	AMMETER	G.E.	NONE	NONE	********			NOT AVA	LAB 33 2% F.S.	1 YEAR	********	********	INACTIVE
421-7954	ELEC/SHAK	ACOUS.PWR	1205/114	13/91	********			NOT AVA	LAB 33 NOT AVA		********	********	INACTIVE
3	AMMETER	G.E.	NONE	NONE	********			NOT AVA	LAB 33 2% F.S.		********	********	INACTIVE
400-0326	ACCELEROM	COLUMBIA	302-6	4747	********			NOT AVA	LAB 33 1% INDICA		********	********	INACTIVE
400-0327	ACCELEROM	COLUMBIA	302-6	4749	********			NOT AVA	LAB 33 1% INDICA		********	********	INACTIVE
5	AMMETER	G.E.	NONE	NONE	********			NOT AVA	LAB 33 2% F.S.		********	********	INACTIVE
421-5702	STROBOTAC	GEN.RADIO	1531-A	NONE	********			NOT AVA	LAB 33 NOT AVA		********	********	INACTIVE
421-5644	PRESS.GAU	BARTON INS	227	227-19714	********			NOT AVA	LAB 33 0.5% F.S.		********	********	INACTIVE
421-5900	ELEC/COUN	HEW.PACKAR	5243L	307-00776	********			NOT AVA	LAB 33		********	********	INACTIVE
421-5918	MEGOHMMET	GEN.RADIO	1862-B	4724	********			NOT AVA	LAB 33 14% LESS		********	********	INACTIVE
421-5927	200 RECOR	BRUSH MARK	RF1783-40	196	********			NOT AVA	LAB 33		********	********	INACTIVE
421-6026	FLOWMETER	BROOKS INS	R-1110-MS-	6305-49270	********			NOT AVA	LAB 33 2% F.S.		********	********	INACTIVE
421-7430	8-CHAN.RE	SANBORN	7706/FR48A	206	********			NOT AVA	LAB 33 2% F.S.		********	********	INACTIVE
421-7441	ELEC/VOLT	SENS.RES	FSD	201756	********			NOT AVA	LAB 33 1% F.S.		********	********	INACTIVE
421-7749	TRI/VOLTM	WEST.H	PA-161	56308	********			NOT AVA	LAB 33 0.5% F.S.		********	********	INACTIVE
421-7750	TRI/VOLTM	WEST.H	PA-161	56309	********			NOT AVA	LAB 33 0.5% F.S.		********	********	INACTIVE
421-7751	AMMETER	MULTI-AMP	155	1161	********			NOT AVA	LAB 33 0.33% F.S		********	********	INACTIVE
421-7752	AMMETER	MULTI-AMP	155	1162	********			NOT AVA	LAB 33 0.33% F.S		********	********	INACTIVE
421-7766	DCP/AMMET	WEST.H	PA-161	56277	********			NOT AVA	LAB 33 0.5% F.S.		********	********	INACTIVE
421-7796	DIG/MULTI	DATA PREC	245	3776	********			NOT AVA	LAB 33 0.5% SPAN		********	********	INACTIVE

EXHIBIT IV

Franklin Research Center
A Division of The Franklin Institute

CALIBRATION TEST REPORT

ID NO.	DESCRIPTION	MANUFACTURER
MODEL NO.	SERIAL NO.	OTHER ID

CONDITION AS RECEIVED ☐ OUT OF TOLERANCE ☐ IN TOLERANCE

FINAL CONDITION ☐ OUT OF TOLERANCE ☐ IN TOLERANCE

PROCEDURE	REVISION AND DATE	FACILITY

CALIBRATION EQUIPMENT

DESCRIPTION	MFR.	MODEL	SER. NO.	ID NOS.	DUE DATE

CALIBRATION DATA (LABEL COLUMNS)

SPECIFIED ACCURACY OR TOLERANCE

REMARKS (STATUS, REPAIR ADJUSTMENTS, ETC.)

DATE CALIBRATED	RECALIBRATION DUE	NAME (PRINTED)	SIGNATURE

QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center
A Division of The Franklin Institute
20th and Race Streets, Phila., Pa. 19103 (215) 448-1000

QUALITY ASSURANCE SYSTEMS

	QASD No. 17-1	Page 1 of 6
	Date Issued 4-5-82	Effective Date 4-5-82
	Revision Number 2	Review Date 4-5-84
	Prepared Robert H. Frye	
	Approved W. J. Ruggiano	QA Manager
TITLE SYSTEM FOR CONTROL OF NONCONFORMING MATERIALS, PARTS OR COMPONENTS	Concurred By T. S. Hermann	Dr. T.S. Hermann, President

1.0 PURPOSE

1.1 This second level document establishes the system necessary for implementing the requirements of Criteria XV and XVI in 10CFR50, Appendix B, and equivalent ANSI sections. The purpose of this document is twofold:

1.1.1 To establish a nonconforming material control system that provides for the documentation, segregation, and disposition of nonconforming material, and the notification to affected organizations.

1.1.2 To establish a Corrective Action System which shall assure that conditions adverse to quality will be properly defined, controlled and actively corrected in a timely way.

2.0 RESPONSIBILITIES

2.1 Any individual who discovers a nonconformance is responsible for initiating a Corrective Action Request and having it reviewed and approved by the Manager of Quality Assurance.

2.2. The Project Manager is responsible for initiation and implementation of Corretive Action Requests that are appropriate to his area of responsibility. Furthermore, he is responsible for ensuring the implementation of the appropriate instructions in this QASD and for filing all completed Nonconformance Reports (NCR) and Corrective Action Requests in the project file.

2.3 The Manager of Quality Assurance is responsible as Chairman of the Material Review Board for the processing (dispositioning) and control of all nonconformance reports.

2.4 The Manager of Quality Assurance is responsible for approving all Corrective Action Requests, for filing all "Corrective Action Request" forms and for ensuring that corrective action is taken in a timely way.

2.5 The Manager of Quality Assurance is responsible for designating a segregated quality-controlled hold area for nonconforming items awaiting final disposition. Furthermore, he shall provide nonconformance material tags or other suitable designation for items found to be discrepant.

3.0 DEFINITIONS

3.1 Nonconformance Report (NCR) is a written report which documents the information required for ultimate disposition of a nonconforming material, part, or component. (See Exhibit I).

3.2 Corrective Action Request (CAR) is a written report which documents the information required to minimize or prevent recurrence of a nonconforming condition on a material, part or component. (See Exhibit II)

3.3 Nonconformance Material Tag (see Exhibit III)

4.0 INSTRUCTIONS

4.1 When an item is determined to be nonconforming, the inspector shall immediately do the following:

4.1.1 Prepare a Nonconformance Report (NCR) after obtaining from the Manager of Quality Assurance an assigned NCR number.

4.1.2 Prepare a Nonconformance Material Tag, and affix it to the item. Identification of nonconforming items may be made by marking the item, provided it does not adversely affect the end use of the item, and is legible and easily recognizable. If identification of each nonconforming item is not practical the container, package or segregated storage area will be identified.

4.1.3 Affix a copy of the Nonconformance Report to the item by use of a plastic holder.

4.1.4 Move the item to the designated quality-controlled hold area. 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 the nonconforming item.

4.1.5 The original Nonconformance Report shall be given to the Manager of Quality Assurance, and a copy provided the responsible Project Manager and Purchasing Manager.

4.2 As Chairman of the Material Review Board, the Manager of Quality Assurance shall do the following in a timely way.

4.2.1 Determine proper disposition by a review with the Project Manager and Sponsor.

4.2.2 Document the agreed upon disposition and obtain written approvals from Sponsor and Project Manager. Technical justification for the acceptability of a nonconforming item (dispositioned repair or use-as-is), shall be documented. The as-built records, if such records are required, shall reflect the accepted deviation.

4.2.3 Review and approve all rework or repair planning which shall include necessary reinspection and acceptance criteria.

4.2.4 Initiate "Corrective Action Request" if required, and take necessary action to ensure corrective action is conducted in a timely way.

5.0 CROSS REFERENCES

5.1 Quality Assurance Manual - Sections 17 and 18

6.0 COUNSEL AND REVIEW CONTACT

6.1 Manager of Quality Assurance

7.0 DISTRIBUTION

7.1 Manager of Quality Assurance

7.2 Department Heads

7.3 Manager of Purchasing

NONCONFORMANCE REPORT

NRC # _____ Project # _____

Date: _____ Contract # _____

Prepared By: _____ Purchase Order # _____

Description of Item:

Location of Item:

Description of Nonconformance:

Disposition of Nonconforming Item:

(Technical justification for the acceptability of a nonconforming item, dispositioned repair or use-as-is shall be documented.)

Corrective Action Request Issued to _____ _____
Date

Approved _____ _____
Project Manager Date

Approved _____ _____
Quality Assurance Manager Date

Signed _____
Project Manager

Approved _____ _____
Client Representative Date

TITLE: SYSTEM FOR CONTROL OF NONCONFORMING MATERIALS, PARTS OR COMPONENTS

CORRECTIVE ACTION REQUEST

TO: Date: _____

Prepared by: _____

Project #: _____

Contract #: _____

Purchase Order: _____

Description of Item:

Description of Nonconformance:

Reply:

Cause:

Action to Prevent Recurrence:

_____ _____
Addressee's Representative Date

Action Approved _____ _____
Project Manager Date

_____ _____
Quality Assurance Manager Date

NONCONFORMANCE MATERIAL TAG

NON CONFORMING
MATERIAL

NCR #_____

QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center A Division of The Franklin Institute 20th and Race Streets, Phila., Pa. 19103 (215) 448-1000 **QUALITY ASSURANCE SYSTEMS**	QASD No. 19-1	Page 1 of 4
	Date Issued 4-5-82	Effective Date 4-5-82
	Revision Number 0	Review Date 4-5-84
	☒ Prepared [signature]	
	☒ Approved [signature] QA Manager	
TITLE QUALITY ASSURANCE RECORDS SYSTEM	Concurred By [signature] Dr. T.S. Hermann, President	

1.0 PURPOSE

1.1 This second level document establishes the system necessary for implementing the requirements of Section 19 of the Franklin Quality Assurance Manual. It was written to implement Criterion XVII of 10CFR50, Appendix B, and the equivalent section of ANSI N45.2 - 1977.

This document is to provide a system for the identification, retention, retrieval and maintenance requirements involved in the collection, handling and/or storage of significant records that furnish evidence of the quality of items and/or activities affecting quality.

2.0 RESPONSIBILITIES

2.1 The Sponsor of the project is responsible for clearly defining all applicable codes, standards and regulations concerning record requirements, so that the subcontractor (FRC/FIRL) knows the appropriate record generation, transmittal and maintenance requirements to be applied both during work and subsequent to completion of work.

2.2 The Project Manager is responsible for reviewing the project's contractual requirements, and determining the Quality Assurance records which need to be collected, handled and/or stored.

2.3 The Quality Assurance Manager is responsible for the following:

a) Giving guidance to the Project Manager in defining the Quality Assurance records which need to be collected, handled and/or stored. Typically, this guidance is given at time of review/ approval of procurement and/or contractual document sign-off.

b) Determining the location and storage facility configuration which will adequately satisfy the requirements of ANSI N45.2.9 - 1979.

c) Auditing to ensure compliance with the overall requirements defined in Section 19 of the Quality Assurance Manual and this supporting QASD.

2.4 The Nuclear Engineering Department (NED) Librarian is responsible for implementing those parts of this instruction which are specifically described for the NED Librarian.

3.0 DEFINITIONS

3.1 Record is to be interpreted as a Quality Assurance Record, which is documentary evidence of the quality of an item and/or activity affecting quality. A document is considered a Quality Assurance Record when the document has been completed.

4.0 INSTRUCTIONS

4.1 The Nuclear Engineering Department Librarian shall ensure that the following actions take place in a timely manner:

4.1.1 When a new case is assigned by the Proposals Office to the department, a folder is prepared. Labels showing case number, sponsor and responsible laboratory are affixed to both sides of the file folder.

4.1.2 The new case number, sponsor, laboratory number, scope, and date are logged in an accession book for the cases.

4.1.3 A catalog card is prepared for the active sponsor file. Prospective sponsors of cases are interfiled with active sponsors of projects. Cards are filed first alphabetically by sponsor, and secondly, in numerical order by either case number or project number.

4.1.4 When a case file becomes inactive, its number in the case accession book is circled in red. The sponsor case is removed from the active sponsor file and placed in the inactive sponsor file. The case number on the file folder label is also circled in red.

4.1.5 When the sponsor signs a contract the case becomes a project, and the project number is added to the listing in the case accession book. The case folder is relabeled to a project folder.

4.1.6 The new project number, sponsor, laboratory number, scope and date are entered in an accession book for projects. The catalogue card is updated by entering the project number.

4.1.7 When the project terminates:

a) The appropriate number in the project accession book is circled in red.

b) The sponsor card is removed from the active file and placed in the inactive sponsor file.

c) The project number on the file folder label is also circled in red.

4.2 The Project Manager shall ensure that the following actions take place in a timely manner:

4.2.1 That he is aware of the appropriate Quality Assurance records that are to be dealt with on a project. This shall be done by review of the contractual requirements. As guidance the Project Manager shall differentiate between those records which must be prepared while work is in process, and those records which must be generated at completion of the work effort and then retained "by or for the sponsor".

4.2.2 That all appropriate Quality Assurance records are collected (generated), sent to and received by the NED Librarian with the following minimum instructions defined to the NED Librarian:

a) Project involved,

b) Classification of record (i.e., whether it should be retained by Franklin for the sponsor or sent to sponsor),

c) Retention time of record; (i.e., retention time that has been specified in the contractual requirements of the project),

d) Verify that the records are those designated and that they are legible,

e) Final disposition requirements (i.e., after completion of retention time period and before removal of records from this controlled environment, the Sponsor and Project Manager, as a minimum, shall approve in writing the final disposition).

(See Exhibit I for an example of the transmittal control form that may be used by the Project Manager).

4.3 The Manager of Quality Assurance shall ensure that the following actions take place in a timely manner:

4.3.1 Define the records storage location. The location shall be FRC Room 410.

4.3.2 Define the records storage facility configuration. The records shall be stored in a fire resistant safe, UL Class 350-2 Hour (B), Diebold Model 2073.

5.0 CROSS REFERENCES

5.1 Quality Assurance Manual - Section 19

5.2 ANSI N45.2.9 - 1979

6.0 COUNSEL AND REVIEW CONTACT

6.1 Manager of Quality Assurance

7.0 DISTRIBUTION

7.1. Manager of Quality Assurance

QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center
A Division of The Franklin Institute
20th and Race Streets, Phila., Pa. 19103 (215) 448-1000

QUALITY ASSURANCE SYSTEMS

QASD No. 20-1		Page 1 of 3	
Date Issued 4-5-82		Effective Date 4-5-82	
Revision Number 0		Review Date 4-5-84	
☒ Prepared			
☒ Approved	QA Manager		
Concurred By	Dr. T.S. Hermann, President		

TITLE INTERNAL QUALITY ASSURANCE AUDIT SYSTEM

1.0 PURPOSE

1.1 The purpose of this procedure is to provide an audit plan (checklist) for verifying compliance with all aspects of the established Quality Assurance Program, and to determine the effectiveness of that program. This system is intended to verify conformance of FRC's procedures and activities to those prescribed in the Quality Assurance Manual and related Quality Assurance documents:

1) Quality Assurance Systems Dcouments
2) Quality Assurance Procedures
3) Quality Assurance Administrative Instructions.

2.0 RESPONSIBILITIES

2.1 The Quality Auditor, (e.g. the Quality Assurance Manager or his designated alternate), shall conduct a random audit in accordance with this plan at least once a year. The Quality Auditor will establish the random time of the audit, conduct the audit, review the results, prepare the Audit Report Summary (Exhibit I), initiate corrective action and conduct a follow-up audit, as necessary, to ensure the timely completion of corrective action.

3.0 DEFINITIONS

3.1 An audit is a documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the quality program have been developed, documented and implemented in accordance with specified requirements.

4.0 INSTRUCTIONS

4.1 The Quality Auditor shall conduct the annual audit using all portions of the checklist (Exhibit II). The Quality Auditor may at any time conduct specific project audits using those portions of the checklist (Exhibit II) which correspond to the applicable criteria of 10 CFR 50, Appendix B, as defined contractually.

4.2 All items on the checklist shall be answered YES, NO or NI (Needs Improvement). For all NI nonconformities, give additional information, including recommended corrective action and person responsible for implementing the corrective action.

4.3 The Quality Auditor shall contact the responsible person concerning the nonconformity, and obtain an approved corrective action plan including the schedule for completion.

4.4 An "Audit Report Summary" (Exhibit I) shall be used to document:
- All nonconformities
- Agreed upon corrective actions
- Designated person responsible for action
- Corrective action completion date.

4.5 The completed "Audit Report Summary" shall be distributed to the designated person responsible for the action and to the President of FRC.

4.6 The designated person responsible for the corrective action shall sign the "Audit Report Summary" when he has completed the corrective action and shall return it to the Manager of Quality Assurance.

4.7 The Manager of Quality Assurance shall assure that corrective action has been completed in a timely way.

5.0 CROSS REFERENCES

5.1 Quality Assurance Manual - Section 20.

6.0 COUNSEL AND REVIEW CONTACT

6.1 Manager - Quality Assurance

7.0 DISTRIBUTION

7.1 Manager - Quality Assurance

7.2 Manager of the affected department of section

7.3 Project Manager/Engineer/Technician who is responsible for implementing the corrective action.

EXHIBIT I

INTERNAL
QUALITY ASSURANCE
AUDIT REPORT SUMMARY

FROM: Quality Auditor _____
Date of Audit _____

TO: FRC President _____
Department Manager _____
Project Manager/Engineer/Technician _____

The purpose of this "Audit Report Summary" is to determine the effectiveness of Franklin's Quality Assurance Program. (See Quality Assurance Manual - Section 20 and Supporting QASD No. 20-1.)

Description of Nonconformity	Agreed Upon Corrective Action	Responsible Individual	Agreed Upon Completion Date

Please sign, date and return this "Audit Report Summary" to the Manager of Quality Assurance when you have completed the corrective action.

Responsible Individual _____ Date _____

EXHIBIT II

I Organization

Findings

1. Does the organization chart indicate the functional relationship of the quality organization to management and to other groups? _____

2. Is the organization chart current? _____

3. Are persons performing Q.A. functions independent and free of production pressure and do they have access to higher management? _____

4. Are the authority and duties of persons performing Q.A. functions clearly established and delineated in writing? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

II Quality Assurance Program — Findings

1. Is the Assurance Control Program and procedures in the form of a manual and/or other formal instructions? _____

2. Are the Quality Assurance Program and procedures supported and approved by management? _____

3. Have all QASDs and QAPs been reviewed and approved by the Manager of Quality Assurance, and has this approval been done within the time frame specified on the document by the review date? _____

4. Have all QASDs been reviewed and approved (concurred with) by the President of FRC? _____

5. Does the Manager of Quality Assurance maintain adequate records to assure proper assignment of document control numbers for QAPs and QASDs? _____

6. Are "Activities Affecting Quality" documented in instructions, and is the documentation followed under controlled conditions? _____

7. Does the Quality Assurance Program recognize the need and provide for special process controls, test equipment, tools and skills including necessary indoctrination and training of personnel performing activities affecting quality? _____

8. Does the Quality Assurance program recognize the need and provide for the verification of quality characteristics by appropriate inspection or test? _____

9. Is the status and adequacy of the overall Quality Assurance Program regularly reviewed (through audits or other measurement means) by management that is responsible for the Program's execution? As a minimum, there should be an annual review with the FRC President. _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

EXHIBIT II

III Design Control

	Findings
1. Does the Quality Assurance Program require a documented design control system for translating customer requirements and changes into design documents, drawings, or operating procedures?	
2. Is there a documented procedure for control and distribution of latest applicable drawings, specifications, engineer change orders, and other operational changes?	
3. Review the implementation of QASD No. 9-1 with a Project Manager. Are there any significant problems?	
4. Review the implementation of QAAI No. 1-1 with a Project Manager. Are there any significant problems?	
5. Does the Quality Assurance Program require a documented system for technical verification of design activities or test lab/engineering evaluation service activities?	
6. Review the implementation of QASD No. 6-1 with a Project Manager. Are there any significant problems?	

FINDINGS: (NI = Needs Improvement Explanation)

Auditor: _____ Date: _____

IV Procurement Document Control — Findings

1. Does the Quality Assurance Program require a system to assure that applicable requirements (codes, standards, regulatory requirements, Quality Assurance Procedures, etc.) are included or referenced in the purchase order documentation? _____

2. Does the Quality Assurance Program require that the Manager of Quality Assurance review and approve all appropriate procurement documents for inclusion of adequate quality requirements? _____

3. Select one project which contractually requires Criterion IV of 10CFR50, Appendix B, or its equivalent and review the implementation of any procedures (QASDs or QAPs) which may have been generated with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

EXHIBIT II

V Instructions, Procedures and Drawings — Findings

1. Are written procedures, i.e., QAPs and QASDs, available to, and used by, individuals performing activities affecting quality? _____

2. Are these procedures approved by the Manager of Quality Assurance or his designated alternate? _____

3. Does the Quality Assurance Program require that these procedures include appropriate criteria for determining quality? _____

4. Are project reportable data reported on data sheets, travelers, or other similar work instruction forms, and do they contain Quality Assurance approved inspection or examination points? _____

5. Do indexes or lists exist for quality-related instructions, procedures, and drawings to establish latest revision and status of documents? _____

6. Select one project that contractually requires Criterion VI of 10CFR50, Appendix B or its equivalent to be met and review the project folder for completeness. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

VI Document Control — Findings

1. Does the Quality Assurance Program require that measures be taken to establish a system for the control of documents which prescribe activities affecting quality? _____

2. Select one project that contractually requires Criterion V of 10CFR50, Appendix B or its equivalent to be met, and review the implementation of QAAI No. 1-1 with the appropriate Project Manager. Are there any significant problems? _____

3. Select one project that contractually requires Criterion VI of 10CFR50, Appendix B or its equivalent to be met, and review the implementation of QASD No. 9-1 with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

VII Control of Purchased Materials, Equipment, and Services — Findings

1. Does the Quality Assurance Program require that a system be established to assure that materials, equipment, and services comply with procurement document requirements? _____

2. Does the Quality Assurance Program require that the quality capabilities of procurement sources, including those furnishing special process services, be evaluated prior to procurement? _____

3. Is a list of approved sources maintained and periodically updated? _____

4. Does the Quality Assurance Program require that source inspection or audit be performed as necessary to assure the required quality of an item? _____

5. Select one project which has contractually required Criterion VII of 10CFR50, Appendix B or its equivalent to be met and review the implementation of QASD No. 7-1 or other Quality Assurance document on this subject with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

VIII Identification and Control of Materials, Parts, and Components

Findings

1. Does the Quality Assurance Program require the establishment of an approved system for identifying and controlling all appropriate materials, parts, or components? _____

2. Select one project which has contractually required Criterion VIII of 10CFR50, Appendix B or equivalent to be met, and review all approved Quality Assurance documents (QASDs or QAPs) with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

IX Control of Special Processes — Findings

1. Does the Quality Assurance Program require applicable documentation to assure that special processes are accomplished according to applicable codes, standards, or other sponsor-designated requirements? _____

2. Does the Quality Assurance Program require maintaining qualification documentaton for personnel, processes, and equipment? _____

3. Select one project which has contractually required Criterion IX of 10CFR50, Appendix B or equivalent to be met, and review any approved procedures (QASDs or QAPs) that may have been generated in support of this section, with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

X Inspection — Findings

1. Does the Quality Assurance Program require a documented inspection system to verify that customer-designated design requirements are satisfied? _____

2. Has an inspection system been documented for a project? For example, are there written approved procedures (QAPs or QASDs) for receiving, in-process, and/or final product inspections? _____

3. If the answer to 2. above is yes, then select two procedures and answer the following.

   3.1 Do the inspection procedures include appropriate acceptance/rejection criteria? _____
   3.2 Are the inspection results recorded? _____
   3.3 Are examinations, measurements, or test results documented and evaluated by qualified personnel? (In part, qualified means individuals other than those who performed the work being inspected.) _____
   3.4 Are provisions made for assuring adherence to customer-specified hold points? _____
   3.5 Are valid statistical Q.C. methods employed and/or is adequate process control monitoring used for items not inspected 100%? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

XI Test Control — Findings

1. Does the Quality Assurance Program require that a testing program be documented when the testing is required to demonstrate that structures systems and components will perform satisfactorily in service? _____

2. Does the Quality Assurance Program require that the test procedure include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions? _____

3. Does the Quality Assurance Program require that test results be evaluated/verified by an authorized individual to assure that test requirements have been satisfied? _____

4. Select one project which has contractually required Criterion XI of 10CFR50, Appendix B or equivalent to be met, and review all approved Quality Assurance documents (QASDs or QAPs) with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

_____

_____

_____

_____

Auditor: _____ Date: _____

EXHIBIT II

XII Control of Measuring and Test Equipment — Findings

1. Does the Quality Assurance Program require applicable documentation to ensure control of measuring and test equipment? _____

2. Does the documented system include periodic calibration of all measuring and test equipment that is used in quality-related activities and/or generates project-reportable data? _____

3. Are calibration standards traceable to the National Bureau of Standards? _____

4. Review the implementation of QASD No. 15-1 with the Technical Associate. Are there any significant problems? _____

5. Select from the shop floor two measuring or test devices, one having an active status and one having an inactive status. Review all gage calibration historical records for completeness and correctness. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

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Auditor: _____ Date: _____

XIII Handling, Storage, and Shipping — Findings

1. Does the Quality Assurance Program require the documentation of a system covering handling, storage, and shipping of material and equipment? _____

2. Does the Quality Assurance Program require the documentation in appropriate procedures (QASDs or QAPs) of special requirements, such as special protective environments, that may be necessary to prevent damage or deterioration of equipment, etc.? _____

3. Select one project which contractually requires Criterion XIII of 10CFR50 Appendix B or its equivalent to be met, and review the implementation of the approved QASDs or QAPs which were generated with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

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Auditor: _____ Date: _____

XIV Inspection, Test, and Operating Status — Findings

1. Does the Quality Assurance Program require a documented system for identifying the inspection, test, or operational status of parts or components? _____

2. Select one project which has contractually required Criterion XIV of 10CFR50, Appendix B or equivalent to be met, and review the implementation of any supporting QAP with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

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Auditor: _____ Date: _____

XV Nonconforming Materials, Parts, or Components — Findings

1. Does the Quality Assurance Program require a documented nonconforming material control system that provides for documentation, segregation and disposition of nonconforming material, and the notification to affected organizations? _____

2. Select one project that contractually requires Criterion XV of 10CFR50 Appendix B or its equivalent to be met, and review the implementation of QASD No. 17-1 with the appropriate Project Manager. This review should include such things as: (1) Is the responsibility/authority for determining the disposition of nonconforming items defined? (2) Do procedures provide for acceptance, rejection, rework, or repair and re-inspection? (3) Is defective or questionable material always identified as to its status? (4) Do procedures assure that the sponsor's acceptance or instructions are obtained on all nonconforming items? (5) Does the procedure address record maintenance, corrective action, and management review? Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

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Auditor: _____ Date: _____

XVI Corrective Action — Findings

1. Does the Quality Assurance Program require that a corrective action system be documented to assure that the cause of conditions such as failures, malfunctions, defective materials and nonconformances is identified and corrected, unless action to correct the cause of the condition is determined to be inappropriate? _____

2. Does the request for corrective action require (1) identification of cause, (2) corrective and/or preventive action, (3) schedule for completion, and (4) a responsible individual? _____

3. Are corrective action requests issued when a quality problem exists? _____

4. Select a project which contractually requires Criterion XVI of 10CFR50, Appendix B or its equivalent to be met, and review all "Corrective Action Request" forms for correctness and completeness with the appropriate Project Manager. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

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Auditor: _____ Date: _____

XVII Quality Assurance Records — Findings

1. Does the Quality Assurance Program require applicable documentation to assure the proper handling/storage of Quality Assurance records? _____

2. Is there a system for transmittal of appropriate records to sponsor? _____

3. Are records of data generated for a project compiled and maintained? _____

4. Are typical retention periods defined? _____

5. Are record storage facilities adequate to prevent loss by fire, water, or environmental deterioration? _____

6. Review the implementation of QASD No. 19-1 with the NED Librarian. Are there any significant problems? _____

7. Select one project that contractually requires Criterion XVII of 10CFR50, Appendix B or its equivalent to be met, and review the contents of its file folder for completeness. Are there any significant problems? _____

FINDINGS: (NI = Needs Improvement Explanation)

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Auditor: _____ Date: _____

EXHIBIT II

XVIII Audits	Findings
1. Does the Quality Assurance Program require periodic audits?	
2. Is there a documented internal audit procedure, and is it adequate? For example, does the procedure provide for (1) use of checklist, (2) training of audit personnel, (3) follow-up corrective action, and (4) re-audit of deficient areas?	
3. Does the Quality Assurance Program require audits, to the extent necessary, of sub-vendor organizations?	
4. Are audit results documented and reviewed by management having responsibility in the area audited?	

FINDINGS: (NI = Needs Improvement Explanation)

Auditor: _____ Date: _____