

QUALITY ASSURANCE PROGRAM

**A Description of the
Nuclear Power Businesses
Quality Assurance Program**

COMBUSTION  ENGINEERING

REVISION 5, OCTOBER 1989

ABSTRACT

This report describes the quality assurance program employed by the Nuclear Power Businesses Division of Combustion, Inc., for the supply of items and services subject to the requirements of 10CFR50, Appendix B. The program is based on and is responsive to the requirements of ANSI/ASME NQA-1. "Quality Assurance Program Requirements for Nuclear Facilities (1983 Edition with Addenda 1a (1983))"; the ASME Boiler and Pressure Vessel Code Section III, Nuclear Power Plant Components (1986 Edition), and the guidance in Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (Rev. 03).

Table of Contents

<u>Title</u>	<u>Page No.</u>
Cover Sheet	i
Abstract	ii
Table of Contents	iii
I. Introduction	1
II. Nuclear Power Businesses Quality Policy	2
III. Quality Assurance Criteria	4
III.1 Organization	4
III.2 Quality Assurance Program	6
III.3 Design Control	8
III.4 Procurement Document Control	16
III.5 Instructions Procedures and Drawings	18
III.6 Document Control	19
III.7 Control of Purchased Items and Services	20
III.8 Identification and Control of Items	23
III.9 Control of Processes	23
III.10 Inspection	24
III.11 Test Control	25
III.12 Control of Measuring and Test Equipment	27
III.13 Handling, Storage and Shipping	28
III.14 Inspection, Test and Operating Status	29
III.15 Control of Nonconforming Items	29
III.16 Corrective Action	30
III.17 Quality Assurance Records	31
III.18 Audits	32

Table of Contents (Continued)

Figures

<u>Figure No.</u>	<u>Title</u>	<u>Page No.</u>
II-1	Organization Chart-Nuclear Quality Systems	35
II-2	Organization Chart-Nuclear Power Businesses	36

Tables

<u>Table No.</u>	<u>Title</u>	<u>Page No.</u>
III-1	Responsibilities of Nuclear Quality Systems	37
III-2	Responsibilities of Nuclear Power Businesses Business Units	38
III-3	Clarifications to NQA-1 and/or Regulatory Guide 1.28 (Rev. 03)	39
III-4	Typical List of Quality Assurance Procedures	40

I. INTRODUCTION

I.1 Purpose

This report describes the quality assurance program employed by the Nuclear Power Businesses Division of Combustion Engineering, Inc., for the supply of items and services subject to the requirements of 10CFR50, Appendix B.

I.2 Scope

This report includes a description of controls employed at the Nuclear Power Businesses (NPB) facilities noted below. Section II presents the NPB commitment to quality and describes the NPB quality assurance organization and responsibilities. Section III describes the quality assurance controls employed to address each criterion of 10CFR50, Appendix B. The controls apply to all NPB facilities unless otherwise indicated.

The NPB facilities and the activities involved at each facility include:

Facility

Activities

NPB Headquarters,
Windsor, CT (with
offices also in
Chattanooga, TN)

Engineering services and NSSS
design, procurement, testing,
inspection, repair, installation,
and spare parts

Nuclear Fuels
Manufacturing,
Windsor, CT. and
Hematite, MO

Manufacture of nuclear fuel
pellets, fuel assemblies and
control element assemblies and
associated activities

C-E Controls/Electro-
Mechanics, New
Britain, CT and
Windsor, CT

Design and manufacture of
instrumentation & control
systems and associated activities

C-E Newington,
Newington, NH

Design and manufacture of
mechanical systems and
associated activities

I.3 Revision Control

Revisions to this report will be in accordance with the standards specified in 10CFR50.55 (f) (3). Specifically;

- o within 90 days, NRC will be informed of changes to this program that do not reduce previously accepted commitments;
- o changes that reduce commitments will be submitted for NRC approval prior to implementation.

II. NUCLEAR POWER BUSINESSES QUALITY POLICY

II.1 Policy Statement

The President, Nuclear Power Businesses, has authorized the following statement concerning quality assurance policy:

"A primary objective of Nuclear Power Businesses is to deliver to our customers defect free, competitive products and services on time that fully comply with contract requirements.

The Vice-President, Nuclear Quality Systems has the responsibility for defining the NPB quality assurance program

and shall bring to the attention of the President, Nuclear Power Businesses any quality problem that cannot be resolved within the normal execution of this responsibility".

II.2 Quality Assurance Organization

The Quality Assurance (QA) organization in NPB is shown in Figure II-1.

The Vice President, Nuclear Quality Systems (NQS) is responsible to assure that the QA policy, goals and objectives are transmitted through levels of management and imposed on quality functions. This is accomplished by distribution of Quality Assurance Manuals which contain QA policy statements.

Responsibility for nuclear quality assurance rests with the President, Nuclear Power Businesses and is delegated to the Vice President, Nuclear Quality Systems, who may further delegate specific activities to NQS personnel. Such delegation includes authority to stop work for noncompliance to requirements. Stop work orders are dispositioned by NQS and may be originated at any organization level and unit in NPB and executed at the level of a Manager, Director, Vice President or President for action. In all cases where personnel perform quality assurance functions, this delegation provides them authority and freedom to initiate, recommend, or provide solutions to quality problems through management channels.

Compliance with quality requirements is measured through planned surveillance and/or audit activities and corrective action follow-up by NQS personnel. NQS is independent of other organizations within NPB as shown in Figure II-2. NQS interprets quality related industry standards for intent and guidance and is responsible for assuring that all quality assurance related procedures used in NPB comply with established QA requirements.

III. QUALITY ASSURANCE CRITERIA

This section describes each of the eighteen (18) elements of the Combustion Engineering, Inc., Nuclear Power Businesses Division quality assurance program.

III. 1 Organization

Combustion Engineering, Inc., (C-E) has corporate headquarters at Stamford, Connecticut, and is a diversified energy systems and services company. It contains several divisions, one of which is Nuclear Power Businesses. The President, Nuclear Power Businesses Division (NPB) is responsible for the supply of nuclear systems, nuclear fuel and nuclear services. QA responsibilities originate within NPB as illustrated in Figures II-1 and II-2. NPB is headquartered at 1000 Prospect Hill Road, Windsor, Connecticut 06095.

Each project under contract at NPB is coordinated by a Project, Program, or Task Manager who is a member of either the Nuclear Systems, Nuclear Services or Nuclear Fuel organizations. The Project/Task Manager is responsible for coordinating and documenting all project work, assuring conformance with contract requirements and maintaining communication channels among NPB, the customer, and all other participating organizations.

The Vice President, Nuclear Quality Systems (NQS) reports at the same organizational level as other NPB Vice Presidents. Responsibilities of NQS are listed in Table III-1. These responsibilities are carried out through the NQS staff (Figure II-1) and by coordination of all QA activities within NPB. Details on responsibilities and interfaces among NQS and other organizations are contained in QA manuals and procedures. These interface relationships address items such as auditing, investigation of quality problems, and implementation of corrective action. Responsibilities of the other NPS units are listed in Table III-2.

NQS functions as an independent communication channel between senior NPB management and line management. This assures that senior NPB management is appraised of quality matters and that the NQS staff receive and comply with directives from the President, Nuclear Power Businesses via the Vice President, Nuclear Quality Systems.

The Vice President, Nuclear Quality Systems meets as necessary and at least monthly with the NQS management staff to discuss quality issues, schedule quality efforts, establish goals and identify areas for improvements. These meetings are supplemented by reports from the NQS management staff to the Vice President, NQS and from the Vice President, Nuclear Quality Systems to the President, Nuclear Power Businesses.

The detailed organizational structure of NQS as well as the number of personnel in NQS may change over time depending on quality needs as well as business needs. However, NQS will not become involved in activities unrelated to QA that would prevent full attention to QA matters.

NQS personnel selection is based on knowledge of NPB operations; QA regulations, practices and standards; past working experience in QA or related activities in nuclear power or a similar high technology industry and education considerations. In addition, NQS management assignments are also based on evaluated management experience in similarly responsible positions.

III.2 Quality Assurance Program

III.2.1 Summary Description

The QA program described herein is employed by NPB for the supply of items and services subject to the requirements of 10CFR50 Appendix B. The program is based on and responsive to the requirements of ANSI/ASME NQA-1 "Quality Assurance Program Requirements for Nuclear Facilities", the ASME Code, and the guidance in Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)". Alternatives to the explicit requirements and guidance given in NQA-1 and/or Regulatory Guide 1.28 are described in Table III-3.

III.2.2 Program Control

The requirements of this program are implemented at each NPB facility through QA manuals and procedures applicable to the activities conducted at each facility. All such documents are reviewed, approved and controlled by NQS to assure compliance with program requirements.

III.2.3 Evaluation of Program Effectiveness

The scope, status, implementation and adequacy of the QA program are assessed by senior levels of management in several ways. The President, Nuclear Power Businesses receives a monthly report from the Vice President, Nuclear Quality Systems covering major quality issues such as: significant internal and customer audit findings, industry quality-related developments, and quality improvement needs. Quality issues and assessments are discussed during regular staff meetings with the Vice Presidents involved. The Vice President, Nuclear Quality Systems is assessed, at least annually, for the performance of the QA program by the President, Nuclear Power Businesses through a documented management appraisal system.

III.2.4 Personnel Indoctrination and Training

The responsibility for assuring that personnel performing activities affecting quality are suitably trained rests with the organization performing those activities. Detailed personnel training requirements for each NPB facility are contained in QA procedures. NQS is responsible for assuring that training requirements are met.

Indoctrination, training and qualification of personnel performing engineering, purchasing, fabricating, installing, handling, shipping and storing activities consists of at least:

- o indoctrination in the purpose, scope and implementation of QA manuals, and applicable instructions and procedures through self-study,
- o proficiency tests and/or performance reviews, and/or on-the-job observations as determined by management, to determine adequacy of training and qualification,
- o maintenance of proficiency by performance review, and/or reexamination, and/or retraining as determined by management.

Indoctrination, training and qualification of NQS personnel verifying quality - affecting activities consists of the three items above and in addition the following:

- o training and qualification in the principles, techniques and requirements of the activity being performed. Documentation for these formal programs normally include the program objective, content, attendees, date(s) of the training or certification, and appropriate approvals.

For all of the above, training and qualification is documented in certificates and/or procedures that delineate the specific functions personnel are qualified to perform as well as the basis for the qualification.

III.3 DESIGN CONTROL

III.3.1 General

Quality assurance procedures are used to assure that design activities are carried out in a planned, controlled and timely manner and that applicable design requirements are established and correctly translated into design documents such as calculations, specifications and drawings.

These procedures provide specific instructions for accomplishment of design activities by defining requirements for design inputs and outputs including:

- o document format and content,
- o document identification,
- o review and approval,
- o design verification,
- o issuance and distribution,
- o revision control,
- o indication of document status,
- o record retention.

The procedures apply to design/engineering activities including such disciplines as reactor physics; stress, thermal, hydraulic and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; fuel design; instrumentation and controls design; and delineation of acceptance criteria for inspections and tests.

The procedures cover the total design process to assure that:

- o appropriate design basis requirements including quality standards are selected, specified, and included in the design;
- o deviations from standards are controlled;
- o materials, parts, equipment, and processes (including commercially obtained items) essential to the safety-related functions of basic components are reviewed for suitability of application and compatibility with overall system design criteria;
- o design interfaces among participating organizations internal and external to NPB are identified and controlled;
- o design work is verified or checked for adequacy;
- o design changes, including field changes, are subject to the same degree of control as applied to the original work.

Compliance to design control procedures is monitored by NQS internal compliance audits.

III.3.2 Design Inputs

Design work begins with the definition of the design requirements or design bases information. These requirements come from several sources internal and external to NPB. Typical sources include previously approved designs, those from engineering and product development efforts, contracts (eg., equipment performance criteria, design life, regulatory requirements, codes and standards, interface requirements, etc.), Standard Safety Analysis Reports, topical report, and information from industry or government funded research activities.

A Project/Task Manager (or equivalent) supplies the Cognizant Organization(s) (CO) with the design requirements or design bases and applicable quality requirements that are specified in contract documents, bid specifications, regulations and industry standards as applicable to the respective efforts. Within the CO, specific tasks are established and assigned to cognizant engineers. The CO is responsible for selection and documentation of design inputs including the identification, substantiation, and documentation of changes from previously approved designs.

The CO assures that design inputs have been verified or annotated to clearly indicate data or assumptions that must be confirmed by later design efforts or tests and that the design inputs are traceable by reference to the source of the data. Design documents containing input data are approved by the author and verifier(s) of the documents.

III.3.3 Design Calculations

The CO is responsible for selection of input data and analysis method, justification of assumptions, and preparation of design calculations.

Documentation of design calculations is detailed in purpose, method, assumptions, design input, references and units so that a person technically qualified in the subject can review and understand the design and verify the results without recourse to the originator.

Computer codes (used in design analyses or supplied to clients) are uniquely identified, tested and verified to assure accuracy of method. Procedures are used to preclude use of unverified modifications. Sample problems used in the verification are retained as records and include unique identification of the version of the computer code and documentation of inputs and outputs. Evidence of testing and verification of a given version of a computer code is documented and includes the signature of the author and verifier(s) of the code testing documentation. Dissemination of information on computer code errors is provided via a computer program error notification system. Computer source codes are protected by security methods to preclude unintentional, unplanned or unauthorized modifications.

A qualified individual or group is assigned to verify the design work (see III.3.7, Design Verification). When a standardized or previously proven design is used, the verification process is not duplicated, however, the applicability of the standardized design is checked with respect to meeting pertinent inputs.

The cover sheet or revision page of the document includes provisions for unique identification and the signatures of the author(s) and verifier(s).

III.3.4 Design Specifications

The CO is responsible for the preparation of design specifications. These specifications contain a complete basis for construction of items in accordance with the requirements of the ASME Code, contractual documents, regulations, and other applicable information, and in conjunction with design drawings, contain all necessary information regarding materials and design. A design specification includes:

- o functions and boundaries of the items covered,
- o the design requirements including all required overpressure protection requirements,
- o the environmental conditions including radiation,
- o the safety classification of the items covered,
- o material requirements including impact test requirements,
- o operability requirements as appropriate,
- o the effective ASME Code Edition, Addenda and Cases and other appropriate industry standards to be used for construction,
- o records required to be maintained,
- o special inspection, testing, and quality assurance requirements.

A qualified individual or group is assigned to verify the specification (see III.3.7, Design Verification). The cover sheet or revision page of the document includes provisions for unique identification and approvals of the author and verifier(s).

III.3.5 Design Drawings

The CO is responsible for the preparation of design drawings. These drawings include functional requirements for system/component interfaces, arrangement and layout, which are not directly used for producing an item. Examples include: piping and instrument diagrams, layout drawings, general arrangement drawings, and electrical diagrams. A drawing request system is used to define the scope and purpose for the drawing, the technical requirements to be incorporated and any special features or notes to be included. The CO reviews the design drawing for technical content and agreement with calculations, analyses, or other applicable design specification requirements. Additionally, a qualified individual or group is assigned to verify the contents of the drawing (see III.3.7, Design Verification).

III.3.6 Other Design Documents

The CO is responsible for preparation of other design documents needed to define or describe engineering requirements. These documents typically include items such as: design bases or design data information; system descriptions; interface requirements; test requirements; guidelines for startup and operation; guidelines for installation; engineering studies; and software verification plans and results. A qualified individual or group is assigned to verify the design document (see III.3.7, Design Verification). The cover sheet or revision page of the document includes provisions for unique identification and approvals by the author and verifier(s).

III.3.7 Design Verification

Design output is reviewed to verify its adequacy. This verification provides assurance that the output meets the specified inputs and is correct and complete.

Verification activities are performed by an individual or group other than those who performed the original work. The verification may be performed by the originator's supervisor provided the supervisor is the only individual in the CO competent to perform the verification and provided:

- o the supervisor did not specify the design approach, and did not rule out certain design considerations,
- o the supervisor did not establish the design input.

Audits by NQS address the use of supervisors as design verifiers to guard against abuse.

The CO determines the particular design verification method(s) to be used and designates the individual or group responsible for the verification efforts. The acceptable verification methods include design reviews, alternate calculations, and qualification testing and are defined as follows:

- o Design Reviews - independent review to assure that the information is correct and satisfactory.
- o Alternate Calculations - preparation of calculations or analyses using alternate methods to verify by comparison the correctness of the original work.
- o Qualification Testing - suitable testing of a model, prototype or initial production unit.

Qualification testing (as opposed to acceptance testing) is performed to test requirements established by the CO. The testing requirements include test conditions that simulate the most adverse design conditions (operating modes and environment) for the specific design feature(s) being verified. Test results are documented by the testing organization and evaluated by the CO to assure that test

requirements have been met. When tests are being performed on models or mockups, scaling laws are established and verified and results are subject to error analysis when applicable prior to use in final design work.

Design Verification procedures address responsibilities of verifiers, items to be verified and documentation required.

Results of the verification are documented, including identification of the verifier(s). Design verification is completed prior to relying upon the component, system, part or structure to perform its safety-related function.

III.3.8 Revision Control

Design document revisions are subject to the same review, approval and distribution controls as those applied to the original work. Revision level notation is used to assure that obsolete or superseded documents are not used inadvertently. Quality assurance procedures include requirements for evaluation of reported changes resulting from items such as:

- o qualification, preoperational, or operational test problems,
- o interference problems during construction,
- o disposition of nonconformances,
- o revised inputs (i.e., changes in regulatory or customer requirements), and
- o operational experience.

Where changes to previously verified work have been made, verification is repeated by the organization currently responsible for the work or by an equally qualified organization having access to the pertinent information.

III.3.9 Interface Control

Quality assurance procedures contain the organizational structure within which the program is implemented and delineate the authority and responsibility of the CO's involved. The organizational interfaces among contributing CO's, both internal and external to NPB, are controlled in accordance with these procedures.

Three procedures control the flow of design information by requiring the formal release of outputs involving interface information to other functional groups. This is accomplished within NPB by documented correspondence or standard document distribution forms and external to NPB by letters or approved procurement documents. The transmittal identifies the verification status of the information or document and, where necessary, identifies incomplete items which require further verification. Where it is necessary to transmit design information orally or by other informal means, follow-up by a controlled document is provided. Interface communications are traceable from a request through a related response to assure completeness and accuracy.

III.4 PROCUREMENT DOCUMENT CONTROL

Controlled procedures are used for the preparation, review and approval of procurement documents. Groups that prepare, review and approve procurement documents are identified in the procedures. These groups include design groups, (CO's per Section III.3), procurement groups, and NQS.

Procurement documents include (either directly or by reference) the following requirements, as applicable:

- o regulatory, ASME Code and industry standards;
- o tests and inspections, including acceptance criteria;
- o quality assurance program elements;
- o quality assurance records retention times and disposition;
- o reporting, approving and dispositioning nonconformances;
- o rights of access by NPB and/or its representative(s);
- o documentation submittal, review and approval;
- o extension of requirements to sub-suppliers;
- o technical/design (including drawings and specifications);
- o administrative; and
- o special processing.

It is the responsibility of the NPB organization that prepares the procurement document to assure that all required elements are addressed. Procurement documents are reviewed and approved by personnel trained in QA procedures prior to issue. This approval is also applicable to supplements issued to change the requirements of the original procurement.

The procurement process for commercial-grade⁽¹⁾ items and services uses the same review and approval cycle. These are bought to commercial standards where standards are available. Commercial items that become part of a system may be tested as part of the completed system. Procurement documents for standard commercial or previously approved items including spare or replacement parts essential to the safety functions of structures, systems, and components, are reviewed and approved by personnel trained in QA procedures.

(1) Controls limited to those items and services to be subsequently dedicated by NPB as "basic components".

III.5 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Quality affecting activities such as engineering, manufacturing, inspection, testing, certification, handling, storage, shipping, etc., are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. Quality assurance procedures require that these documents include or reference quantitative or qualitative acceptance criteria for determining that the activity has been satisfactorily accomplished.

The following is a summary of the types of instructions, procedures, and drawings used to control quality affecting activities.

QA Manuals, Procedures and Instructions - documents containing the systems and procedures that specify and describe the activities performed within MPB to provide adequate confidence that an item or service provided meets applicable requirements. A typical list of QA procedures is given in Table III-4.

Procurement Documents - documents that specify requirements for purchase of an item or service including purchase requisitions, drawings, process or material specifications, procedures or instructions.

Process Control Documents - documents that are used to control operations on items. These operations include: forming, machining, assembling, welding, brazing, heat treatment, examination, inspection, testing, plating, etc.. These documents include:

- o Process Sheets/Travelers/Work Orders - contain steps and the sequencing of operations performed to produce or install an item.

- o Manufacturing Drawings - contain or reference item form and fit requirements, such as, size, shape, materials, joining, finishing, torquing, etc., for directly producing an item and include specific acceptance criteria for these characteristics. Examples include assembly drawings and detail drawings.

- o Process Instructions/Procedures - contain details on methodology, parameters, and acceptance criteria for operations performed in manufacturing, repair, installation, inspection, testing, warehousing, dedication, etc.. Typically, these documents are used to control operations such as nondestructive examination, inspection, cleaning, packaging, preservation, shipping, handling, welding, brazing, heat treatment, and similar special processes.

III.6 DOCUMENT CONTROL

Quality assurance procedures are used to assure current and appropriate documents are used. These procedures control issuance of instructions, procedures, and drawings that specify quality requirements or that prescribe activities affecting quality. The procedures specify how documents are reviewed for adequacy, approved for release, and distributed to and used at the location where the prescribed activity is performed.

These procedures address items such as:

- o identification of organizations responsible for preparing, reviewing, approving, issuing and revising documents. This includes design documents, Safety Analysis Reports, nonconformance reports, as-built documents, and those documents identified in Section III. 5;

- o use of distribution lists or equivalent to assure that the proper personnel or organizations are provided the required documents to perform the work;
- o document identification to assure that the proper document is used in performing a particular activity. The identification includes the document number or any other relevant information that identify the document to be used;
- o ascertaining that proper documents are accessible and are being used. This is accomplished by use of document lists and/or files showing the latest applicable revision or use of receipt control systems. This assures that the latest applicable documents have been received and obsolete revisions recalled or discarded, where appropriate.

Changes to documents are reviewed, approved, and released by the organizations responsible for the work unless other organizations are specifically designated. In all cases, the reviewing organization(s) has access to pertinent information or background data upon which to base approval.

III.2 CONTROL OF PURCHASED ITEMS AND SERVICES

Items and services are procured from approved suppliers. QA procedures specify requirements for supplier evaluation and selection, control of supplier generated documents, acceptance of the item or service (by documentation review, source surveillance, source and/or receiving inspection), control of nonconforming conditions, supplier performance evaluations (assessments and audits), and qualification of NPB audit, inspection and surveillance personnel.

When specified in procurement documents, NPB performs surveillance of suppliers during fabrication, inspection, testing, and release of items and services. Quality procedures provide guidance for surveillance activities. Where no established quality standards exist for a specific supplier, the specific technical requirements of the procurement documents are used as the basis for surveillance. The degree of surveillance varies with the degree of importance of equipment, supplier performance, and complexity of items. The degree of surveillance is determined by the organization that prepared the order and by NQS. This surveillance is performed using instructions which define the operation or process to be witnessed and the verifications to be made.

The procurement of spare or replacement parts and components are governed by customer order requirements.

For commercial-grade items which are supplied as safety-related but where specific QA control cannot be imposed in a practical manner, specific provisions are made during receiving inspection or source surveillance to verify that requirements of the procurement document have been met.

Initial supplier approval is via survey or evaluation that is conducted by NQS. The purpose of these are to verify that the new supplier is capable of complying with the quality requirements in the procurement documents. The results are documented and any identified deficiencies are resolved prior to starting work.

Supplier approval is maintained by annual evaluations and periodic audits. The annual evaluations take into consideration items such as supplier furnished documentation; results of prior surveillances, inspections, and audits; and item or service operating performance. The periodic audits are

normally performed on a triennial basis and are consistent with the guidance in Regulatory Guide 1.28 (Rev. 3). The scope and frequency of audits depends on many factors, such as those given in Table III-3. The audits address the applicable criteria of 10CFR50 Appendix B.

Suppliers that have received ASME approval are approved on the basis of the ASME approval.

For items shipped to a NPB manufacturing or warehouse facility, receiving and/or source surveillance procedures are used to assure that the item and specified documentation comply with the procurement document requirements. Measures are established to assure that items accepted and released are identified as to their inspection status in order to prevent the use or installation of non-accepted items and provide for the entry only of accepted items into the warehouse. The status is identified on the item or on documentation traceable to the item.

For items procured by NPB and shipped to a nuclear power plant site, NQS issues a certification which indicates acceptance of the item. The certification includes specific information identifying the item and the applicable procurement documents, and certifies that the item meets all applicable procurement requirements, including documentation requirements. The certification includes identification of any NPB approved deviations from the procurement requirements and is approved by authorized personnel. Procedures identify the actions necessary to initiate, authorize, issue, distribute, and revise certifications. These procedures include provisions for review and acceptance of supplier furnished documentation (e.g. certificates of conformance, certified material test reports, non-destructive examination reports) and for identifying and following-up contingent conditions that require additional

action after delivery to the power plant site. A contingent condition is any condition prohibiting the actual use of material or equipment on-site for its specified purpose. Such items may be shipped to the site to permit partial testing or preparation for use to proceed, but actual use as intended will not be permitted until the contingent condition is resolved. Contingent conditions are monitored and their close-out is documented.

The measures established for item acceptance and supplier auditing provide the means for evaluating the supplier's certificates of conformance to ensure that they are valid.

III. 8 IDENTIFICATION AND CONTROL OF ITEMS

Identification requirements are controlled by procedures and are specified in the procurement and process control documents for quality related products and services.

Item identification may be by heat number, part number, equipment or service records or other appropriate means using a method which will not adversely affect the fit, function or quality of the item supplied. Identification and control of items (including consumables), is the responsibility of the organization responsible for the item.

Identification of items is traceable to documents such as design documents, procurement documents, mill test reports or inspection records. Identification of items is verified and documented prior to release of the item for further use.

III.9 CONTROL OF PROCESSES

Special processes include those inspection or manufacturing activities that satisfy the following:

- o The results of which are highly dependent on the control of the process and/or skill of the operator; and
- o The quality of the activity can neither be determined by inspection, nor it is considered advantageous to perform destructive examinations or tests.

Special processes include activities such as welding, heat treating, non-destructive examination, and cleaning.

These type of processes are controlled by documents such as process sheet travelers and special processing procedures which are generated in accordance with QA procedures. These documents address items such as:

- o process procedure, personnel and equipment qualification requirements
- o process prerequisites
- o acceptance criteria
- o environmental conditions

Process procedures and/or control documents are approved by NQS. Equipment and personnel associated with special processes are qualified in accordance with applicable codes, standards, QA procedures and/or contract requirements. Qualification records are reviewed by NQS, and are maintained and kept current by responsible organizations.

III.10 INSPECTION

Inspections are performed in accordance with instructions procedures and/or control documents which are reviewed by NQS and approved by the responsible organization. These

instructions/procedures provide criteria for determining accuracy requirements of inspection equipment, how and when inspections are performed; and, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

Inspections are performed by personnel other than those who performed or directly supervised the activity being inspected and who do not report directly to the immediate supervisors who are responsible for the activity being inspected. The personnel performing inspections are trained, qualified and certified in accordance with procedures. The records of qualifications and certifications of inspectors are kept current by the responsible organization.

Instructions and procedures include, as appropriate, identification of characteristics and activities to be inspected, a description of the method of inspection, identification of the individuals or groups responsible for performing the inspection, acceptance and/or rejection criteria, identification of required procedures, drawings and specifications including revisions, special inspection equipment and accuracy requirements, recording of the results of the inspection, and the inspector or data recorder.

The organization or individual performing the inspection is normally responsible for evaluating the results and determining the acceptability of the inspected item.

III.11 TEST CONTROL

Acceptance testing (such as hydrostatic, pre-operational, etc.), and destructive examination testing (such as, metallurgical, etc.) is performed using controlled procedures. The test procedures address the requirements as specified in test requests, specifications and/or codes and standards. Test

procedures are submitted for review and approval prior to testing and the testing is witnessed by assigned and qualified personnel. Test procedures contain the following, as applicable:

- o Provisions for assuring that prerequisites for the test have been met;
- o Required instrumentation and accuracies;
- o Instructions for conducting the test and for acquiring and recording the data necessary for evaluation;
- o Witnessing of the testing by qualified personnel;
- o Required environmental conditions;
- o Acceptance and/or rejection criteria required to evaluate the test;
- o Recording the performance of the test;
- o Use and identification of calibrated equipment;
- o Code and contract requirements;
- o Test personnel qualification;
- o Method of recording test results;
- o Verification that the test procedures have been reviewed and approved.

Test procedures and/or controlling documents are approved by NQS.

Test results, as a minimum, identify the item tested, date of the test, the procedure and revision level, the tester or data recorder, identification number of the equipment, test conditions, time, type of observation, results and acceptability, individual evaluating test results, and noted nonconformances. The test results are evaluated and documented as specified in the test procedure.

Gages, instruments, and other inspection, measuring and testing equipment and devices used in activities affecting quality are required to be of the proper range, type and accuracy in order to verify conformance to established requirements. Procedures contain the detailed requirements for the calibration (technique and frequency) and control, and describe organizational responsibilities for establishing, implementing, and assuring effectiveness of the calibration program.

Standards used for calibration have known valid relationships to recognized national standards. These standards have an accuracy adequate to verify that measuring and test equipment being calibrated are within the tolerance requirements for which they are being used. When possible and practical, measuring and test equipment are calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated. Greater uncertainty may be acceptable when limited by "state-of-the-art". Where national standards do not exist for reference standards, the basis of the calibration is documented.

The method and interval of calibration for each item is defined in procedures. These are based on the type of equipment, stability characteristics, required accuracy and other conditions affecting measurement control. Each item is identified to permit traceability to the calibration test data. This identification may be by either label, tag, or color coding, or other means as provided for by procedure. This identification also indicates the date of the next required calibration.

When an instrument is found to be out of calibration, an investigation to determine the validity of previous inspections performed with the instrument and the acceptability of items inspected or tested since the last calibration is conducted. Inspections or tests are repeated on affected items as necessary.

NQS audits organizational units responsible for control of measuring and test equipment to assure compliance with applicable procedures.

III.13 HANDLING, STORAGE AND SHIPPING

Procedures are used to control handling, storage and shipping of items to ensure the maintenance of quality from source through delivery to the customer. These procedures may be in various formats such as process sheets, travelers, work orders, drawings, shipping instructions, process specifications, and instructions. The procedures specify or describe cleaning, handling, storage, packaging, shipping and preservation methods to preclude item damage, loss, or deterioration by environmental conditions. These activities are accomplished by trained personnel.

The application of quality considerations to handling, storage, and shipping is based upon considerations such as the level of sensitivity of the item to environmental conditions, its resistance to physical forces, and its relative replaceability. When required for particular items, special equipment (such as containers, shock absorbers, accelerometers and special tools or handling devices) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) are specified, provided, and verified when required. These special tools or handling devices are inspected, tested, and controlled in accordance with procedures. Only experienced or trained personnel are used to work with these devices.

Handling, storage, and shipping procedures and/or controlling documents are approved by NQS. Equipment and personnel qualification records are audited by NQS.

III.14 INSPECTION, TEST AND OPERATING STATUS

Documents, such as travelers, process sheets, and work orders are used for identifying required inspections, tests, examinations, and processing status of items. The documents indicate the status of the operation(s) being performed, the required signatures (or other similar means), and the date indicating when a given operation, test, inspection, or examination was completed. Quality assurance procedures control the use of travelers, process sheets and work orders including methods for making sequence changes and identification of nonconforming items. No sequence change is allowed if it compromises the safety function of the item. Any change to travelers, etc are subject to the same controls as the original. These documents accompany items throughout processing.

Status indicators such as tags, forms, labels, etc. may also be used to identify status of items. These indicators indicate the current status such as: a) acceptability or approval of the item, b) a hold situation where a nonconformance exists, and c) rejection where an item is unacceptable for the use that it was intended. When such indicators are used, only NQS is authorized to affix and remove inspection status indicators. This assures control of any possible inadvertent bypassing of required inspections, tests, and operations. NQS may waive certain check points, etc. at its discretion.

III.15 CONTROL OF NONCONFORMING ITEMS

A nonconforming item is defined as that which does not meet specified requirements.

Procedures are used to control the identification, documentation, segregation (when practical), review and disposition of nonconforming items (including computer codes), and include notification to affected organizations if disposition is other than scrap. These procedures identify individuals or groups, including NQS, authorized to disposition and approve nonconformances, verification requirements, and describe the segregation and/or control of nonconforming items to prevent inadvertent use. Nonconformances are resolved prior to shipment of an item.

Documentation contains the identification of the nonconforming items, a description of the nonconformance and its disposition including re-inspection requirements, and documented approval of this disposition. When nonconforming items are repaired or otherwise made suitable for their intended use, they are inspected or tested in accordance with the original inspection and test requirements or acceptable alternatives.

Individuals dispositioning nonconformances are selected based on experience and competence related to the item being evaluated, and an understanding of the requirements. These individuals have access to necessary background information.

Nonconformances are periodically evaluated by NQS for quality trends. Findings considered significant are reported to management for review and assessment.

III.16 CORRECTIVE ACTION

Conditions adverse to quality, such as nonconformances, failures, malfunctions, deficiencies, deviations, or defective materials and equipment, are identified, documented and reported to appropriate levels of management. These conditions may be identified by suppliers, surveillance, inspection or audit activities at suppliers, internal audits/inspections, customer audits, agency audits/inspections or by independent investigations conducted by NQS.

QA procedures specify how conditions adverse to quality are documented and reported to cognizant parties, including appropriate levels of management, for action and for assuring that corrective action is suitably identified, accepted and implemented in a timely manner.

These procedures require identification of cause (as deemed necessary), corrective action to prevent recurrence, verification of implementation; and follow-up and close-out of internal audit, and supplier audit/surveillance audit findings. Follow-up action is taken by NQS to verify corrective action. NQS concurrence with the action is documented

Trend analyses are periodically performed on surveillance and audit activities. Results of such analyses are reported to appropriate levels of management.

III.17 QUALITY ASSURANCE RECORDS

Quality Assurance records are preplanned, generated, stored, and maintained so as to provide objective evidence that quality assurance requirements have been met. The records program is planned for a standard system but may be expanded or specifically modified in accordance with individual contract requirements. The system includes provisions for records such as: design, manufacturing, procurement, installation, inspection, and qualification.

NQS is responsible for the maintenance of quality record files. Files are indexed to facilitate storage and retrieval. The records are reviewed for completeness, per procedure requirements, prior to retention and are available for review by customers, for those records applicable to that customer's contract(s).

Unless otherwise authorized, suppliers are required to submit a copy of designated quality records to NPB for transmittal to the customer(s) before the procurement order is concluded. Prior to shipment of a purchased item, the quality records compiled by the supplier are reviewed for completeness and acceptability. The results of these reviews are recorded. Test results are reviewed and evaluated for adequacy, as necessary, during surveillance visits to supplier's facilities.

III.18 AUDITS

Internal compliance audits are performed by NQS on applicable NPB organization units at least once per calendar year. External audits of suppliers are performed by NQS at a frequency commensurate with the suppliers scope of supply and status and importance of the suppliers' activity.

An annual audit schedule is established indicating the frequency and organization(s) to be audited. The audits include review of activities affecting quality. Since all elements of the QA Program do not apply to all activities, only the applicable elements are monitored during audits. Audit frequencies and areas to be audited may be modified based on previous audit findings and conditions such as organization changes, major procedure revisions, deficiencies and nonconformances, and verification of corrective action. The audit schedule may be revised if necessary.

NQS personnel assigned to perform audits are qualified and certified prior to their performing audits. All audits performed by NQS are led by a lead auditor. Qualification is based on training, education, experience, and successful completion of examination. Auditors have no direct responsibility in the areas

audited. NQS may employ qualified auditors from other organizations to perform audits and/or NQS may use the results of supplier audits performed by other organizations. However, NQS retains responsibility for the audits in such cases.

An audit plan identifies the area to be audited, audit scope, requirements, audit personnel, organizations to be notified, applicable documents, schedule, and procedures or checklists to be used. The organization(s) responsible for the activity or area being audited is notified in advance of scheduled audits.

An audit report is issued and signed by the Lead Auditor and includes the following information, as appropriate:

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

The audit report is transmitted to the audited organization(s)' cognizant management.

If deficiencies are found during the audit the following actions are performed:

- o The auditor(s) documents the deficiencies in the audit report with a required response date.
- o The audited organization documents corrective action and returns the response to the auditor within the required response time.

- o Auditors assure that deficiencies are answered in the allotted time and that adequate corrective action has been implemented or scheduled; verify the adequacy and completeness of corrective action; close out the deficiency when the reported condition has been resolved; and assure that relevant audit documents are retained as records including the plan, report and corrective action completion.

- o Incomplete corrective action responses are brought to the attention of the applicable business unit management for resolution and if necessary to the Vice President, Nuclear Quality Systems or President, Nuclear Power Businesses. Follow-up action is taken until corrective action is completed.

Nuclear Quality Systems

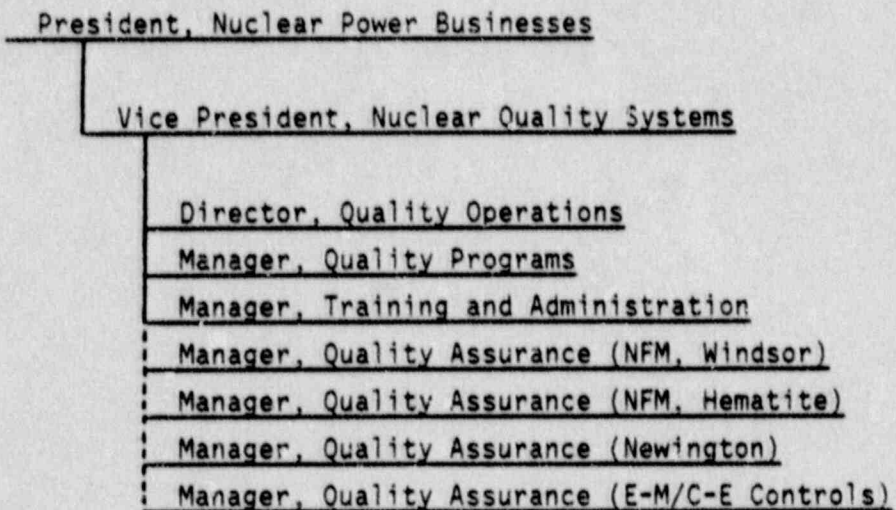


Figure II-1

Nuclear Power Businesses

President, Nuclear Power Businesses

Vice President, Nuclear Quality Systems

Vice President, Nuclear Systems⁽¹⁾

Vice President, Nuclear Fuel⁽²⁾

Vice President, Nuclear Services

Controller

(1) includes C-E Controls/Electro-Mechanics and C-E Newington facilities.

(2) includes Nuclear Fuels Manufacturing facilities.

Figure II-2

Table III-1

Responsibilities of Nuclear Quality Systems

Interface with all NPB organizations in the solution of day to day quality problems.

Provide for NPB the necessary direction for quality through approval and distribution of quality policies, manuals and procedures.

Provide an assessment of the scope, status, implementation and adequacy of the NPB QA program.

Conduct the QA internal audit program.

Provide interpretations for QA Standards.

Perform quality data collection and trend analysis.

Maintain NQS personnel training and qualification records.

Perform supplier evaluations.

Perform systems audits at supplier facilities.

Review resolution of deviations/nonconforming conditions.

Review procurement orders.

Establish and execute witness and hold points (surveillance and/or inspection).

Monitor conformance to procurement requirements.

Table III-2

Responsibilities of Nuclear Power Businesses Units

Nuclear Systems:

1. Design, procurement and fabrication of Nuclear Steam Supply System (NSSS) components, systems and structures for NSSS contracts.
2. NSSS Licensing
3. Design and fabrication of instrumentation and control systems.

Nuclear Services:

1. Engineering, examination, installation, repair and maintenance services to operating nuclear power plants.
2. Nuclear power plant spare parts.
3. Design, procurement, and fabrication of components, systems and structures to operating nuclear power plants.

Nuclear Fuel:

1. Design, procurement and fabrication of nuclear fuel (both initial and reload cores) and related products and services.

Controller:

1. Administrative management duties, such as accounting.

Table III-3

Clarifications to NQA-1 and/or Regulatory Guide 1.28 (Rev. 03)

<u>Section</u>	<u>Clarification</u>
Regulatory Guide 1.28 paragraph C.1	Training procedures are used to ensure that individuals are qualified in a manner commensurate with the requirements of their job description, operating procedures ensure that activities are accomplished at the correct inspection/organization level; this may be used in lieu of personnel level ratings.
Regulatory Guide 1.28 Paragraph C.3.2.1	The frequency of auditing a supplier is based on: i) if active work is in progress under a purchase order, ii) results of quality trend evaluations, iii) quality classification of item or service, iv) processes being employed, v) item or service complexity or uniqueness, vi) number of planned surveillances, vii) number of current orders.
NQA-1 Supplement 175-1 Paragraph 2.3	Record validation/authentication is controlled by procedure.
paragraph 4.0	Applies only to records transferred to permanent storage (all other records are classified as "working" files).

Table III-4

Typical List of Quality Assurance Procedures

- o Preparation and Control of Quality Plans
- o Stop Work Order
- o Indoctrination & Training of Personnel
- o Certification Program for Inspection,
Examination and Testing Personnel
- o Certification Program for Audit Personnel
- o Certification Program for Nondestructive
Examination Personnel
- o Qualification of Registered Professional Engineers
for ASME Code Certifying Activities
- o Establishment of Equipment Safety & Quality Classifications
- o Design Input
- o Design Analysis
- o Design Interface Control
- o Design Verification
- o Preparation, Control & Retention of Drawings
- o Design Specifications
- o Design Change, Field Change, Corrective Action
- o Safety Analysis Reports (SAR) and SAR Changes
Design Reports
- o Control of Supplier Technical Change Requests

Table III-4 (continued)

- o Preparation, Review & Approval of Purchase Orders
- o Dedication of Commercial Grade Items
- o Preparation & Control of Quality Assurance Procedures
- o Preparation & Control of Operating Procedures
- o Preparation & Control of Technical Operating Procedures
- o Preparation & Control of QA Specifications
- o Control of Quality Assurance Manuals
- o Preparation & Control of Contract Operating Procedures
- o Preparation & Control of Welding Procedure Specifications
- o Supplier Evaluation & Selection Approved Suppliers List
- o Control of Supplier Document Submittals
- o Control of Supplier Nonconformances
- o Source Surveillance
- o Certification of Satisfactory Completion of Work
- o Inspection
- o Control of Measuring & Test Equipment
- o Control of Nonconforming Items
- o Corrective Action Report
- o Quality Trend Analysis
- o Records Retention
- o Owner's Records Package (Purchased Items)
- o Control of N Symbol Stamping
- o Internal QA Audit
- o Supplier Audits

BUSINESSES
NUCLEAR POWER ~~SYSTEMS~~

CENPD-210

QUALITY ASSURANCE PROGRAM

A Description of the
Nuclear Power ~~Systems~~ **Businesses**
Quality Assurance Program

COMBUSTION ENGINEERING

5,
6,
REVISION A, SEPTEMBER 1988

~~May 1989~~
October 1989

(1983 Edition with
Addenda 1a (1983))

ABSTRACT

Businesses

Energy

This report describes the quality assurance program employed by the Nuclear Power ~~Systems~~ Division of Combustion Engineering, Inc., ~~Power Systems~~ for the supply of items and services subject to the requirements of 10CFR50, Appendix B. The program is based on and ^{is} responsive to the requirements of ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"; the ASME Boiler and Pressure Vessel Code Section III, Nuclear Power Plant Components, and the guidance in Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (Rev. 03).

(1986 Edition)

Table of Contents

<u>Title</u>	<u>Page No.</u>
Cover Sheet	i
Abstract	ii
Table of Contents	iii
I. Introduction	1
II. Nuclear Power ^{<i>Businesses</i>} Systems ' Quality Policy	2
III. Quality Assurance Criteria	4
III.1 Organization	4
III.2 Quality Assurance Program	6
III.3 Design Control	8
III.4 Procurement Document Control	16
III.5 Instructions Procedures and Drawings	18
III.6 Document Control	19
III.7 Control of Purchased Items and Services	20
III.8 Identification and Control of Items	23
III.9 Control of Processes	23
III.10 Inspection	24
III.11 Test Control	25
III.12 Control of Measuring and Test Equipment	26 27
III.13 Handling, Storage and Shipping	28
III.14 Inspection, Test and Operating Status	29
III.15 Control of Nonconforming Items	29
III.16 Corrective Action	30
III.17 Quality Assurance Records	31
III.18 Audits	32

Table of Contents (Continued)

Figures

<u>Figure No.</u>	<u>Title</u>	<u>Page No.</u>
II-1	Organization Chart-Nuclear Quality Systems	35
II-2	Organization Chart-Nuclear Power Systems <i>Businesses</i>	36

Tables

<u>Table No.</u>	<u>Title</u>	<u>Page No.</u>
III-1	Responsibilities of Nuclear Quality Systems	37
III-2	Responsibilities of Nuclear Power Systems <i>Businesses</i> Business Units	38
III-3	<i>CLARIFICATIONS</i> Alternatives to NQA-1 and/or Regulatory Guide 1.28 (Rev. 03)	39
<i>III-4</i>	<i>Typical List of Quality Assurance Procedures</i>	<i>40</i>

I. INTRODUCTION

I.1 Purpose

Businesses
This report describes the quality assurance program employed by the Nuclear Power ~~Systems~~ Division of Combustion Engineering, Inc., ~~Power Systems~~, for the supply of items and services subject to the requirements of 10CFR50, Appendix B.

I.2 Scope

Businesses
This report includes a description of controls employed at the Nuclear Power ~~Systems~~ (NPX) facilities noted below. Section II presents the NPX ^B commitment to quality and describes the NPX ^B quality assurance organization and responsibilities. Section III describes the quality assurance controls employed to address each criterion of 10CFR50, Appendix B. The controls apply to all NPX ^B facilities unless otherwise indicated.

^B
The NPX ^B facilities and the activities involved at each facility include:

Facility

Activities

^B
NPX Headquarters,
Windsor, CT (with
offices also in
Chattanooga, TN)

Engineering services and NSSF
design, procurement, testing,
inspection, repair, installation,
and spare parts

Nuclear Fuels
Manufacturing,
Windsor, CT. and
Hematite, MO

Manufacture of nuclear fuel
pellets, fuel assemblies and
control element assemblies and
associated activities

C-E Controls/Electro-
Mechanics, New
Britain, CT and
Windsor, CT

Design and manufacture of
instrumentation & control
systems and associated activities

C-E Newington,
Newington, NH

Design and manufacture of
mechanical systems and
associated activities

I.3 Revision Control

Revisions to this report will be in accordance with the standards specified in 10CFR50.55 (f) (3). Specifically;

- o within 90 days, NRC will be informed of changes to this program that do not reduce previously accepted commitments;
- o changes that reduce commitments will be submitted for NRC approval prior to implementation.

II. NUCLEAR POWER ^{Businesses} ~~SYSTEMS~~ QUALITY POLICY

II.1 Policy Statement

The ~~Executive Vice~~ ^{Businesses} President, Nuclear Power ~~Systems~~, has authorized the following statement concerning quality assurance policy:

"A primary objective of Nuclear Power ~~Systems~~ ^{Businesses} is to deliver to our customers defect free, competitive products and services on time that fully comply with contract requirements.

The Vice-President, Nuclear Quality Systems has the responsibility for defining the NP~~S~~ ^B quality assurance program

and shall bring to the attention of the ~~Senior Vice~~ President, Nuclear Power ~~Systems~~ ^{BUSINESSES} any quality problem that cannot be resolved within the normal execution of this responsibility".

II.2 Quality Assurance Organization

The Quality Assurance (QA) organization in NPX^B is shown in Figure II-1.

The Vice President, Nuclear Quality Systems (NQS) is responsible to assure that the QA policy, goals and objectives are transmitted through levels of management and imposed on quality functions. This is accomplished by distribution of Quality Assurance Manuals which contain QA policy statements.

Responsibility for nuclear quality assurance rests with the ~~Executive Vice~~ President, Nuclear Power ~~Systems~~ ^{BUSINESSES} and is delegated to the Vice President, Nuclear Quality Systems, who may further delegate specific activities to NQS personnel. Such delegation includes authority to stop work for

noncompliance to requirements. Stop work orders may be originated at any organization level ^{and units in NPB} and executed at the level of a Manager, Director, ~~or~~ Vice President, ^{or President} for action. In all cases where personnel perform quality assurance functions, this delegation provides them authority and freedom to initiate, recommend, or provide solutions to quality problems through management channels.

Compliance with quality requirements is measured through planned surveillance and/or audit activities and corrective action follow-up by NQS personnel. NQS is independent of other organizations within NPX^B as shown in Figure II-2. NQS interprets quality related industry standards for intent and guidance and is responsible for assuring that all quality assurance related procedures used in NPX^B comply with established QA requirements.

9.1

are dispositioned by NQS and

III. QUALITY ASSURANCE CRITERIA

This section describes each of the eighteen (18) elements of the Combustion Engineering, Inc., ~~Power Systems~~, Nuclear Power ~~Systems~~ ^{BUSINESSES} Division quality assurance program.

III. 1 Organization

Combustion Engineering, Inc., (C-E) has corporate headquarters at Stamford, Connecticut, and is a diversified energy systems and services company. It contains several divisions, one of which is Nuclear Power ~~Systems~~ ^{BUSINESSES}. The ~~Executive Vice President~~ ^{Customer} Nuclear Power ~~Systems~~ ^{BUSINESSES} Division (NP^B) is responsible for the supply of nuclear systems, nuclear fuel and nuclear services. QA responsibilities originate within NP^B as illustrated in Figures II-1 and II-2. NP^B is headquartered at 1000 Prospect Hill Road, Windsor, Connecticut 06095.

Each project under contract at NP^B is coordinated by a Project, Program, or Task Manager who is a member of either the Nuclear Systems, Nuclear Services or Nuclear Fuel organizations. The Project/Task Manager is responsible for coordinating and documenting all project work, assuring conformance with contract requirements and maintaining communication channels among NP^B, the customer, and all other participating organizations. ^B

The Vice President, Nuclear Quality Systems (NQS) reports at the same organizational level as other NPA Vice Presidents. Responsibilities of NQS are listed in Table III-1. These responsibilities are carried out through the NQS staff (Figure II-1) and by coordination of all QA activities within NPA. Details on responsibilities and interfaces among NQS and other organizations are contained in QA manuals and procedures. These interface relationships address items such as auditing, investigation of quality problems, and implementation of corrective action. Responsibilities of the other NPS units are listed in Table III-2.

NQS functions as an independent communication channel between senior NPA management and line management. This assures that senior NPA management is appraised of quality matters and that the NQS staff receive and comply with directives from the ~~Executive Vice President~~, Nuclear Power ~~Systems~~ ^{BUSINESSES} via the Vice President, Nuclear Quality Systems.

The Vice President, Nuclear Quality Systems meets as necessary and at least monthly with the NQS management staff to discuss quality issues, schedule quality efforts, establish goals and identify areas for improvements. These meetings are supplemented by reports from the NQS management staff to the Vice President, NQS and from the Vice President, Nuclear Quality Systems to the ~~Executive Vice~~ President, Nuclear Power ~~Systems~~ ^{BUSINESSES}.

The detailed organizational structure of NQS as well as the number of personnel in NQS may change over time depending on quality needs as well as business needs. However, NQS will not become involved in activities unrelated to QA that would prevent full attention to QA matters.

NQS personnel selection is based on knowledge of NPX^B operations; QA regulations, practices and standards; past working experience in QA or related activities in nuclear power or a similar high technology industry and education considerations. In addition, NQS management assignments are also based on evaluated management experience in similarly responsible positions.

III.2 Quality Assurance Program

III.2.1 Summary Description

The QA program described herein is employed by NPX^B for the supply of items and services subject to the requirements of 10CFR50 Appendix B. The program is based on and responsive to the requirements of ANSI/ASME NQA-1 "Quality Assurance Program Requirements for Nuclear Facilities" the ASME Code, and the guidance in Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)".^{11/10} Alternatives to the explicit requirements and guidance given in NQA-1 and/or Regulatory Guide 1.28 are described in Table III-8.

III.2.2 Program Control

The requirements of this program are implemented at each NPX^B facility through QA manuals and procedures applicable to the activities conducted at each facility. All such documents are reviewed, approved and controlled by NQS to assure compliance with program requirements.

III.2.3 Evaluation of Program Effectiveness

The scope, status, implementation and adequacy of the QA program are assessed by senior levels of management in several ways. The ~~Executive Vice~~ President, Nuclear Power ~~Systems~~^{BUSINESSES} receives a monthly report from the Vice President, Nuclear Quality Systems covering major quality issues such as: significant internal and customer audit findings, industry quality-related developments, and quality improvement needs. Quality issues and assessments are discussed during regular staff meetings with the Vice Presidents involved. The Vice President, Nuclear Quality Systems is assessed, at least annually, for the performance of the QA program by the ~~Executive Vice~~ President, Nuclear Power ~~Systems~~^{BUSINESSES} through a documented management appraisal system.

III.2.4 Personnel Indoctrination and Training

The responsibility for assuring that personnel performing activities affecting quality are suitably trained rests with the organization performing those activities. Detailed personnel training requirements for each NP~~A~~^B facility are contained in QA procedures. NQS is responsible for assuring that training requirements are met.

Indoctrination, training and qualification of personnel performing engineering, purchasing, fabricating, installing, handling, shipping and storing activities consists of at least:

- o indoctrination in the purpose, scope and implementation of QA manuals, and applicable instructions and procedures through self-study,
- o proficiency tests and/or performance reviews, and/or on-the-job observations as determined by management, to determine adequacy of training and qualification,
- o maintenance of proficiency by performance review, and/or reexamination, and/or retraining as determined by management.

Indoctrination, training and qualification of NQS personnel verifying quality - affecting activities consists of the three items above and in addition the following:

- o training and qualification in the principles, techniques and requirements of the activity being performed. Documentation for these formal programs normally include - the program objective, content, attendees, date(s) of the training or certification, and appropriate approvals.

For all of the above, training and qualification ^{is documented} ~~records~~ and/or procedures ^{that} delineate the specific functions personnel are qualified to perform as well as the basis for the qualification.

Q.8

in certificates →

III.3 DESIGN CONTROL

III.3.1 General

Quality assurance procedures are used to assure that design activities are carried out in a planned, controlled and timely manner and that applicable design requirements are established and correctly translated into design documents such as calculations, specifications and drawings.

These procedures provide specific instructions for accomplishment of design activities by defining requirements for design inputs and outputs including:

- o document format and content,
- o document identification,
- o review and approval,
- o design verification,
- o issuance and distribution,
- o revision control,
- o indication of document status,
- o record retention.

Q.11

The procedures ^{apply} ~~are applied~~ to design/engineering activities ~~as~~ ~~required by contract~~ including such disciplines as reactor physics; stress, thermal, hydraulic and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; fuel design; instrumentation and controls design; and delineation of acceptance criteria for inspections and tests.

The procedures cover the total design process to assure that:

- o appropriate design basis requirements including quality standards are selected, specified, and included in the design;
- o deviations from standards are controlled;
- o materials, parts, equipment, and processes (including commercially obtained items) essential to the safety-related functions of basic components are reviewed for suitability of application and compatibility with overall system design criteria;
- o design interfaces among participating organizations internal and external to NPS are identified and controlled;
- o design work is verified or checked for adequacy;
- o design changes, including field changes, are subject to the same degree of control as applied to the original work.

Q.10

Compliance to design control procedures is monitored by NPS internal ^{Revision 5} compliance audits.

III.3.2 Design Inputs

Design work begins with the definition of the design requirements or design bases information. These requirements come from several sources internal and external to NPS. ~~The~~ ^{Typical} sources include ~~requirements from~~ previously approved designs, ~~and~~ from engineering and product development efforts, ~~The external sources include requirements from~~ contracts (e.g. ^{eg} equipment performance criteria, design life, regulatory requirements, codes and standards, interface requirements, etc.) and information from industry or government funded research activities.

A Project/Task Manager (or equivalent) supplies the Cognizant Organization(s) (CO) with the design requirements or design bases and applicable quality requirements that are specified in contract documents, bid specifications, regulations and industry standards as applicable to the respective efforts. Within the CO, specific tasks are established and assigned to cognizant engineers. The CO is responsible for selection and documentation of design inputs including the identification, substantiation, and documentation of changes from previously approved designs.

The CO assures that design inputs have been verified or annotated to clearly indicate data or assumptions that must be confirmed by later design efforts or tests and that the design inputs are traceable by reference to the source of the data. Design documents containing input data are approved by the author and verifier(s) of the documents.

Q.14
Standard
N. Safety Analysis Reports,
topical report,

III.3.3 Design Calculations

The CO is responsible for selection of input data and analysis method, justification of assumptions, and preparation of design calculations.

Documentation of design calculations is detailed in purpose, method, assumptions, design input, references and units so that a person technically qualified in the subject can review and understand the design and verify the results without recourse to the originator.

Computer codes (used in design analyses) are uniquely identified, ~~computer codes~~ tested and verified to assure accuracy of method. Procedures are used to preclude use of unverified modifications. Sample problems used in the verification are retained as records and include unique identification of the version of the computer code and documentation of inputs and outputs. Evidence of testing and verification of a given version of a computer code is documented and includes the signature of the author and verifier(s) of the code testing documentation. Dissemination of information on computer code errors is provided via a computer program error notification system. Computer source codes are protected by security methods to preclude unintentional, unplanned or unauthorized modifications.

no supplied to clients)

G4

A qualified individual or group is assigned to verify the design work (see III.3.7, Design Verification). When a standardized or previously proven design is used, the verification process is not duplicated, however, the applicability of the standardized design is checked with respect to meeting pertinent inputs.

The cover sheet or revision page of the document includes provisions for unique identification and the signatures of the author(s) and verifier(s).

III.3.4 Design Specifications

The CO is responsible for the preparation of design specifications. These specifications contain a complete basis for construction of items in accordance with the requirements of the ASME Code, contractual documents, regulations, and other applicable information, and in conjunction with design drawings, contain all necessary information regarding materials and design. A design specification includes:

- o functions and boundaries of the items covered,
- o the design requirements including all required overpressure protection requirements,
- o the environmental conditions including radiation,
- o the safety classification of the items covered,
- o material requirements including impact test requirements,
- o operability requirements as appropriate,
- o the effective ASME Code Edition, Addenda and Cases and other appropriate industry standards to be used for construction,
- o records required to be maintained,
- o special inspection, testing, and quality assurance requirements.

A qualified individual or group is assigned to verify the specification (see III.3.7, Design Verification). The cover sheet or revision page of the document includes provisions for unique identification and approvals of the author and verifier(s).

III.3.5 Design Drawings

The CO is responsible for the preparation of design drawings. These drawings include functional requirements for system/component interfaces, arrangement and layout, which are not directly used for producing an item. Examples include: piping and instrument diagrams, layout drawings, general arrangement drawings, and electrical diagrams. A drawing request system is used to define the scope and purpose for the drawing, the technical requirements to be incorporated and any special features or notes to be included. The) reviews the design drawing for technical content and agreement with calculations, analyses, or other applicable design specification requirements. Additionally, a qualified individual or group is assigned to verify the contents of the drawing (see III.3.7, Design Verification).

III.3.6 Other Design Documents

The CO is responsible for preparation of other design documents needed to define or describe engineering requirements. These documents typically include items such as: design bases or design data information; system descriptions; interface requirements; test requirements; guidelines for startup and operation; guidelines for installation; engineering studies; and software verification plans and results. A qualified individual or group is assigned to verify the design document (see III.3.7, Design Verification). The cover sheet or revision page of the document includes provisions for unique identification and approvals by the author and verifier(s).

III.3.7 Design Verification

Design output is reviewed to verify its adequacy. This verification provides assurance that the output meets the specified inputs and is correct and complete.

With the approval of a supervisor's management,

Verification activities are performed by an individual or group other than those who performed the original work. The verification may be performed by the originator's supervisor provided the supervisor is the only individual in the CO competent to perform the verification or provided:

address the

- o the supervisor did not specify the design approach, *and*, and ~~the~~ did not rule out certain design considerations, *and*
- o the supervisor did not establish the design input.

Audits by NQS 1 cover the frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.

The CO determines the particular design verification method(s) to be used and designates the individual or group responsible for the verification efforts. The acceptable verification methods include design reviews, alternate calculations, and qualification testing and are defined as follows:

- o Design Reviews - independent review to assure that the information is correct and satisfactory.
- o Alternate Calculations - preparation of calculations or analyses using alternate methods to verify by comparison the correctness of the original work.
- o Qualification Testing - suitable testing of a model, prototype or initial production unit.

Qualification testing (as apposed to acceptance testing) is performed to test requirements established by the CO. The testing requirements include test conditions that simulate the most adverse design conditions (operating modes and environment) for the specific design feature(s) being verified. Test results are documented by the testing organization and evaluated by the CO to assure that test

Design Verification procedures address responsibilities of verifiers, items to be verified and documentation required.

Q.15

requirements have been met. When tests are being performed on models or mockups, scaling laws are established and verified and results are subject to error analysis when applicable prior to use in final design work.

Results of the verification are documented, ~~including~~ ^{including} identification of the verifier(s). Design verification is completed prior to relying upon the component, system, part or structure to perform its safety-related function.

III.3.8 Revision Control

Design document revisions are subject to the same review, approval and distribution controls as those applied to the original work. Revision level notation is used to assure that obsolete or superseded documents are not used inadvertently. Quality assurance procedures include requirements for evaluation of reported changes resulting from items such as:

- o qualification, preoperational, or operational test problems,
- o interference problems during construction,
- o disposition of nonconformances,
- o revised inputs (i.e., changes in regulatory or customer requirements), and
- o operational experience.

Where changes to previously verified work have been made, verification is repeated by the organization currently responsible for the work or by an equally qualified organization having access to the pertinent information.

III.3.9 Interface Control

Quality assurance procedures contain the organizational structure within which the program is implemented and delineate the authority and responsibility of the CO's involved. The organizational interfaces among contributing CO's, both internal and external to NPS, are controlled in accordance with these procedures.

Three procedures control the flow of design information by requiring the formal release of outputs involving interface information to other functional groups. This is accomplished within NPS by documented correspondence or standard document distribution forms and external to NPS by letters or approved procurement documents. The transmittal identifies the verification status of the information or document and, where necessary, identifies incomplete items which require further verification. Where it is necessary to transmit design information orally or by other informal means, follow-up by a controlled document is provided. Interface communications are traceable from a request through a related response to assure completeness and accuracy.

III.4 PROCUREMENT DOCUMENT CONTROL

Controlled procedures are used for the preparation, review and approval of procurement documents. Groups that prepare, review and approve procurement documents are identified in the procedures. *These groups include design groups (CO's per Section IV.3), procurement groups, and NPS.* Procurement documents include (either directly or by reference) the following requirements, as applicable:

Q.20

- o regulatory, ASME Code and industry standards;
- o tests and inspections, including acceptance criteria;
- o quality assurance program elements;
- o quality assurance records retention times and disposition;
- o reporting, approving and dispositioning nonconformances;
- o rights of access by NPS and/or its representative(s);
- o documentation submittal, review and approval;
- o extension of requirements to sub-suppliers;
- o technical/design (including drawings and specifications);
- o administrative; and
- o special processing.

B

It is the responsibility of the NPX organization that prepares the procurement document to assure that all required elements are addressed. Procurement documents are reviewed and approved by personnel trained in QA procedures prior to issue. This approval is also applicable to supplements issued to change the requirements of the original procurement.

The procurement process for commercial-grade⁽¹⁾ items and services uses the same review and approval cycle. These are bought to commercial standards where standards are available. Commercial items that become part of a system may be tested as part of the completed system. Procurement documents for standard commercial or previously approved items including spare or replacement parts essential to the safety functions of structures, systems, and components, are reviewed and approved by personnel trained in QA procedures.

(1) Controls limited to those items and services to be subsequently dedicated by NPX as "basic components".

B

III.5 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Quality affecting activities such as engineering, manufacturing, inspection, testing, certification, handling, storage, shipping, etc., are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. Quality assurance procedures require that these documents include or reference quantitative or qualitative acceptance criteria for determining that the activity has been satisfactorily accomplished.

The following is a summary of the types of instructions, procedures, and drawings used to control quality affecting activities.

QA Manuals, Procedures and Instructions - documents containing the systems and procedures that specify and describe the activities performed within NP² to provide adequate confidence that an item or service provided meets applicable requirements.

Q.6
typical list of QA procedures is given in Table III-4

Procurement Documents - documents that specify requirements for purchase of an item or service including purchase requisitions, drawings, process or material specifications, procedures or instructions. ⁴ III-4

Process Control Documents - documents that are used to control operations on items. These operations include: forming, machining, assembling, welding, brazing, heat treatment, examination, inspection, testing, plating, etc.. These documents include:

o Process Sheets/Travelers/Work Orders - contain steps and the sequencing of operations performed to produce or install an item.

- o Manufacturing Drawings - contain or reference item form and fit requirements, such as, size, shape, materials, joining, finishing, torquing, etc., for directly producing an item and include specific acceptance criteria for these characteristics. Examples include assembly drawings and detail drawings.

- o Process Instructions/Procedures - contain details on methodology, parameters, and acceptance criteria for operations performed in manufacturing, repair, installation, inspection, testing, warehousing, dedication, etc.. Typically, these documents are used to control operations such as nondestructive examination, inspection, cleaning, packaging, preservation, shipping, handling, welding, brazing, heat treatment, and similar special processes.

III.6 DOCUMENT CONTROL

Quality assurance procedures are used to assure current and appropriate documents are used. These procedures control issuance of instructions, procedures, and drawings that specify quality requirements or that prescribe activities affecting quality. The procedures specify how documents are reviewed for adequacy, approved for release, and distributed to and used at the location where the prescribed activity is performed.

These procedures address items such as:

- o identification of organizations responsible for preparing, reviewing, approving, issuing and revising documents. This includes design documents, Safety Analysis Reports, nonconformance reports, as-built documents, and those documents identified in Section III. 5;

- o use of distribution lists or equivalent to assure that the proper personnel or organizations are provided the required documents to perform the work;
- o document identification to assure that the proper document is used in performing a particular activity. The identification includes the document number or any other relevant information that identify the document to be used;
- o ascertaining that proper documents are accessible and are being used. This is accomplished by use of document lists and/or files showing the latest applicable revision or use of receipt control systems. This assures that the latest applicable documents have been received and obsolete revisions recalled or discarded, where appropriate.

Changes to documents are reviewed, approved, and released by the organizations responsible for the work unless other organizations are specifically designated. In all cases, the reviewing organization(s) has access to pertinent information or background data upon which to base approval.

III.7 CONTROL OF PURCHASED ITEMS AND SERVICES

Items and services are procured from approved suppliers. QA procedures specify requirements for supplier evaluation and selection, control of supplier generated documents, acceptance of the item or service (by documentation review, source surveillance, source and/or receiving inspection), control of nonconforming conditions, supplier performance evaluations (assessments and audits), and qualification of NPS audit, inspection and surveillance personnel.

B

When specified in procurement documents, NPX performs surveillance of suppliers during fabrication, inspection, testing, and release of items and services. Quality procedures provide guidance for surveillance activities. Where no established quality standards exist for a specific supplier, the specific technical requirements of the procurement documents are used as the basis for surveillance. The degree of surveillance varies with the degree of importance of equipment, supplier performance, and complexity of items. The degree of surveillance is determined by the organization that prepared the order and by NQS. This surveillance is performed using instructions which define the operation or process to be witnessed and the verifications to be made.

The procurement of spare or replacements parts and components are governed by customer order requirements.

For commercial-grade items which are supplied as safety-related but where specific QA control cannot be imposed in a practical-manner, specific provisions are made during receiving inspection or source surveillance to verify that requirements of the procurement document have been met.

Initial supplier approval is via survey or evaluation that is conducted by NQS. The purpose of these are to verify that the new supplier is capable of complying with the quality requirements in the procurement documents. The results are documented and any identified deficiencies are resolved prior to starting work.

Supplier approval is maintained by annual evaluations and periodic audits. The annual evaluations take into consideration items such as supplier furnished documentation; results of prior surveillances, inspections, and audits; and item or service operating performance.

~~The periodic audits address the applicable contents of 10CFR50 Appendix B.~~

Q.5 - Inset 1

These audits are based on the guidance in Regulatory Guide 1.28 (Rev 3) with the classifications given in Table III-3.

Insert 1

The periodic audits are normally performed on a triennial basis and are consistent with the guidance in Regulatory Guide 1.28 (Rev 3). ~~The scope of such audits is~~

→ The scope and frequency of audits depends on many factors, such as those given in Table III-3. The audits address the applicable criteria of 10 CFR 50 Appendix B.

Suppliers that have received ASME approval are approved on the basis of the ASME approval.

For items shipped to a NPS^B manufacturing or warehouse facility, receiving and/or source surveillance procedures are used to assure that the item and specified documentation comply with the procurement document requirements. Measures are established to assure that items accepted and released are identified as to their inspection status in order to prevent the use or installation of non-accepted items and provide for the entry only of accepted items into the warehouse. The status is identified on the item or on documentation traceable to the item.

For items procured by NPS and shipped to a nuclear power plant site, NQS issues a certification which indicates acceptance of the item. The certification includes specific information identifying the item and the applicable procurement documents, and certifies that the item meets all applicable procurement requirements, including documentation requirements. The certification includes identification of any NPS approved deviations from the procurement requirements and is approved by authorized personnel. Procedures identify the actions necessary to initiate, authorize, issue, distribute, and revise certifications. These procedures include provisions for review and acceptance of supplier furnished documentation (e.g. certificates of conformance, certified material test reports, non-destructive examination reports) and for identifying and following-up contingent conditions that require additional action after delivery to the power plant site. A contingent condition is any condition prohibiting the actual use of material or equipment on-site for its specified purpose. Such items may be shipped to the site to permit partial testing or preparation for use to proceed, but actual use as intended will not be permitted until the contingent condition is resolved.

Contingent conditions are monitored and their close-out is documented.

The measures established for item acceptance and supplier auditing provide the means for evaluating the supplier's certificates of conformance to ensure that they are valid.

III. 8 IDENTIFICATION AND CONTROL OF ITEMS

Identification requirements are controlled by procedures and are specified in the procurement and process control documents for quality related products and services.

Item identification may be by heat number, part number, equipment or service records or other appropriate means using a method which will not adversely affect the fit, function or quality of the item supplied. Identification and control of items (including consumables), is the responsibility of the organization responsible for the item.

Identification of items is traceable to documents such as design documents, procurement documents, mill test reports or inspection records. Identification of items is verified and documented prior to release of the item for further use.

III.9 CONTROL OF PROCESSES

Special processes include those inspection or manufacturing activities that satisfy the following:

- o The results of which are highly dependent on the control of the process and/or skill of the operator; and
- o The quality of the activity can neither be determined by inspection, nor it is considered advantageous to perform destructive examinations or tests.

Special processes include activities such as welding, heat treating, non-destructive examination, and cleaning.

These type of processes are controlled by documents such as process sheet travelers and special processing procedures which are generated in accordance with QA procedures. These documents address items such as:

- o process procedure, personnel and equipment qualification requirements
- o process prerequisites
- o acceptance criteria
- o environmental conditions

Process procedures and/or control documents are approved by NQS. Equipment and personnel associated with special processes are qualified in accordance with applicable codes, standards, QA procedures and/or contract requirements. Qualification records are reviewed by NQS, and are maintained and kept current by responsible organizations.

III.10 INSPECTION

Inspections are performed in accordance with instructions procedures and/or control documents which are reviewed by NQS and approved by the responsible organization. These instructions/procedures provide criteria for determining accuracy requirements of inspection equipment, how and when inspections are performed; and, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

Inspections are performed by personnel other than those who performed or directly supervised the activity being inspected and who do not report directly to the immediate supervisors who are responsible for the activity being inspected. The personnel performing inspections are trained, qualified and certified in accordance with procedures. The records of qualifications and certifications of inspectors are kept current by the responsible organization.

Instructions and procedures include, as appropriate, identification of characteristics and activities to be inspected, a description of the method of inspection, identification of the individuals or groups responsible for performing the inspection, acceptance and/or rejection criteria, identification of required procedures, drawings and specifications including revisions, special inspection equipment and accuracy requirements, recording of the results of the inspection, and the inspector or data recorder.

The organization or individual performing the inspection is normally responsible for evaluating the results and determining the acceptability of the inspected item.

III. 11 TEST CONTROL

Acceptance testing (such as hydrostatic, pre-operational, etc.), and destructive examination testing (such as, metallurgical, etc.) is performed using controlled procedures. The test procedures address the requirements as specified in test requests, specifications and/or codes and standards. Test procedures are submitted for review and approval prior to testing and ~~the~~ testing is witnessed by assigned and qualified personnel. Test procedures contain the following, as applicable:

- o Provisions for assuring that prerequisites for the test have been met;
- o Required instrumentation and accuracies;

9.21

- o Instructions for conducting the test and for acquiring and recording the data necessary for evaluation;
- o Witnessing of the testing by qualified personnel.
- o Required environmental conditions;
- o Acceptance and/or rejection criteria required to evaluate the test;
- o Recording the performance of the test;
- o Use and identification of calibrated equipment;
- o Code and contract requirements;
- o Test personnel qualification;
- o Method of recording test results;
- o Verification that the test procedures have been reviewed and approved.

Test procedures and/or controlling documents are approved by NQS.

Test results, as a minimum, identify the item tested, date of the test, the procedure and revision level, the tester or data recorder, identification number of the equipment, test conditions, time, type of observation, results and acceptability, individual evaluating test results, and noted nonconformances. The test results are evaluated and documented as specified in the test procedure.

III.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Gages, instruments, and other inspection, measuring and testing equipment and devices used in activities affecting quality are required to be of the proper range, type and accuracy in order to verify conformance to established requirements. Procedures contain the detailed requirements for the calibration (technique and frequency) and control, and describe organizational responsibilities for establishing, implementing, and assuring effectiveness of the calibration program.

Standards used for calibration have known valid relationships to recognized national standards. These standards have an accuracy adequate to verify that measuring and test equipment being calibrated are within the tolerance requirements for which they are being used. When possible and practical, measuring and test equipment are calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated. Greater uncertainty may be acceptable when limited by "state-of-the-art". Where national standards do not exist for reference standards, the basis of the calibration is documented.

The method and interval of calibration for each item is defined in procedures. These are based on the type of equipment, stability characteristics, required accuracy and other conditions affecting measurement control. Each item is identified to permit traceability to the calibration test data. This identification may be by either label, tag, or color coding, or other means as provided for by procedure. This identification also indicates the date of the next required calibration.

When an instrument is found to be out of calibration, an investigation to determine the validity of previous inspections performed with the instrument and the acceptability of items inspected or tested since the last calibration is conducted. Inspections or tests are repeated on affected items as necessary.

NQS audits organizational units responsible for control of measuring and test equipment to assure compliance with applicable procedures.

HANDLING, STORAGE AND SHIPPING

Q. 23

Procedures are used to control handling, storage and shipping of items to ensure the maintenance of quality from source through delivery to the customer. These procedures may be in various formats such as process sheets, travelers, work orders, drawings, shipping instructions, process specifications, and instructions. The procedures specify or describe cleaning, handling, storage, packaging, shipping and preservation methods to preclude item damage, loss, or deterioration by environmental conditions. ~~When required,~~ These activities are accomplished by ~~appropriately~~ trained personnel.

The application of quality considerations to handling, storage, and shipping is based upon considerations such as the level of sensitivity of the item to environmental conditions, its resistance to physical forces, and its relative replaceability. When required for particular items, special equipment (such as containers, shock absorbers, accelerometers and special tools or handling devices) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) are specified, provided, and verified when required. These special tools or handling devices are inspected, tested, and controlled in accordance with procedures. Only experienced or trained personnel are used to work with these devices.

Handling, storage, and shipping procedures and/or controlling documents are approved by NQS. Equipment and personnel qualification records are audited by NQS.

III.14 INSPECTION, TEST AND OPERATING STATUS

Documents, such as travelers, process sheets, and work orders are used for identifying required inspections, tests, examinations, and processing status of items. The documents indicate the status of the operation(s) being performed, the required signatures (or other similar means), and the date indicating when a given operation, test, inspection, or examination was completed. Quality assurance procedures control the use of travelers, process sheets and work orders including methods for making sequence changes and identification of nonconforming items. ~~X~~ These documents accompany items throughout processing.

Q.24

Status indicators such as tags, forms, labels, etc. may also be used to identify status of items. These indicators indicate the current status such as: a) acceptability or approval of the item, b) a hold situation where a nonconformance exists, and c) rejection where an item is unacceptable for the use that it was intended. When such indicators are used, only NQS is authorized to affix and remove inspection status indicators. This assures control of any possible inadvertent bypassing of required inspections, tests, and operations. NQS may waive certain check points, etc. at its discretion.

III.15 CONTROL OF NONCONFORMING ITEMS

A nonconforming item is defined as that which does not meet specified requirements.

No sequence change is allowed if it compromises the safety, function of the item. Any change to travelers, etc are subject to the same controls as the original.

Procedures are used to control the identification, documentation, segregation (when practical), review and disposition of nonconforming items (including computer codes), and include notification to affected organizations if disposition is other than scrap. These procedures identify individuals or groups, including NQS, authorized to disposition and approve nonconformances, verification requirements, and describe the segregation and/or control of nonconforming items to prevent inadvertent use.

Q.2.6 →

Q.27 →

Nonconformances are resolved prior to shipment of an item.

Documentation contains the identification of the nonconforming items, a description of the nonconformance and its disposition including re-inspection requirements, and documented approval of this disposition. When nonconforming items are repaired or otherwise made suitable for their intended use, they are inspected or tested in accordance with the original inspection and test requirements or acceptable alternatives.

Individuals dispositioning nonconformances are selected based on experience and competence related to the item being evaluated, and an understanding of the requirements. These individuals have access to necessary background information.

Q.26

Nonconformances are periodically evaluated by NQS for quality trends. Findings considered significant are reported to management for review and assessment.

III.16

CORRECTIVE ACTION

Conditions adverse to quality, such as nonconformances, failures, malfunctions, deficiencies, deviations, or defective materials and equipment, are identified, documented and reported to appropriate levels of management. These conditions may be identified by suppliers, surveillance, inspection or audit activities at suppliers, internal audits/inspections, customer audits, agency audits/inspections or by independent investigations conducted by NQS.

Q. 29

QA procedures specify how conditions adverse to quality are documented and reported to cognizant parties, including appropriate levels of management, for action and for assuring that corrective action is suitably identified, accepted and implemented *in a timely manner*

Q. 28

These procedures require identification of cause (as deemed necessary), corrective action to prevent recurrence, verification of implementation; and follow-up and close-out of internal audit, and supplier audit/surveillance audit findings. Follow-up action is taken by NQS to verify corrective action. *NQS concurrence with the action is documented.*

Trend analyses are periodically performed on surveillance and audit activities. Results of such analyses are reported to appropriate levels of management.

III.17 QUALITY ASSURANCE RECORDS

Quality Assurance records are preplanned, generated, stored, and maintained so as to provide objective evidence that quality assurance requirements have been met. The records program is planned for a standard system but may be expanded or specifically modified in accordance with individual contract requirements. The system includes provisions for records such as: design, manufacturing, procurement, installation, inspection, and qualification.

NQS is responsible for the maintenance of quality record files. Files are indexed to facilitate storage and retrieval. The records are reviewed for completeness, per procedure requirements, prior to retention and are available for review by customers, for those records applicable to that customer's contract(s). ~~Quality records are maintained in accordance with contract requirements.~~

Q. 30

Unless otherwise authorized, suppliers are required to submit a copy of designated quality records to NPS for transmittal to the customer(s) before the procurement order is concluded. Prior to shipment of a purchased item, the quality records compiled by the supplier are reviewed for completeness and acceptability. The results of these reviews are recorded. Test results are reviewed and evaluated for adequacy, as necessary, during surveillance visits to supplier's facilities.

III.18 AUDITS

Q.31

Internal compliance audits are performed ^{by NQS} on applicable NPX^B organization units at least once per calendar year. External audits of suppliers are performed ^{by NQS} at a frequency commensurate with the suppliers scope of supply and status and importance of the suppliers' activity.

An annual audit schedule is established indicating the frequency and organization(s) to be audited. The audits include review of activities affecting quality. Since all elements of the QA Program do not apply to all activities, only the applicable elements are monitored during audits. Audit frequencies and areas to be audited may be modified based on previous audit findings and conditions such as organization changes, major procedure revisions, deficiencies and nonconformances, and verification of corrective action. The audit schedule may be revised if necessary.

Q.31
All audits performed by NQS are led by a lead auditor

NQS personnel assigned to perform audits are qualified and certified prior to their performing audits. A Qualification is based on training, education, experience, and successful completion of examination. Auditors have no direct responsibility in the areas audited. ³² NQS may employ ~~qualified~~ qualified auditors from other organizations to perform audits and/or NQS may use the results of supplier audits performed by other organizations. ^{Revision 5:} However, NQS retains responsibility for the audits in such cases.

An audit plan identifies the area to be audited, audit scope, requirements, audit personnel, organizations to be notified, applicable documents, schedule, and procedures or checklists to be used. The organization(s) responsible for the activity or area being audited is notified in advance of scheduled audits.

An audit report is issued and signed by the Lead Auditor and includes the following information, as appropriate:

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

The audit report is transmitted to the audited organization(s)' cognizant management.

If deficiencies are found during the audit the following actions are performed:

- o The auditor(s) documents the deficiencies in the audit report with a required response date.
- o The audited organization documents corrective action and returns the response to the auditor within the required response time.

o Auditors assure that deficiencies are answered in the allotted time and that adequate corrective action has been implemented or scheduled; verify the adequacy and completeness of corrective action; close out the deficiency when the reported condition has been resolved; and assure that relevant audit documents are retained as records including the plan, report and corrective action completion.

the applicable business unit

o Incomplete corrective action responses are brought to the attention of management for resolution and if necessary to the Vice President, Nuclear Quality Systems. Follow-up action is taken until corrective action is completed.

*or President,
Nuclear Power
Businesses.*

Q. 34

Nuclear Quality Systems

~~Executive Vice President, Nuclear Power Systems~~

Businesses

Vice President, Nuclear Quality Systems

Director, Quality Operations

Manager, Quality Programs

Manager, Training and Administration

Manager, Quality Assurance (NFM, Windsor)

Manager, Quality Assurance (NFM, Hematite)

Manager, Quality Assurance (Newington)

Manager, Quality Assurance (E-M/C-E Controls)

Figure II-1

Nuclear Power ~~Systems~~ ^{Businesses}

~~Senior Vice President, Nuclear Power Systems~~ ^{Businesses}

<u>Vice President, Nuclear Quality Systems</u>
<u>Vice President, Nuclear Systems (1)</u>
<u>Vice President, Nuclear Fuel (2)</u>
<u>Vice President, Nuclear Services</u>
<u>Controller</u>

- (1) includes C-E Controls/Electro-Mechanics and C-E Newington facilities.
- (2) includes Nuclear Fuels Manufacturing facilities.

Figure II-2

Table III-1

Responsibilities of Nuclear Quality Systems

Interface with all NP^BA organizations in the solution of day to day quality problems.

Provide for NP^BA the necessary direction for quality through approval and distribution of quality policies, manuals and procedures.

Provide an assessment of the scope, status, implementation and adequacy of the NPS QA program.

Conduct the QA internal audit program.

Provide interpretations for QA Standards.

Perform quality data collection and trend analysis.

Maintain NQS personnel training and qualification records.

Perform supplier evaluations.

Perform systems audits at supplier facilities.

Review resolution of deviations / *nonconforming conditions*

Review procurement orders.

Establish and execute witness and hold points (surveillance and/or inspection).

Monitor conformance to procurement requirements.

Table III-2

Responsibilities of Nuclear Power ~~Systems~~ Business Units *es' units*

Nuclear Systems:

1. Design, procurement and fabrication of Nuclear Steam Supply System (NSSS) components, systems and structures for NSSS contracts.
2. NSSS Licensing
3. Design and fabrication of instrumentation and control systems.

Nuclear Services:

1. Engineering, examination installation, repair and maintenance services to operating nuclear power plants.
2. Nuclear power plant spare parts.
3. Design, procurement, and fabrication of components, systems and structures to operating nuclear power plants.

Nuclear Fuel:

1. Design, procurement and fabrication of nuclear fuel (both initial and reload cores) and related products and services.

Controller:

1. Administrative management duties, such as accounting.

Clarifications

Table III-3

~~Alternatives~~ to NQA-1 and/or Regulatory Guide 1.28 (Rev. 03)

Section

Regulatory Guide 1.28 paragraph C.1

Classification
~~Alternative~~

~~Not applicable to personnel who do not do inspection, testing or nondestructive examination (NDE)~~

Q.5

Training procedures as used to ensure that

may be used

~~The existing program~~
Individuals are qualified in a manner commensurate with the requirements of their job description, operating procedures ensure that activities are accomplished at the correct inspection/organization level; this ~~is~~ in lieu of personnel level ratings.

Regulatory Guide 1.28
Paragraph C.3.2.1

The frequency of auditing a supplier is based on:

- i) if active work is in progress under a purchase order,
- ii) results of quality trend evaluations,
- iii) quality classification of item or service,
- iv) processes being employed,
- v) item or service complexity or uniqueness,
- vi) number of planned surveillances,
- vii) number of current orders.

NQA-1 Supplement 175-1
paragraph 2.3

Record validation *authentication* is controlled by procedure, ~~in lieu of stamping, initialing or signing.~~

~~paragraph 2.6~~

~~Record retention period is as~~
~~controlled by procedure in lieu of stamping.~~

Q.5

paragraph 4.0

Applies only to records transferred to permanent storage (all other records are classified as "working" files).

Table III-4

Typical List of Quality Assurance Procedures.

- Preparation and Control of Quality Plans.....
- Stop Work Order.....
- Indoctrination & Training of Personnel.....
- Certification Program for Inspection, Examination and Testing Personnel.....
- Certification Program for Audit Personnel.....
- Certification Program for Nondestructive Examination Personnel.....
- Qualification of Registered Professional Engineers for ASME Code Certifying Activities.....
- Establishment of Equipment Safety & Quality Classifications.....
- ~~Design Process Description~~.....
- Design Input.....
- Design Analysis.....
- Design Interface Control.....
- Design Verification.....
- Preparation, Control & Retention of Drawings.....
- Design Specifications.....
- Design Change, Field Change, Corrective Action.....
- ~~Other Design Documents~~.....
- Safety Analysis Reports (SAR) and SAR Changes.....
- ~~ASME Code~~ Design Reports.....
- ~~Open~~
Control of Supplier Technical Change Requests (TCRS).....

TABLE OF CONTENTS

Table III Continued

<u>QAP</u>	<u>TITLE</u>	<u>REVISION</u>	<u>EFFECTIVE DATE</u>
4.1	Preparation, Review & Approval of Purchase Orders.....	0	9/1/89
4.2	Dedication of Commercial Grade Items.....	(LATER)	
5.1	QA Review of Client Contracts.....	0	9/1/89
5.2	Preparation and Control of Quality Assurance Procedures.....	0	9/1/89
5.3	Preparation & Control of Operating Procedures.....	0	9/1/89
5.4	Preparation & Control of Technical Operating Procedures.....	0	9/1/89
5.5	Preparation & Control of QA Specifications.....	0	9/1/89
5.6	Pre-Construction Preparation Guidelines.....	0	9/1/89
6.1	Control of Quality Assurance Manuals.....	0	9/1/89
6.2	Preparation & Control of Contract Operating Procedures.....	0	9/1/89
6.3	Preparation & Control of Welding Procedure Specifications.....	0	9/1/89
7.1	Supplier Evaluation & Selection.....	0	9/1/89
7.2	Approved Suppliers List.....	0	9/1/89
7.3	Control of Supplier Document Submittals & Request for Approval or Review (RAR) Process.....	0	9/1/89
7.4	Control of Supplier Nonconformances & Deviation from Contract Requirements (DCR) Process.....	0	9/1/89
7.5	Open		
7.6	Source Surveillance.....	0	9/1/89
8.1	Certification of Satisfactory Completion of Work...	0	9/1/89
10.1	Inspection.....	0	9/1/89
12.1	Control of Measuring & Test Equipment.....	(LATER)	

TABLE OF CONTENTS

*Table III -
 Continued*

<u>QAP</u>	<u>TITLE</u>	<u>REVISION</u>	<u>EFFECTIVE DATE</u>
15.1	Control of Nonconforming Items.....	(LATER)	
16.1	Corrective Action Report.....	0	9/1/89
16.2	Quality Trend Analysis.....	0	9/1/89
17.1	Records Retention.....	0	9/1/89
17.2	Owner's Records Package(Purchased Items).....	0	9/1/89
17.3	Owner's Records Package (Field Activities).....	0	9/1/89
17.4	Control of N Symbol Stamping.....	0	9/1/89
18.1	Internal QA Audit.....	0	9/1/89
18.2	Supplier Audits.....	0	9/1/89

LIST OF EXHIBITS

<u>EXHIBIT NO.</u>	<u>TITLE</u>	<u>REVISION</u>	<u>EFFECTIVE DATE</u>
2.1-1	Record of Initial Indoctrination and Training	0	9/1/89
2.1-2	Individual QA Program/Procedure Training Record	0	9/1/89
2.1-3	Group Training Record	0	9/1/89
2.2-1	Certification Record (Test and Inspection)	0	9/1/89
2.2-2	Eye Examination Record (Test and Inspection)	0	9/1/89
2.3-1	Record of Auditor Qualification	0	9/1/89
2.3-2	Record of Lead Auditor Qualification	0	9/1/89
2.4-1	Eye Examination Record (NDE)	0	9/1/89
2.4-2	Certification Record (NDE)	0	9/1/89