QUALITY ASSURANCE PROGRAM DESCRIPTION

CENPD-210A

REVISION 7A

ASEA BROWN BOVERI
COMBUSTION ENGINEERING NUCLEAR SYSTEMS
COMBUSTION ENGINEERING NUCLEAR FUEL

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

June 1, 1992

Charles B. Brinkman, Acting Director
Nuclear Systems Licensing
ABB Combustion Engineering Nuclear Power
1000 Prospect Hill Road
Post Office Box 500
Windsor, Connecticut 06095-0500

Dear Mr. Brinkman:

SUBJECT: ACCEPTABILITY OF REVISION 7 OF CENPD-210

Your letter of March 12, 1992, enclosed Revision 7 of the description of ABB Combustion Engineering Nuclear Power's quality assurance (QA) program, CENPD-210. Revision 7 updated the QA program description to reflect organizational changes since Revision 6. Further clarification was given in your letter of April 30, 1992.

We have completed our review of Revision 7 as submitted with your two letters. We compared Revision 7 against the previously accepted Revision 6.

Based on our review, we find the revised QA program description acceptable and in compliance with the criteria of Appendix B to 10 CFR Part 50.

Thank you for keeping us informed of changes to CENPD-210. Please place a copy of this acceptance letter in the report, identify the report as Revision 7A of CENPD-210, and forward a copy to the NRC per 10 CFR 50.4. Any questions on this subject should be addressed to the QA reviewer, Jack Spraul, on (301) 504-1023.

Gary G. Zech, Chief
Performance and Quality Evaluation Branch
Division of Licensee Performance
and Quality Evaluation

ABSTRACT

This report describes the quality assurance program employed by ABB Combustion Engineering Nuclear Systems and ABB Combustion Engineering Nuclear Fuel 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

Table of Contents (Continued)

Figures

Tables

I. INTRODUCTION

I.1 Purpose

This report describes the quality assurance program employed by ABB Combustion Engineering Nuclear Systems (NS) and ABB Combustion Engineering Nuclear Fuel (NF) for the supply of items and services subject to the requirements of 10CFR50, Appendix B. NS and NF are business units of ABB Combustion Engineering Nuclear Power.

I.2 Scope

This report includes a description of controls employed at the facilities noted below. Section II presents the commitment to quality and describes the 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 facilities unless otherwise indicated.

The facilities and the activities involved at each facility include:

Facility	Activities
Headquarters, Windsor, CT (with offices also in Chattanooga, TN)	Engineering services, nuclear fuel design and NSSS design, procurement, testing, inspection, repair and installation.

Nuclear Fuel Manufacturing, Windsor, CT and Hematite, MO	Manufacture of nuclear fuel pellets, fuel assemblies and control element assemblies and associated activities
ABB Electro-Mechanics, New Britain, CT	Design and manufacture of instrumentation & control systems and associated activities
ABB Newington Operations, 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.

Responsibility for implementimg the above is assigned to ABB Combustion Engineering Nuclear Systems.

II. QUALITY POLICY

II.1 Policy Statement

The Presidents of ABB Combustion Engineering Nuclear Systems and ABB Combustion Engineering Nuclear Fuel have authorized the following statement concerning quality assurance policy:

"A primary objective of ABB Combustion Engineering Nuclear Systems and ABB Combustion Engineering Nuclear Fuel is to deliver to our clients defect free, competitive products and services on time that fully comply with contract requirements."

Quality Assurance management within NS and NF has the responsibility for defining their unit's quality assurance program and shall bring to the attention of the President any quality problem that cannot be resolved within the normal execution of this responsibility.

II.2 Quality Assurance Organization

The Nuclear Systems and Nuclear Fuel organizations are shown in Figures II-1 and II-2.

Regardless of the specific organizational structure and organizational titles, Quality Assurance (QA) management is responsible to assure that the QA policy, goals and objectives are transmitted through levels of management. This is accomplished by distribution of Quality Assurance Manuals which contain QA policy statements.

It remains the responsibility of functional line management to assure that the above policy, goals and objectives are met.

Responsibility for nuclear quality assurance rests with each unit's President and is delegated to QA management who may further delegate specific activities to their personnel. Such delegation includes authority to stop work for noncompliance to requirements. Stop work orders are dispositioned by QA and may be originated at any organization level and unit 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 quality assurance personnel. QA is independent of other organizations as shown in Figures II-1 and II-2. QA interprets quality related industry standards for intent and guidance and is responsible for assuring that all quality assurance related procedures used comply with established QA requirements. Each unit participates in an inter-unit audit program to verify that each is implementing its quality assurance program as necessary for items/services provided to each other. When items/services are provided from one unit to another, management of the unit providing the item/service is responsible for the work.

III. QUALITY ASSURANCE CRITERIA

This section describes each of the eighteen (18) elements of the quality assurance program.

III. 1 Organization

ABB Combustion Engineering Nuclear Systems and ABB Combustion Engineering Nuclear Fuel have headquarters at Windsor, Connecticut. These units supply nuclear systems, nuclear fuel and related services.

Each project under contract is coordinated by a Project, Program, or Task Manager who is a member of either the Nuclear Systems 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 with the client and all other participating organizations.

Quality Assurance management has direct access to the President of their unit (see Figures II-1 and II-2). Responsibilities of QA are listed in Table III-1. These responsibilities are carried out through the QA staff and by coordination of all QA activities. Details of responsibilities and interfaces among QA 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.

QA functions as an independent communication channel between senior management and line management. This assures that senior management is

appraised of quality matters and that the QA staff receive and comply with directives from the President.

QA management meets regularly with the QA staff to discuss quality issues, schedule quality efforts, establish goals and identify areas for improvements. These meetings are normally held monthly but may be at shorter or longer internals depending on the significance of quality assurance activities and issues at that time. In addition, these meetings are supplemented by reports from the QA management staff to the respective President.

The detailed organizational structure of QA as well as the number of personnel in QA may change over time depending on quality needs as well as business needs. However, QA will not become involved in activities unrelated to QA that would prevent full attention to QA matters when necessary. QA personnel selection is based on knowledge of 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, QA 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 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-2.

In addition to the above, the applicable elements of ASME NQA-2, "Quality Assurance Requirements for Nuclear Facility Application" are applied to activities associated with the ABB Combustion Engineering Nuclear Power Standard Plant Design ("System 80+™ Standard Design" as described in CESSAR-DC). The application of NQA-2 requirements and/or those in ANSI N45.2 and its associated daughter standards for other than CESSAR-DC activities is dependent on client contract requirements.

III.2.2 Program Control

The requirements of this program are implemented at each facility through QA manuals and procedures applicable to the activities conducted at each facility. All such documents are reviewed, approved and controlled by QA 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 receives a monthly report from QA management covering major quality issues such as significant internal and client audit findings, industry quality-related developments and quality improvement needs. Quality issues and assessments are discussed during each President's staff meetings. An annual, independent assessment of the QA program is performed by personnel outside a business unit's QA organization. This assessment is documented and any corrective actions are identified and tracked.

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 facility are contained in QA procedures. QA 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 QA 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 (both internal and external) 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 QA 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. Typical sources include previously approved designs, those from engineering and product development efforts, contracts (e.g., 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/Analyses

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 to preclude uncontrolled 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 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, as applicable:

- functions and boundaries of the items covered,
- the design requirements including all required overpressure protection requirements,
- the environmental conditions including radiation,
- the safety classification of the items covered,
- material requirements including impact test requirements,
- 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 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 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. In exceptional circumstances verification may be performed by the originator's supervisor, provided: the supervisor is the only technically qualified individual in the CO; the need is individually documented and approved in advance by the supervisor's management; the supervisor did not specify the design approach, and did not rule out certain design considerations; the supervisor did not establish the design inputs used in the design.

Audits by QA cover the frequency and effectiveness of 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 review, alternate calculation, and qualification testing and are defined as follows:

- Design Review - independent critical review to assure that the information is correct and satisfactory.

- o Alternate Calculation - 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),
- 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) are controlled in accordance with these procedures.

These procedures control the flow of design information by requiring the formal release of outputs involving interface information to other functional groups. This is accomplished internally by documented correspondence or standard document distribution forms and externally 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 QA.

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 NS and NF 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 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 purchased 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.

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 to provide adequate confidence that an item or service provided meets applicable requirements. A typical list of QA procedures is given in Table III-3.

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[1] Controls limited to those items and services to be subsequently dedicated as "basic components".

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:

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

- 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.

- 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:

- 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;

- use of distribution lists or equivalent to assure that the proper personnel or organizations are provided the required documents to perform the work;

- 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;

- 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 or marking documents as obsolete. 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 audit, inspection and surveillance personnel.

When specified in procurement documents, surveillances are performed 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 QA. 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 client 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 critical characteristics are met.

Initial supplier approval is via survey or evaluation that is conducted by QA. The purpose of this is 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. In accordance with IE Information Notice 86-21, suppliers that have received ASME approval are considered "Approved Suppliers" on the basis of the ASME approval.

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 criteria of 10CFR50, App. B and are normally performed on a triennial basis. An alternative to the guidance in paragraph C.3.2.1 of Regulatory Guide 1.28 (Rev. 3) is given in Table III-2.

For items shipped to a NS/NF 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 allow entry of only accepted items into the warehouse. The status is identified on the item or on documentation traceable to the item.

For items procured and shipped to a nuclear power plant site, QA 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 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 conformances, 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 for its specified purpose. Such items may be shipped to the client to permit partial testing or preparation for use to proceed, but actual use as intended will not be permitted until the contingent conditon 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 supplier 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:

- The results of which are highly dependent on the control of the process and/or skill of the operator; and
- 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 sheets, travelers and special processing procedures which are generated in accordance with QA procedures. These documents address items such as:

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

Process procedures and/or control documents are approved by QA. 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 QA, 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 QA 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:

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

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

QA 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 client. 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 QA. Equipment and personnel qualification records are audited by QA.

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 QA is authorized to affix and remove inspection status indicators. This assures control of any possible inadvertent bypassing of required inspections, tests, and operations. QA 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

QA, 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 QA 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, client audits, agency audits/inspections or by independent investigations conducted by QA.

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 QA to verify corrective action. QA 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. QA is responsible for the maintenance of permanent 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 clients, for those records applicable to that client's contract. Unless otherwise authorized, suppliers are required to submit a copy of designated quality records for transmittal to the client(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 QA on applicable organization units at least once per calendar year. External audits of suppliers are performed by QA at a frequency commensurate with the supplier scope of supply and status and importance of the supplier 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.

QA personnel assigned to perform audits are qualified and certified prior to performing audits. All audits performed by QA 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. QA may employ qualified auditors from other organizations to perform audits and/or QA may use the results of supplier audits performed by other organizations. However, QA 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 cognizant management. If deficiencies are found during the audit the following actions are performed:

- o The auditor 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 President. Follow-up action is taken until corrective action is completed.

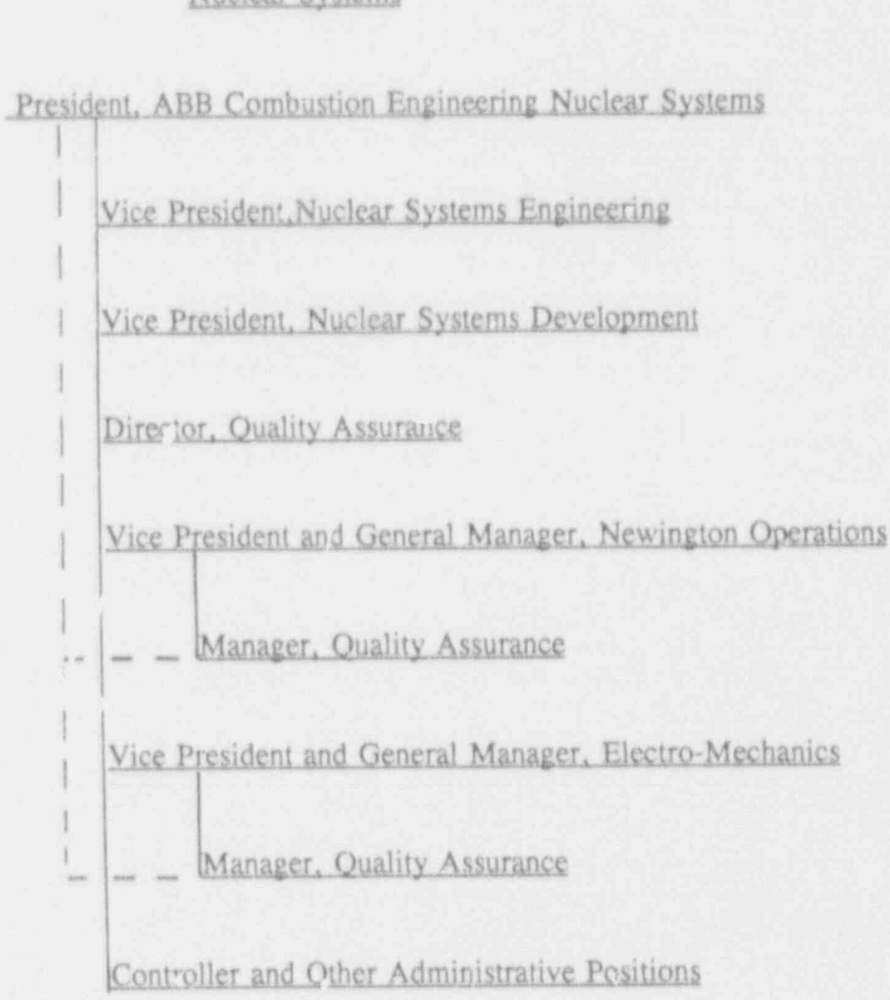
Nuclear Systems
President, ABB Combustion Engineering Nuclear Systems
Vice President, Nuclear Systems Engineering
Vice President, Nuclear Systems Development
Director, Quality Assurance
Vice President and General Manager, Newington Operations
Manager, Quality Assurance
Vice President and General Manager, Electro-Mechanics
Manager, Quality Assurance
Controller and Other Administrative Positions

Figure II-1

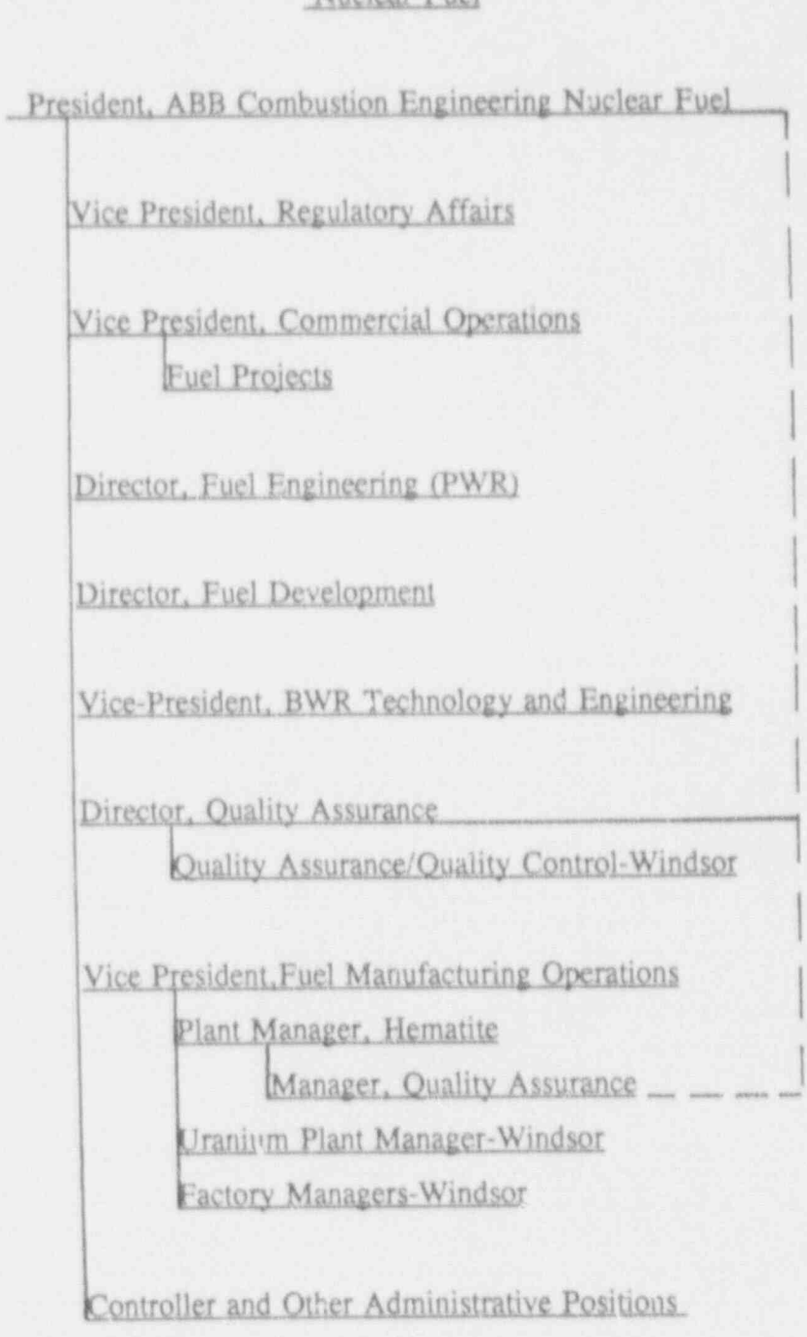
Nuclear Fuel
President, ABB Combustion Engineering Nuclear Fuel
Vice President, Regulatory Affairs
Vice President, Commercial Operations
Fuel Projects
Director, Fuel Engineering (PWR)
Director, Fuel Development
Vice-President, BWR Technology and Engineering
Director, Quality Assurance
Quality Assurance/Quality Control-Windsor
Vice President,Fuel Manufacturing Operations
Plant Manager, Hematite
Manager, Quality Assurance
Uranium Plant Manager-Windsor
Factory Managers-Windsor
Controller and Other Administrative Positions

Figure II-2

Table III-1

Responsibilities of Quality Assurance Organization

- Interface with all NS or NF organizations in the solution of day to day quality problems.
- Provide 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 QA program.
- Conduct the QA internal audit program.
- Provide interpretations for QA Standards.
- Interface with the U.S. Nuclear Regulatory Commission on quality policies, procedures and requirements.
- Perform quality data collection and trend analysis.
- Maintain QA personnel training and qualification records.
- Perform supplier evaluations.
- Perform 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

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

Regulatory Guide 1.28	
Paragraph C. 1 Clarification	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.
Paragraph C.3.2.1 Alternative	An audit of approved suppliers' quality assurance program is conducted on a triennial basis unless: i) there is no active work in progress (note: auditing will resume when work resumes); or ii) documentation reviews and surveillance and/or inspections and/or independent tests show acceptable quality assurance program implementation; or iii) the procurement is for ASME Code items from suppliers that hold valid ASME Certificates of Authorization or Quality Systems Certificates. In this case acceptable quality assurance program implementation will be verified by documentation review and one or more of the following depending upon procurement scope and complexity: a) audit b) surveillance c) inspection d) independent test.
NQA-1 Supplement 17S-1	
Paragraph 2.3 Clarification	Record validation/authentication is by identification in procedures and logging.
Paragraph 4.0 Clarification	Applies only to records transferred to permanent storage (all other records are classified as "working" files). "Working" files are controlled to assure adequate preservation and safe keeping while awaiting transfer to permanent storage, or the client, or expiration of retention requirements.

Table III-3

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
- Determination of Quality Class
- Design Input
- Design Analysis
- Design Interface Control
- Design Verification
- Preparation, Control & Retention of Drawings
- Specifications
- Design Change, Field Change, Corrective Action
- Safety Analysis Reports (SAR) and SAR Changes
- Design Reports
- Control of Supplier Technical Change Requests
- Preparation, Review & Approval of Purchase Orders
- Dedication of Commercial Grade Items
- Preparation & Control of Quality Assurance Procedures

Table III-3 (continued)

- 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 and Control of Field Work
- o Preparation & Control of Welding Procedure Specifications
- o Supplier Evaluation & Approval (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 Compliance Audits
- o Supplier Audits