

Babcock & Wilcox Nuclear Energy, Inc.

800 Main Street Lynchburg Virginia 24504



Quality Assurance Program for the Design
Certification of the B&W *mPower*TM Reactor

Topical Report

08-00000320-000

N-R0003



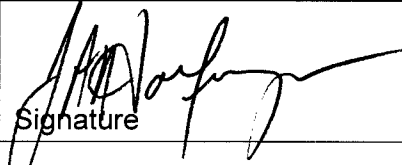

March 31, 2010

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Babcock & Wilcox Nuclear Energy, Inc.

Quality Assurance Program for the Design
 Certification of the B&W *mPower*™ Reactor
 Topical Report
 08-00000320-000
 N-R0003
 3/31/10

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This report contains 54 pages including the cover page.

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Revision History

Revision	Section(s) or Page(s)	Description of Change
000		Original Issue

Document No. 08-00000320-000	Title: Quality Assurance Program for the Design Certification of the B&W <i>mPower</i> ™ Reactor
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Abstract

This topical report describes the Babcock & Wilcox Nuclear Energy, Inc. quality assurance program for the design certification of the B&W *mPower*™ reactor. It has been prepared in accordance with the requirements of Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50), "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," ASME NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities (with Addenda)," and is consistent with the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants."

The topical report is divided into 18 sections conforming to the requirements noted in Appendix B to 10 CFR Part 50. Furthermore, the QAP includes sections on non-safety related quality controls and regulatory commitments. Policies, procedures, and instructions that implement the program assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP.

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Title:
Quality Assurance Program for the Design Certification of the
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Statement of Policy and Authority



babcock & wilcox nuclear energy

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March 31, 2010

STATEMENT OF POLICY AND AUTHORITY

Babcock & Wilcox Nuclear Energy (B&W NE) is totally committed to strict adherence to the Quality Assurance Program (QAP) as set forth in this topical report that meets the requirements of Appendix B to 10 CFR Part 50 and the applicable regulatory guides.

The Director of Quality Assurance is responsible for the preparation and approval of this QAP and its revisions. He is responsible for reviewing and assuring full compliance with this QAP and for updating it as required.

The Director of Quality Assurance and all other Department Managers have my full support in all aspects of this program to attain full compliance with the requirements. Each of the Department Managers of B&W NE is responsible for the implementation of this Quality Assurance Program in their respective areas. Personnel involved in design activities shall comply with the requirements of this QAP. They may delegate any or all work to properly qualified personnel but shall retain responsibility thereof.

The Director of Quality Assurance shall have the authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; to verify implementation of solutions; and to assure that further processing, delivery, or use are controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

The Director of Quality Assurance is independent from cost and schedule considerations and is given free access to those levels of responsible management where appropriate action can be effected. This includes direct access to me.

If differences of opinion arise between Department Managers regarding the quality of an item, these conflicts will be brought to the attention of the Director of Quality Assurance for resolution. Any conflicts that remain unsolved will be brought to my attention for final resolution.


C. M. Mowry, President
Babcock & Wilcox Nuclear Energy

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Introduction

General

This document describes the Babcock & Wilcox Nuclear Energy, Inc. (B&W NE) quality assurance program (QAP) for the design certification of the B&W *mPower* reactor. It has been prepared in accordance with the requirements of Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50), "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," ASME NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities (with Addenda)," and is consistent with the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants." The QAP for the design certification of the B&W *mPower* reactor is implemented by the applicable sections of the B&W NE Nuclear Quality System Manual.

The document contains 18 sections demonstrating conformance to the requirements of Appendix B to 10 CFR Part 50, and contains sections on non-safety related quality controls and regulatory commitments. Changes to the QAP description that do not reduce the commitments will be submitted in accordance with 10 CFR 50.54, as applicable. Changes that reduce the commitments in this QAP will be submitted to the NRC for approval prior to implementation.

Scope/Applicability

The QAP, as described in this report, is applied to safety-related structures, systems and components of the B&W *mPower* reactor design certification project.

The scope of the design certification project does not include fabrication, construction, installation or use. Therefore, not all elements are applicable to the design certification project. Each section of the QAP designates the applicability of the requirements to the B&W *mPower* reactor design certification project. Definitions are provided in Appendix A for select terms as used in this document.

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1. Organization

1.1 Application

Section 1, "Organization," applies to the design certification project.

This section complies with Criterion I, "Organization," of 10 CFR Part 50, Appendix B, and Basic Requirement 1, "Organization," and Supplement 1S-1, "Supplementary Requirements for Organization," of ASME NQA-1-1994.

1.2 Implementation

This section describes the Babcock & Wilcox Nuclear Energy, Inc. (B&W NE) organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying quality assurance program (QAP) implementation. The organizational structure includes corporate and design functions for development of the B&W *mPower* reactor including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAP.

The Director of Quality Assurance is responsible to ensure that the size of the Quality Assurance organization is commensurate with the duties and responsibilities assigned.

B&W NE is an operating group of the Babcock & Wilcox Company (Figure 1.1). The Modular Reactor organization of B&W NE is responsible for the execution of the B&W *mPower* reactor design certification project. Several organizations within B&W NE implement and support the QAP. These organizations include, but are not limited to Babcock & Wilcox Canada, Nuclear Service, Project Management Office, Licensing and Quality Assurance.

Design interfaces with other B&W operating groups or interfaces with external design organizations are conducted in accordance with procurement document control requirements. All interfacing organizations are considered suppliers. Each organization utilized has been evaluated in accordance with QAP requirements and maintained on the B&W NE approved suppliers list (ASL).

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the B&W NE QAP.

1.2.1 Babcock & Wilcox Nuclear Energy, Inc.

B&W NE has the responsibility for all commercial nuclear power related activities conducted by Babcock & Wilcox. The President of B&W NE is responsible for the management of the nuclear

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operations. The following organizations are involved in the design of nuclear power plants and components and support the B&W *mPower* reactor project (Figure 1.2).

1.2.1.1 Modular Reactors

The Modular Reactors organization reports to and is part of B&W NE. The Program Director reports to the President of B&W NE and is responsible for the B&W *mPower* reactor design and development including the preparation, review, approval, and verification.

1.2.1.2 Quality Assurance

The Director of Quality Assurance reports to the President of B&W NE with the authority and organizational freedom to permit independence from cost and schedule considerations (Figure 1.3). The Director of Quality Assurance or his designee(s) have direct access to responsible management at all levels where appropriate action can be effected. The Director of Quality Assurance has sufficient authority, access to work areas, and organizational freedom to identify quality problems, initiate, recommend or provide solutions, verify implementation of corrective action, and control further processing of nonconforming items until the proper disposition is determined.

The Director of Quality Assurance is responsible for:

- preparation, maintenance and implementation of the QAP
- assuring that an appropriate quality system has been established and implemented
- approving quality procedures and manuals prepared by departments and projects for conformance to quality assurance policies
- assessing and verifying that activities affecting quality have been correctly performed.
- administration of records retention
- identifying quality problems, initiating documented action leading to a solution, and verifying implementation of solutions
- performance of supplier surveys and audits
- providing qualified and trained quality assurance engineers for project and staff functions
- providing quality-related indoctrination and training for personnel as required for personnel whose activities affect quality

1.2.1.3 Nuclear Services

The Vice President of Nuclear Services reports to the President of B&W NE. This organization is responsible for inspection and maintenance of pressurized and boiling water reactors.

1.2.1.4 Project Management Office

The Director of the Project Management Office reports to the President of B&W NE. This organization is responsible for project management processes and provides project managers and personnel to support various projects within the company.

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1.2.1.5 Nuclear Manufacturing

The Vice President of Nuclear Manufacturing reports to the President of B&W NE. This organization is responsible for the establishing and maintaining the infrastructure to manufacture commercial nuclear components.

1.2.1.6 Licensing

The Director of Licensing reports to the President of B&W NE. This organization is responsible for B&W NE licensing activities including the design certification application for the B&W *mPower* reactor.

1.2.1.7 B&W Canada

B&W Canada (BWC) nuclear operations reports to and is part of B&W NE. The President of BWC reports to the President of B&W NE. BWC designs and manufactures nuclear power equipment, including nuclear heat exchangers and steam generators, and provides nuclear plant services. This organization provides component design support to Modular Reactors.

1.2.1.8 B&W Nuclear Operations Group (NOG)-Mount Vernon/Barberton

B&W NOG-Mount Vernon and B&W NOG-Barberton report to and are part of the B&W Nuclear Operations Group, Inc., that provides nuclear components for the United States government. This organization also provides component design support to Modular Reactors.

1.2.1.9 B&W NOG-Euclid

B&W NOG-Euclid reports to and is part of the B&W Nuclear Operations Group, Inc., that provides nuclear components for the United States government. This organization also provides component design support to Modular Reactors.

1.2.1.10 B&W Supply Management Service Center

The Director of B&W Supply Management Service Center reports to the Director of Operational Excellence, IT, and Supply Management and supports B&W NE. The Purchasing Manager reports to the Director of B&W Supply Management Service Center. The procurement organization has the overall responsibility for safety-related procurement activities.

1.2.1.11 Human Resource

The Vice President of Human Resources reports to the President of B&W and supports B&W NE. This organization is responsible for human resource functions.

1.2.1.12 Global Sales

The Director of Global Sales reports to the President of B&W NE. This organization is responsible for business marketing, proposal management, and customer relations.

1.2.2 Authority to Stop Work

Quality assurance and inspection personnel have the authority and the responsibility to stop work in progress that is not being done in accordance with approved procedures or where safety or structure, system, and component (SSC) integrity may be jeopardized.

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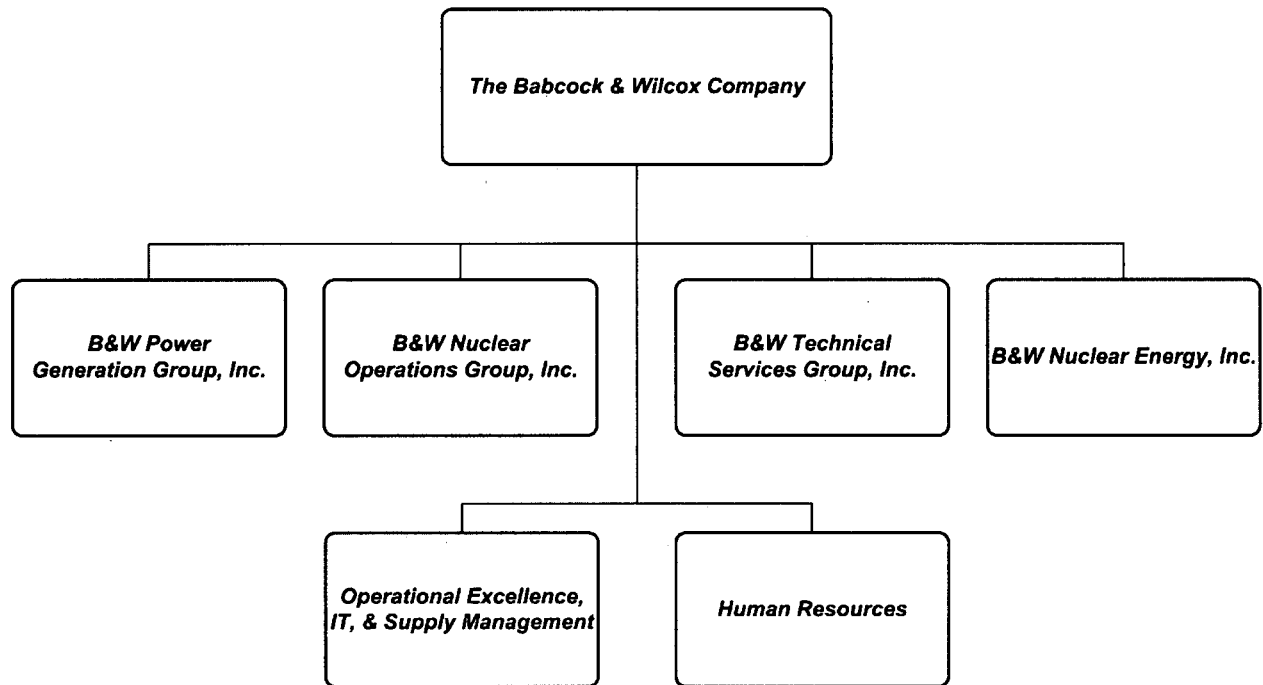


Figure 1.1 Babcock & Wilcox Company Organization

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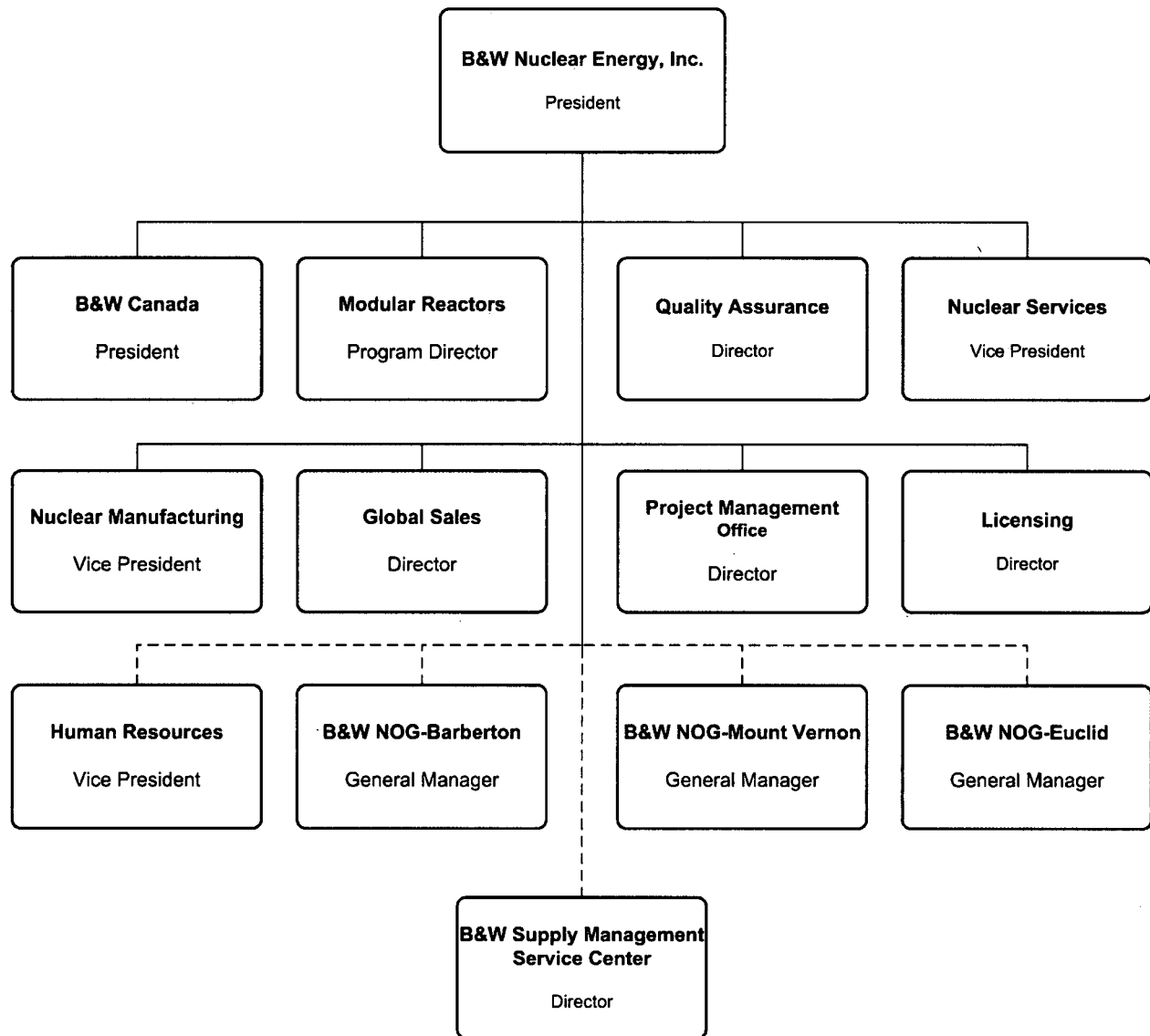


Figure 1.2 B&W NE Organization

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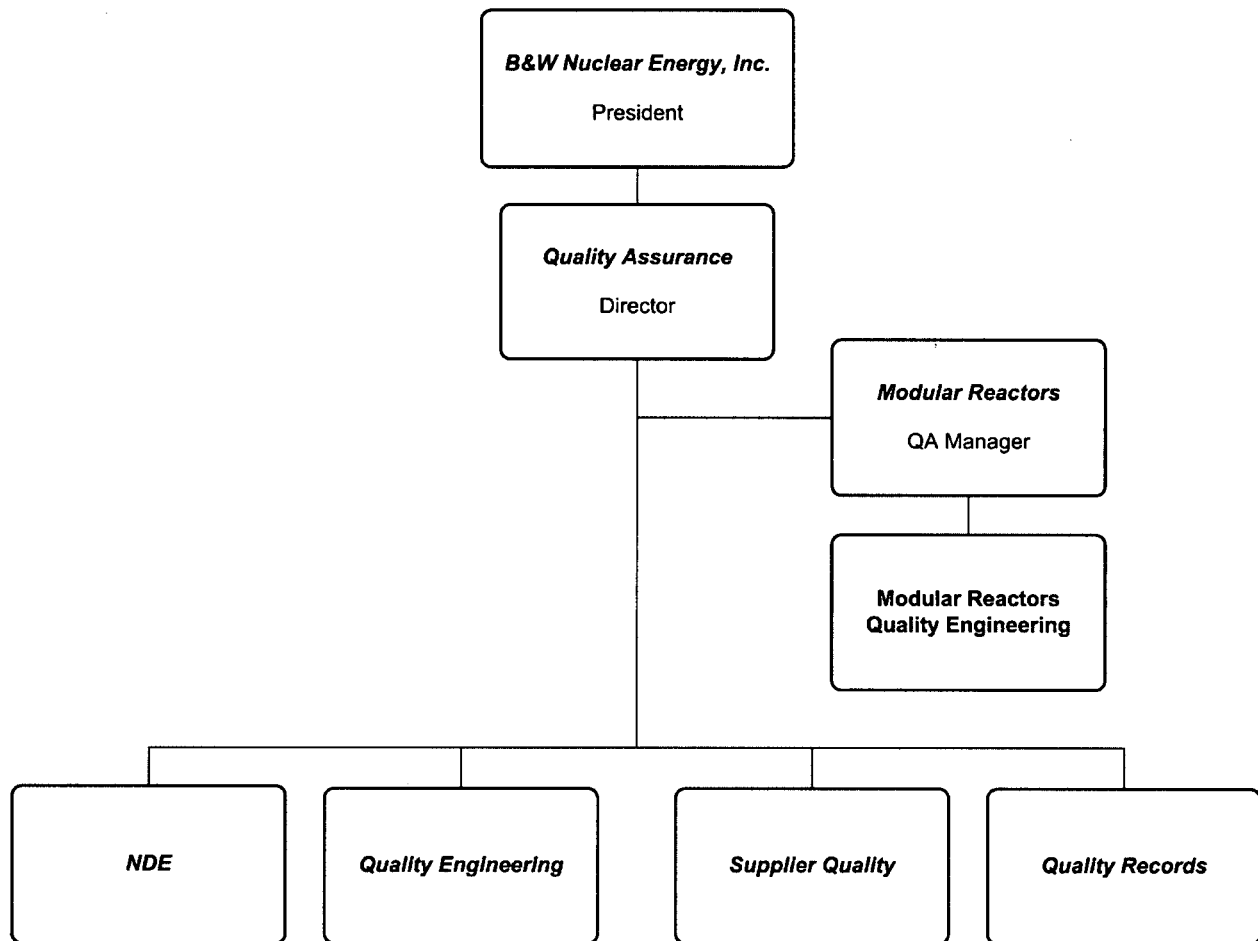


Figure 1.3 B&W NE Quality Assurance Organization

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2. Quality Assurance Program

2.1 Application

The quality assurance program (QAP), as specified in each section of the QAP, applies to the design certification project.

This section complies with Criterion II, "Quality Assurance Program," of 10 CFR Part 50, Appendix B, and Basic Requirement 2, "Quality Assurance Program," and the following Supplements of ASME NQA-1-1994:

2S-1, "Supplementary Requirements for the Qualification of Test and Inspection Personnel"

2S-2, "Supplementary Requirements for the Qualification of Nondestructive Examination Personnel"

2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel"

2S-4, "Supplementary Requirements for Personnel Indoctrination and Training"

2.2 Implementation

B&W NE has established the necessary measures and governing procedures to implement the QAP. B&W NE is committed to implementing the QAP in all aspects of work that are important to the safety of the B&W *mPower* reactor as described and to the extent delineated in the QAP. Further, B&W NE ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR Part 50, Appendix B.

The objective of the QAP is to assure that the B&W *mPower* reactor is designed in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document.

The QAP applies to those quality-related activities associated with the design of safety-related structures, systems, and components (SSCs).

In general, the program requirements specified herein are detailed in implementing procedures that are either B&W NE implementing procedures, or B&W NE approved supplier implementing procedures governed by a supplier quality assurance program.

2.2.1 Responsibilities

Personnel who work directly or indirectly for B&W NE are responsible for achieving acceptable quality in the work covered by the QAP. This includes the activities delineated in Section 1.2.

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B&W NE personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAP are performed as directed by documented instructions, procedures and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The Director of Quality Assurance is responsible to verify that processes and procedures comply with the QAP and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2.2 Periodic Review

Management of those organizations implementing the QAP, or portions thereof, assess the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter.

An annual independent management review is also conducted. The review is performed by B&W NE personnel not affiliated with the specific functions being reviewed or by an approved outside agency.

2.2.3 Issuance and Revision to Quality Assurance Program

Administrative control of the QAP will be in accordance with 10 CFR 50.54(a). Changes to the QAP are evaluated by the project Quality Assurance Manager to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAP. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the design certification application development process. New revisions to the document will be reviewed and approved, at a minimum, by the Director of Quality Assurance.

2.2.4 Indoctrination and Training

Personnel assigned to implement elements of the QAP shall be capable of performing their assigned tasks. To this end, B&W NE establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAP to assure that suitable proficiency is achieved and maintained. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable B&W NE procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAP elements to be employed. Records of personnel training and qualification are maintained.

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3. Design Control

3.1 Application

Section 3, "Design Control," applies to the design certification project.

This section complies with Criterion III, "Design Control," of 10 CFR Part 50, Appendix B, and Basic Requirement 3, "Design Control," and the following Supplements and Subparts of ASME NQA-1-1994:

- 3S-1, "Supplementary Requirements for Design Control"

- 11S-2, "Supplementary Requirements for Computer Program Testing"

Computer software utilized for safety-related design analysis also complies with Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."

3.2 Implementation

B&W NE has established and implements a process to control the design and design changes of items that are subject to the provisions of the QAP. The design process includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces within B&W NE and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. Design change processes and the division of responsibilities for design-related activities are detailed in B&W NE and supplier procedures.

The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes are reviewed and approved by the B&W NE design organization or by other organizations so authorized by B&W NE.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.2.1 Design Verification

B&W NE design processes provide for design verification to ensure that items and activities subject to the provisions of the QAP are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

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Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for item's intended use.

B&W NE normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture, or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2.2 Design Records

B&W NE maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output.

3.2.3 Computer Application Software

The QAP governs the development, procurement, testing, maintenance, and use of computer applications when used in safety-related applications and designated non-safety related applications. B&W NE and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto is documented and approved by authorized personnel. The QAP is also applicable to the administrative functions associated with the maintenance and security

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of computer hardware where such functions are considered essential in order to comply with other QAP requirements such as QA records.

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4. Procurement Document Control

4.1 Application

For the design certification project, the scope of procurement includes engineering, design and testing services as well as the procurement of safety-related software. No equipment or components are being procured as part of the design certification project.

Procurement activities with internal interfacing organizations as well as external organizations providing safety-related products or services are conducted in accordance with procurement document control requirements. Each organization utilized has been evaluated in accordance with QAP requirements and maintained on the B&W NE approved suppliers list.

This section complies with Criterion IV, "Procurement Document Control," of 10 CFR Part 50, Appendix B, and Basic Requirement 4, "Procurement Document Control," and the following supplement of ASME NQA-1-1994:

4S-1, "Supplementary Requirements for Procurement Document Control," with the following clarifications and exceptions:

Section 2.3 of Supplement 4S-1 includes a requirement that procurement documents require suppliers to have a documented QAP that implements NQA-1-1994, Part 1. In lieu of this requirement, B&W NE may require suppliers to have a documented supplier QAP that is determined to meet the applicable requirements of 10 CFR Part 50, Appendix B, as appropriate to the circumstances of the procurement.

Section 3 of Supplement 4S-1 requires procurement documents to be reviewed prior to bid or award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable purchase requisition, including the technical and quality procurement requirements, prior to bid or award of contract. Procurement document changes (e.g., scope, technical or quality requirements) will also receive the quality assurance review.

With regard to service performed by a supplier, B&W NE procurement documents may allow the supplier to work under the B&W NE QAP, including implementing procedures, in lieu of the supplier having its own QAP.

4.2 Implementation

4.2.1 Procurement Process

Purchase requisitions include or reference all necessary requirements to procure items and services from suppliers and are processed in accordance with procurement procedures.

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Purchase requisitions are used by B&W NE Purchasing to place purchase orders (POs) with approved suppliers.

Prior to PO release, B&W NE QA reviews purchase requisitions to assure that the document was prepared, reviewed and approved in accordance with approved procedures and contains all necessary quality requirements.

Changes made as a result of the bid evaluations or pre-contract negotiations are incorporated into the procurement documents. The review of such changes and their effect is completed prior to contract award.

Reviews of changes are the responsibility of personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

Procurement document changes are subject to the same review and approval controls as utilized in the preparation of the original documents.

4.2.2 Procurement Documents

Procurement documents include or reference other documents that include the following information and requirements, as applicable:

- scope of work – statement of the work to be performed by the supplier

- technical requirements – drawings, specifications, codes, standards, regulations, procedures or instructions that describe the items or services furnished as well as test and inspection requirements and equipment, acceptance criteria, and special process instructions for such activities as: fabrication, inspection, cleaning, packaging, handling, shipping, and storage

- quality program requirements – identification of quality requirements imposed on the supplier

- rights of access – the right of access to the supplier's facilities and records, and any sub-tier suppliers by B&W NE and its authorized representatives for inspection, audit, surveillance or hold points

- documentation requirements – identification of supplier documents and records to be prepared, maintained, submitted, and made available for information, review and/or approval including the time of submittal requirements

- nonconformances – requirements for reporting of nonconformances and the dispositioning of nonconformances

- regulatory requirements – requirements for 10 CFR Part 21 posting, evaluating, and reporting

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5. Instructions, Procedures and Drawings

5.1 Application

Section 5, "Instructions, Procedures and Drawings" applies to the design certification project.

This section complies with Criterion V, "Instructions, Procedures and Drawings," of 10 CFR Part 50, Appendix B, and Basic Requirement 5, "Instructions, Procedures and Drawings," of ASME NQA-1-1994.

5.2 Implementation

B&W NE has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures or drawings of a type appropriate to the circumstances to implement the QAP as described in the QAP. Such documents are prepared and controlled according to Section 6. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

Instructions, procedures, or drawings include appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. Instructions and procedures also include the scope of the document, responsibilities, and sequence of activities as appropriate. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Section 6.

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6. Document Control

6.1 Application

Section 6, "Document Control," applies to the design certification project.

This section complies with Criterion VI, "Document Control," of 10 CFR Part 50, Appendix B, and Basic Requirement 6, "Document Control," and Supplement 6S-1, "Supplementary Requirements for Document Control," of ASME NQA-1-1994.

6.2 Implementation

B&W NE has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

- identification of documents to be controlled and their specified distribution
- a method to identify the correct document (including revision) to be used and control of superseded documents
- identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents
- review of documents for adequacy, completeness, and correctness prior to approval and issuance
- a method for providing feedback from users to continually improve procedures and work instructions
- coordinating and controlling interface documents and procedures

The types of documents to be controlled include:

- quality documents – includes instructions and procedures for activities covered by the QAP such as design, construction, installation, operating, maintenance, calibration, and routine testing; nonconformance reports and corrective action reports
- design documents – includes drawings, engineering calculations, design specifications, analyses, and computer codes
- procurement documents – includes purchase orders and related documents, audit, surveillance, and quality verification/inspection procedures

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technical documents – includes inspection, test, special processes procedures and documents

6.2.1 Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Minor changes, (such as typo's) which do not affect the technical scope of documents prepared at the project site and which may be conveniently made by pen and ink correction on the document, shall not require the same review and approval as the original documents. The Quality Control Manager shall be responsible for authorizing the Project Engineer to make minor changes to inspection & test Plans, deviations to inspection & test plans, weld control records and other quality-related project generated documents.

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7. Control of Purchased Material, Equipment and Services

7.1 Application

For the design certification project, the scope of procurement includes engineering, design and testing services as well as the procurement of safety-related software. No equipment or components are being procured as part of the design certification project; therefore, the controls associated with this section apply to the control of the applicable services only.

This section complies with Criterion VII, "Control of Purchased Material, Equipment and Services," of 10 CFR Part 50, Appendix B and Basic Requirement 7, "Control of Purchased Items and Services," and Supplement 7S-1, "Supplemental Requirements for Control of Purchased Items and Services," of ASME NQA-1-1994, with the following clarifications and exceptions:

B&W NE considers that other 10 CFR Part 50 licensees, Authorized Nuclear Inspection agencies, National Institute of Standards and Technology, or other state and federal agencies that may provide items or services are not required to be evaluated or audited.

When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

- (1) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the B&W NE QAP and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.
- (2) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
- (3) A documented review of the supplier's accreditation will be performed and will include a verification of the following:

The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):

National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology

American Association for Laboratory Accreditation (A2LA)

ACLASS Accreditation Services (ACLASS)

International Accreditation Service (IAS)

Laboratory Accreditation Bureau (L-A-B)

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Other NRC-approved laboratory accrediting body

The accreditation encompasses ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

7.2 Implementation

B&W NE has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements. Such control provides for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

7.2.1 Supplier Evaluation and Selection

Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of, or changes the methods or controls for, activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period.

B&W NE may utilize audits conducted by other B&W divisions for supplier qualification provided that the scope and adequacy of the audits meet B&W NE requirements. A single approved suppliers list (ASL) is maintained by B&W NE for all commercial nuclear divisions.

Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

7.2.2 Acceptance of Items or Service

B&W NE establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and construction activities. Verifications occur at the appropriate phases of the

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procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, certificates of conformance, and document reviews (including certified material test report/certificate). Acceptance actions/documents are established with appropriate input from the supplier and completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

7.2.3 Commercial Grade Items or Services

Commercial grade items and/or services for safety-related applications may be procured from suppliers where specific quality controls for nuclear applications cannot be imposed in a practical manner. Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications. Special methods shall be established by the responsible technical manager and quality organization to provide assurance that the item or service specified is the item or service received. If needed, these special quality verification methods may include inspections, tests, commercial grade surveys, source verification, or evaluations of the supplier. Suppliers of commercial grade items and/or services need not appear on the ASL.

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8. Identification and Control of Materials, Parts, and Components

8.1 Application

The scope of the design certification project does not include the identification and control of material, parts and components; therefore, this element is not applicable to the design certification project.

This section does comply with Criterion VIII, "Identification and Control of Materials, Parts and Components" of 10 CFR Part 50, Appendix B, and Basic Requirement 8, "Identification and Control of Items," and Supplement 8S-1, "Supplementary Requirements for Identification and Control of Items," of ASME NQA-1-1994.

8.2 Implementation

B&W NE has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication, construction, installation and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so that they are clear and legible and do not to affect the function or quality of the item. Items shall be stored and handled in a manner so that they are protected from damage and deterioration.

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9. Control of Special Processes

9.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use; therefore, this element is not applicable to the design certification project.

Special processes include but are not limited to welding, heat treating, and nondestructive examination (NDE). Cleaning is considered to be a special process when exceptional and unusual care in cleaning is necessary as defined in the applicable drawings and specifications. Written procedures establish the requirements for the control of special processes used by B&W NE. For the purpose of this topical report, special processes are not being used on the design certification project.

However, this section complies with Criterion IX, "Control of Special Processes," of 10 CFR Part 50, Appendix B and Basic Requirement 9, "Control of Processes," and Supplement 9S-1, "Supplementary Requirements for Control of Processes," of ASME NQA-1-1994.

9.2 Implementation

B&W NE has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and NDE, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

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10. Inspection

10.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use. No equipment or components are being procured as part of the design certification project; therefore, this element is not applicable to the design certification project.

However, this section complies with Criterion X, "Inspection," of 10 CFR Part 50, Appendix B, and Basic Requirement 10, "Inspection," and Supplement 10S-1, "Supplementary Requirements for Inspection," of ASME NQA-1-1994.

10.2 Implementation

B&W NE has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, and operations activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.2.1 Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at a company facility, (3) for final acceptance of fabricated and/or installed items during construction, (4) upon receipt of items for a facility, as well as (5) during maintenance, modification, in-service, and operating activities.

The inspection program establishes requirements for planning inspections such as the group or discipline responsible for performing the inspection where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

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Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2.2 Inspector Qualification

B&W NE has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

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11. Test Control

11.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use; therefore, test control associated with proof tests before installation, preoperational tests, post-maintenance test, post-modification tests, and operational tests are not applicable to the design certification project. Test control is, however, applicable to the testing programs associated with design verification of the B&W *mPower* reactor. Tests may be conducted by B&W NE or by qualified, approved suppliers. Computer programs used for design analyses are certified or verified and validated as required. Computer program testing is addressed in Section 3.

This section complies with Criterion XI, "Test Control," of 10 CFR Part 50, Appendix B, and Basic Requirement 11, "Test Control," and Supplements 11S-1, "Supplementary Requirements for Test Control" and 11S-2, "Supplementary Requirements for Computer Program Testing," of ASME NQA-1-1994.

11.2 Implementation

B&W NE has established a test program to demonstrate that the item will perform satisfactorily in service. Whenever engineering judgment leads to the conclusion that design analysis or previous experience cannot substantiate a design or design feature, design verification testing is conducted as described in this section and Section 3.2.1.

The requirements for such tests are included in test requirement documents prepared by the responsible technical manager. These test requirement documents include, as appropriate, the requirements of this section, scope of the test, technical requirements, and QA requirements.

Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the test, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

Tests are performed and results documented in accordance with applicable technical and regulatory requirements. The results are evaluated and their acceptability determined by the responsible technical manager to ensure that the test requirements have been met. Test records, at a minimum, identify the item tested, date of test, tester or data recorder, type of observations, drawing and/or test procedure, results and acceptability, action taken in

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connection with any deviations noted, person evaluating test results and gage or instrument number used for the test. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAP.

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12. Control of Measuring and Test Equipment

12.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use; therefore, the control of Measuring and Test Equipment (M&TE) associated with proof tests prior to installation, preoperational tests, and operational tests during plant operations is not applicable to the design certification project. However, the control of M&TE associated with tests and testing programs utilized for design verification of the B&W *mPower* reactor are applicable to the project and to organizations that have conducted such tests.

This section complies with Criterion XII, "Control of Measuring and Test Equipment," of 10 CFR Part 50, Appendix B, and Basic Requirement 12, "Control of Measuring and Test Equipment," and Supplement 12S-1, "Supplementary Requirements for Control of Measuring and Test Equipment," of ASME NQA-1-1994 with the following clarifications and exceptions:

The out of tolerance conditions described in paragraph 3.2 refers to when the M&TE is found out of the required accuracy limits. (i.e., out of tolerance) during calibration.

M&TE are not required to be marked with a calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device.

12.2 Implementation

B&W NE has established the necessary measures and procedures to control the calibration, maintenance, and use of M&TE. The provisions of such procedures cover equipment such as indicating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial grade calibration services are controlled as described in Section 7.

These calibration requirements do not apply to rulers, tape measures, levels, and other devices where commercial accuracy is adequate.

Customer supplied M&TE may be used provided a copy of the calibration documentation is supplied with the M&TE and the documentation reviewed and approved by B&W NE.

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13. Handling, Storage, and Shipping

13.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use; therefore, this element is not applicable to the design certification project.

However, this section complies with Criterion XIII, "Handling, Storage and Shipping" of 10 CFR Part 50, Appendix B, and Basic Requirement 13, "Handling, Storage and Shipping," and Supplement 13S-1, "Supplementary Requirements for Handling, Storage and Shipping," and the following subparts of ASME NQA-1-1994:

Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants"

Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants"

13.2 Implementation

B&W NE has established the necessary measures and procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required, to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

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

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

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14. Inspection, Test, and Operating Status

14.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use; therefore, this element is not applicable to the design certification project.

This section complies with Criterion XIV, "Inspection, Test and Operating Status" of 10 CFR Part 50, Appendix B and Basic Requirement 14, "Inspection, Test, and Operating Status," of ASME NQA-1-1994.

14.2 Implementation

B&W NE has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAP in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications and status tracking.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

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15. Nonconforming Materials, Parts, or Components

15.1 Application

The scope of the design certification project does not include fabrication, construction, installation or use; therefore, nonconforming materials, parts, or components are not applicable to the design certification project.

Nonconformances associated with services or documentation are processed in accordance with this section under the corrective action program.

This section complies with Criterion XV, "Nonconforming Materials, Parts, or Components," of 10 CFR Part 50, Appendix B, and Basic Requirement 15, "Control of Nonconforming Items," and Supplement 15S-1, "Supplementary Requirements for the Control of Nonconforming Items," of ASME NQA-1-1994.

15.2 Implementation

B&W NE has established the necessary measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items, and for notification to affected organizations.

Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management.

Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with B&W NE procedures, regulatory requirements, and industry standards.

Nonconformances related to safety-related design, analysis or consulting services that are associated with the design certification, or design approval are controlled and reported in accordance with 10 CFR Part 21, "Reporting of Defects and Noncompliance."

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16. Corrective Actions

16.1 Application

Section 16, "Corrective Action," is applicable to the design certification project.

This section complies with Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B, and Basic Requirement 16, "Corrective Action," of ASME NQA-1-1994.

16.2 Implementation

B&W NE has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. B&W NE procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. B&W NE procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, B&W NE documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, B&W NE may delegate specific responsibilities for corrective actions but B&W NE maintains responsibility for the effectiveness of corrective action measures.

Nonconformances related to safety-related design, analysis or consulting services that are associated with the design certification or design approval are controlled and reported in accordance with 10 CFR Part 21.

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17. Quality Assurance Records

17.1 Application

Section 17, "Quality Assurance Records," applies to the design certification project.

This section complies with Criterion XVII, "Quality Assurance Records," of 10 CFR Part 50, Appendix B, and Basic Requirement 17, "Quality Assurance Records" and Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records," of ASME NQA-1-1994, with the following clarification:

Section 4.2(b), requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. For hard copy records maintained by B&W NE, the records are suitably stored in steel file cabinets or on shelving in containers, except that methods other than binders, folders or envelopes may be used to organize the records for storage.

17.2 Implementation

B&W NE has the necessary measures and procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for B&W NE and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

B&W NE maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and revisions thereto, as well as documentation which identifies the important steps, including sources of input that support the final output.

The requirements and guidelines for receipt, control and retention of permanent quality assurance records contained in ASME NQA-1-1994 and Section III of the ASME Boiler and Pressure Vessel Code are employed for the control construction site quality record files. Identification of the records and method of turnover to the client are established for each project through agreement between B&W NE and the client.

17.2.1 Electronic Records

When using electronic records storage and retrieval systems, B&W NE complies with the guidance of Generic Letter 88-18, "Plant Record Storage on Optical Disks" (October 20, 1988). B&W NE will manage the storage of QA records in electronic media consistent with the intent of RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic

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Media" (October 23, 2000), and the following guides developed by Nuclear information and Records Management Association Inc., (NIRMA):

NIRMA Technical Guide (TG) 11-1998, "Authentication of Records and Media"
NIRMA TG 15-1998, "Management of Electronic Records"
NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance"
NIRMA TG 21-1998, "Electronic Records Protection and Restoration"

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18. Audits

18.1 Application

Section 18, "Audits," applies to the design certification project.

This section complies with Criterion XVIII, "Audits" of 10 CFR Part 50, Appendix B, and Basic Requirement 18, "Audits," and Supplemental 18S-1, "Supplementary Requirements for Audits," ASME NQA-1-1994.

In addition, personnel who perform audits are qualified to the requirements of Supplement 2S-3.

18.2 Implementation

B&W NE has established the necessary measures and governing procedures to implement audits to verify that activities covered by the QAP are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.2.1 Internal Audits

Internal audits of selected aspects of licensing, design, construction phase and operating activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed.

During the early portions of B&W *mPower* reactor activities, audits will focus on areas including, but not limited to, design, document control, procurement, and corrective action. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of procedures, technical specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff, corrective actions, and observation of performance of associated record keeping.

The audits are scheduled on a formal preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the Director of Quality Assurance.

B&W NE is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative

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sampling), and to determine if they are meaningful and comply with the overall QAP. External audits determine the adequacy of the supplier or contractor quality assurance program.

The results of each audit are reported in writing to the Director of Quality Assurance, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

18.2.2 Supplier Audits

Audits of suppliers of safety-related components and/or services are conducted as described in Section 7.

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19. Non-safety Related Quality Controls

19.1 Non-safety Related SSCs - Significant Contributors to Plant Safety

Specific program controls are applied to non-safety related structures, systems, and components (SSCs), for which 10 CFR Part 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAP are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QAP to the non-safety related SSCs and related activities, including the identification of exceptions to the QAP described in Sections 1 through 18 taken for non-safety related SSCs.

19.1.1 Organization

The verification activities described in this part may be performed by the B&W NE line organization. The QA organization described is not required to perform these functions.

19.1.2 QA Program

B&W NE QA requirements for non-safety related SSCs are established in the QAP and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QAP is not required.

19.1.3 Design Control

B&W NE has design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

19.1.4 Procurement Document Control

Procurement documents for items and services obtained by or for B&W NE include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

19.1.5 Instructions, Procedures, and Drawings

B&W NE provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed provides an

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appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

19.1.6 Document Control

B&W NE controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

19.1.7 Control of Purchased Items and Services

B&W NE employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

19.1.8 Identification and Control of Purchased Items

B&W NE employs measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

19.1.9 Control of Special Processes

B&W NE employs process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

19.1.10 Inspection

B&W NE uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

19.1.11 Test Control

B&W NE employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

19.1.12 Control of Measuring and Test Equipment

B&W NE employs measures to control measuring and test equipment use, calibration and adjustment at specific intervals or prior to use.

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19.1.13 Handling, Storage, and Shipping

B&W NE employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

19.1.14 Inspection, Test, and Operating Status

B&W NE employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

19.1.15 Control of Nonconforming Items

B&W NE employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

19.1.16 Corrective Action

B&W NE employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

19.1.17 Records

B&W NE employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

19.1.18 Audits

B&W NE employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this section are implemented by the same programs, processes, or procedures as the comparable activities of Sections 1–18, the audits performed under the provisions of Sections 1–18 may be used to satisfy the review requirements of this section.

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20. Regulatory Commitments

20.1 NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC regulatory guides and the other quality assurance standards that have been selected to supplement and support the B&W NE QAP for the design certification of the B&W *mPower* reactor. B&W NE commits to compliance with these standards to the extent described herein. Commitment to a particular regulatory guide or other QA standard does not constitute a commitment to the regulatory guides or QA standards that may be referenced therein.

20.1.1 Regulatory Guides

Regulatory Guide 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Rev. 4, March 2007.

B&W NE commits to the applicable regulatory position guidance provided in this regulatory guide.

Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Rev. 3, August 1985.

B&W NE commits to the applicable regulatory position guidance provided in this regulatory guide.

Regulatory Guide 1.29, "Seismic Design Classification," Rev. 4, March 2007.

B&W NE commits to the applicable regulatory position guidance provided in this regulatory guide.

20.1.2 Standards

ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications."

B&W NE commits to Parts I and II, as described in the foregoing sections of this QAP.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs).

B&W NE commits to NIRMA TGs as described in Section 17.

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Appendix A - Definitions

Acceptance Criteria

Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirements documents and used to determine whether an item, process, or service is satisfactory.

Annual

Defined as occurring within a calendar year, performance of duties shall not be less than 10 months or more than 14 months. Individual procedures may be more restrictive.

Audit

A documented evaluation performed to verify, by examination of objective evidence, that those selected elements of a previously approved quality program have been developed, documented, and implemented in accordance with specified requirements. An audit does not include surveillance or inspection for the purpose of process control, or acceptance of material or items.

Certificate of Conformance (CoC)

A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services comply with specified requirements.

Characteristic

Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

Critical Characteristic

Those characteristics that are essential for performance of an item's safety-related function(s). Typical critical characteristics are attributes such as form, fit, dimensions, material including physical, mechanical, and chemical properties, electrical, thermal, or other functional parameters.

Commercial Grade Item

When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected, that is, one or more critical characteristics of the item cannot be verified.

Component

An all-inclusive term used in place of any of the following: appurtenance, assembly, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

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Computer Program (Code Software)

A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, and interpreter, or a translator to prepare the program for execution as well as to execute it.

Condition Adverse to Quality

An all inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety and operability.

Construction

An all-inclusive term comprising materials, design, fabrication, examination, testing, inspection, and certification required in the manufacture and installation of an item.

Corrective Action

Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Defective Item

An item which has one or more characteristics that do not comply with specified requirements.

Design Change

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

Design Input

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

Design Output

Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

Design Process

Technical and management processes that commence with identification of design input concluding with the issuance of design output documents.

Deviation

A nonconformance or departure from specified requirements.

Document

Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Documentation

A compilation of those documents concerning a specific function, activity or project.

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Examination

An element of inspection consisting of investigation of materials, components, supplies, or services to determine conformance to those specified requirements which can be determined by such investigations. Examination is usually nondestructive and includes visual, simple physical manipulation, gauging, measurement and written documentation.

Failures

A failing (or number of failings) to perform a duty or expected action.

Handling

An act of physically moving and/or lifting items by hand or mechanical means.

Hold Point

A designated stopping place during or following a specific activity at which inspection or examination is required before further work can be performed.

Inspection

Examination or measurement to verify whether an item or activity conforms to specified requirements.

Inspector

A qualified individual whose duties include verification of quality related activities and who is independent of the activity being verified.

Item

An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, sub-assembly, sub-system, system, or unit.

Measuring & Test Equipment

Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or to acquire data to verify conformance to specified requirements.

Nonconformance

A deficiency in characteristic, documentation, performance, or procedure which renders the quality of an item unacceptable or indeterminate.

Nondestructive Examination

A method of detecting indications of discrepancies without destroying the usefulness of the item or material.

Non-Safety Related

Any item or service that has quality requirements greater than commercial, but less than safety-related as defined by specific customer procurements.

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Objective Evidence

Any statement of fact, information, or record, either quantitative or qualitative pertaining to the quality of an item or service which can be verified by records of tests, examinations, inspections, measurements, or observations.

Procedure

A document which specifies instructions for performance of a particular task. It includes methods to be employed, description of equipment or material to be used, sequence of operations, etc.

Process

One or more operations, methods, functions, procedures, or other specified actions which result in the desired item or result.

Procurement Document

Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchase Requisition

Document used to transmit procurement information/documents to purchasing for the purpose of obtaining bids, placing orders and change orders.

Project Manager

An individual responsible for technical contract, quality, budget, schedule or delivery of a product or service.

Qualification (Personnel)

The characteristics or abilities gained through education, training and/or experience that qualify an individual to perform a required function.

Qualified Procedure

A procedure which incorporates all applicable code and standard requirements, manufacturing parameters, and specifications, which has been proven adequate for the intended purpose.

Quality

The properties or characteristics constituting those prerequisites or specifications, codes, standards, industrial practices, other recognized methods and/or acceptance criteria by which an item is judged.

Quality Assurance

All those planned and systematic actions, including quality administration and quality control, which provide adequate confidence that an item will perform satisfactorily in service.

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Quality Assurance Record

A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Records must be validated by stamps, initials, or signatures of authorized personnel or otherwise authenticated.

Quality Control

Those quality assurance actions which provide a means to control and measure the characteristics of an item or process to established requirements.

Rejection

A disposition which may be imposed on a nonconforming item providing for its withdrawal and isolation from further processing pending an evaluation as to repair, rework, use-as-is, or scrap.

Repair

The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though the item still may not conform to the original requirements in every aspect.

Review/Approval

Acceptance indicated by signature/initials and date.

Rework

The process by which a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though the item still may not conform to the original requirements in every aspect.

Safety-Related

Safety-related items are those nuclear power plant items that must directly function, or must provide the capability for other items to function, to:

- a) assure the integrity of the reactor coolant pressure boundary,
- b) provide the capability to shut down the reactor and maintain it in a safe shutdown condition,
- c) provide the capability to prevent or mitigate the consequences of accidents that could result in potential off-site exposures comparable to the guideline exposures of 10 CFR 50.34(a), 50.67(b)(2), or 100.11, as applicable.

Service

The performance of activities such as design, fabrication, inspection, test, nondestructive examination, destructive examination, audits, and calibration of measuring and test equipment.

Source Inspection or Surveillance

A review, observation or inspection for the purpose of verifying that an action has been accomplished as specified at the location of item procurement or manufacture.

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Special Process

A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both.

Specification

A concise statement of a set of requirements to be satisfied by a product, material, or process indicating, whenever appropriate, the means by which it may be determined whether the requirements given are satisfied.

Supplier

Any individual or organization who furnishes items or services in accordance with a procurement document.

Surveillance

The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

Testing

An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to physical, chemical, environmental, or operating conditions.

Use-As-Is

A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification

The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.