



MIPS-PP-QA-14

**Babcock & Wilcox
Technical Services Group, Inc.**

**MEDICAL ISOTOPE PRODUCTION SYSTEM
Quality Assurance Program Description**

Topical Report

MIPS-PP-QA-14

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INTRODUCTION

The MIPS Program includes Aqueous Homogeneous Reactor(s) (AHR) fueled with low enriched uranium. It also includes the associated extraction and purification system and facilities for the purpose of producing ⁹⁹Mo as a supply material for medical isotope production.

MIPS will be licensed under 10CFR50 as a production and utilization facility, classified as a non-power reactor, and require both construction and operating authorization. Section 50.34 of 10 CFR requires non-power reactors to have a description of the quality assurance program (referred to as QAPD) for the design and construction of the structures, systems, and components of the facility. NUREG 1537 states that Regulatory Guide 2.5 and ANSI/ANS 15.8 provide an acceptable method of complying with the quality assurance program requirements of 10 CFR 50.34.

SCOPE

B&W addresses the requirements of 10CFR50.34(a)(7) for a description of the MIPS Quality Assurance Program in this controlled document. This QAPD and applicable implementing procedures are "program-specific" to the MIPS Program. It meets the intent of the above documents and applicable Technical Services Group (TSG) policies and programs. The procedures that implement the requirements in this document are identified in the Master Procedures List maintained by the Document / Record Manager.

The QAPD describes the administrative and technical controls for ensuring compliance with requirements. It applies to the design, procurement, fabrication, experiments, construction, and testing of the structures, systems, and components of the facility and will be incorporated into the Construction License Application.

APPLICABILITY

The Graded Approach to achieving required levels of quality for Safety-related Structures, Systems, and Components (SSCs) and other components not specifically designated as safety-related is described in Section 2.0 and related implementing documents. The Quality Levels applied to SSCs are defined within three quality levels.

Determination of quality levels for specific SSCs will be made during the development of the SAR and will correlate to the level of safety significance for the specific SSC. As the safety significance of individual SSCs is further understood or applied as a result of the SAR development, the application of specific quality assurance requirements will be specified.

A Quality Level (QL) matrix is used to ensure quality requirements are understood and specified for each SSC. An Applicability Procedure for MIPS will ensure the effective designation and traceability of quality levels. Applicable activities will be performed in accordance with the Graded Approach Quality Level 1 until such time as an SSC may change to another quality level.



MIPS QUALITY POLICY

It is the policy of B&W Technical Services Group, Inc. (B&W TSG or hereafter referred to as the Company) to provide products and services to both internal and external customers under a Quality Assurance Program, which ensures compliance with applicable criteria in 10CFR50, ANSI/ANS 15.8, and all related rules, regulations, codes, and standards.

To ensure these objectives are understood and met, the Program Quality Manager (PQM) is empowered to establish and maintain the QAPD. All personnel at B&W are responsible for ensuring that the quality of our products and services are in accordance with the QAPD. It is maintained at all times in accordance with stated policies, commitments, and requirements. Changes are not valid until they are approved by designated B&W management.

The PQM is delegated the responsibility and authority to define the methods and lead the verification of activities affecting quality internal and external to the MIPS Program. All quality organization personnel, under the direction of the PQM, have the authority, right of access, and freedom to identify quality problems, and initiate and recommend solutions. The quality organization verifies implementation of solutions and ensures that further work is controlled (or stopped if necessary) until nonconforming conditions, deficiencies, or unsatisfactory conditions are corrected.

The QAPD is endorsed by Executive Management and implemented by all MIPS Program Team members, employees, organizations, and suppliers, as required. Quality will not be compromised due to cost and schedule considerations. We will resolve any quality-related conflicts that arise among personnel without compromising applicable QAPD requirements.

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1.0 ORGANIZATION

1.1 Scope

This section describes the MIPS Program Organization and the general roles and responsibilities for the key team members. Overall policies on quality are established by B&W Technical Services Group, Inc. (TSG).

1.2 Requirements

1.2.1 TSG Operations

The President is responsible for the conduct of all operations as well as any services sold to outside customers. The President assigns responsibilities to various staff managers as necessary to achieve quality objectives.

The Program Manager, with direction and support from the Chief Technical Officer (CTO), is responsible to develop organizations consistent with the requirements in TSG quality assurance policies, applicable regulatory requirements, codes, standards, and customer specifications. TSG management has the responsibility to ensure that the quality assurance function for the Program is sufficiently organizationally independent and has the necessary authority to raise and resolve quality issues without regard to cost, schedule, or production pressures.

1.2.2 Program Organization

The Program Functional Structure is shown in Figure 1. The individual assigned responsibility for each function has primary responsibility for quality performance. Quality achievement is verified by others not directly performing the work.

Personnel responsible for ensuring that appropriate controls have been established and personnel performing verification functions have the authority, access and freedom to identify problems, initiate, recommend or provide corrective action and ensure corrective action implementation.

1.2.2.1 Technical & Program Management

The Chief Technical Officer (CTO) periodically reviews cost, schedule, program development activities, technical adequacy of design development, progress reports, quality assessment results, and other program-related information. The CTO delegates the day to day performance of internal and external activities regarding both technical and administrative matters.

1.2.2.2 Program Management

The Program Manager is responsible for the overall performance of internal and external activities regarding both technical and

administrative matters. Performance pertains to cost, schedule, and quality requirements and ensuring adequate resources for effectively achieving the program milestones.

During the design, construction, or modification of the Program, most of the work may be performed by outside organizations or support contractors, and suppliers. The Program Manager's role is primarily one of providing requirements and verifying compliance with those requirements. TSG personnel assigned to the program report to the Program Manager.

1.2.2.3 Environment, Safety, Health, & Quality

The ESH&Q function reports to the TSG President on all matters regarding environmental, safety, health, and quality. In particular to MIPS, program performance and quality-related issues that cannot be resolved at this level will be communicated to the TSG President for review and actions as necessary.

1.2.2.4 Quality Management

The Quality Management function reports directly to the TSG ESH & Q function with program level reporting and interfacing as depicted by the dotted line shown in Figure 1. The Program Quality Manager is responsible for assisting with the identification of quality requirements, ensuring such requirements are understood across the program team, assessing the effectiveness of QAPD implementation, reporting results to program and senior management, and supporting efforts to continuously work towards program and process improvement.

The Program Quality Manager has the responsibility for planning and performing supplier audits, source inspections, and examination of items or services for acceptance.

1.2.2.5 Reactor Systems Engineering

The Reactor Systems Engineering Chief Engineer reports to the Program Manager. The Chief Engineer is responsible for internal and external activities with regard to the design and construction of the MIPS reactor systems. Working closely with MIPS team members and applicable suppliers, the Chief Engineer ensures that applicable requirements are met during the program life.

1.2.2.6 Isotope Separations Engineering

The Isotope Separations Engineering Chief Engineer reports to the Program Manager. The Chief Engineer is responsible for coordinating and monitoring research and development, design and construction activities associated with the development of the MIPS extraction and purification systems. Working closely with MIPS team members and applicable suppliers, the Chief Engineer ensures that applicable requirements are met during the program life.

1.2.2.7 Purchasing

Purchasing is responsible for the administration of all purchase orders with MIPS organizations and suppliers. Purchasing is responsible for coordinating source selection and evaluations with engineering design and the quality organization.

1.2.2.8 Licensing NRC / FDA

The Licensing Manager coordinates the development and implementation of the licensing bases of the MIPS Program. The Licensing Manager is responsible for ensuring clear lines of communication between the NRC/FDA and other regulatory entities (e.g., State regulatory bodies) and MIPS staff. The Licensing Manager will address NRC/FDA/State inspection, assessment, and compliance responsibilities of the MIPS organization and be the point of contact for MIPS regulatory issues.

The Licensing Manager will maintain the MIPS License Application and Environmental Report; i.e., ensure it retains configuration management and traceability to the selected design reference points during the design phase. The Licensing Manager will manage the submittal of licensing documentation and receipt of requests and issuance of responses to NRC or other regulatory Requests for Additional Information (RAI).

1.2.2.9 Project Controls

The Project Controls Manager has the overall responsibility for developing, managing, and revising program schedules, plans, man-hour resource data, program status reports, and other activities as required.

1.2.2.10 Document and Record Management

The Document / Record Manager, with support from assigned team members, is responsible for this function. This includes document control and record management activities. Nuclear information within the scope of this function includes both hard copy and electronic form.

1.2.2.11 Operations

The Operations Manager is responsible for overall facilities operations after official licensing is complete. Operational requirements and needs are factored into the design throughout the design phases as required.

1.2.2.12 Contract Management

The Contract Manager is responsible for all oversight of contractors and subcontractors (suppliers) and management-related aspects associated with their execution of the design, fabrication, procurement, construction, and testing of the SSC's of the facility.

1.2.2.13 Contractor Organizations

Contractor organizations are responsible for their portion of the execution of the design, fabrication, procurement, construction, and testing of the SSCs of the facility. Such contractors are responsible for identifying, implementing, and verifying flow-down of quality requirements as applicable.

1.2.2.14 Subcontractors (Suppliers)

Subcontractors (Suppliers) are responsible for their portion of the execution of the design, fabrication, procurement, construction, and testing of the SSCs of the facility. Such contractors are responsible for identifying, implementing, and verifying flow-down of quality requirements as applicable.

Program Functional Structure

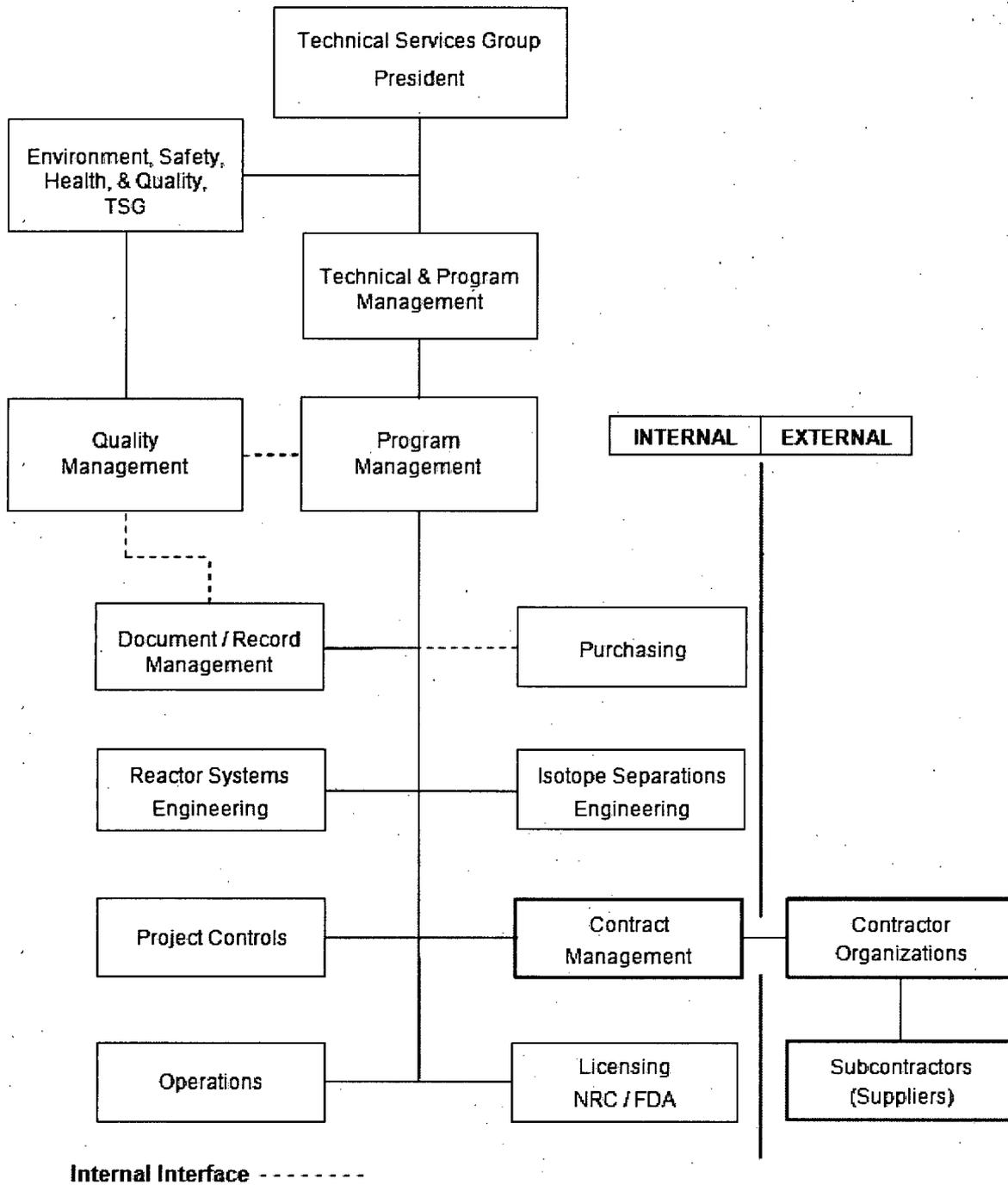


Figure 1

2.0 QUALITY ASSURANCE PROGRAM

2.1 Scope

This section describes the requirements for establishing, implementing, and managing the Quality Assurance Program (otherwise known as QAPD) for the MIPS Program. Its intent is to describe commitments to applicable requirements in ANSI/ANS 15.8-1995, "Quality Assurance Program Requirements for Research Reactors."

It encompasses the policies, processes, procedures, instructions, controlled documents, and quality records as applicable. This includes provisions for identifying activities that affect quality relating to the administrative and technical aspects internal and external to the overall MIPS Program.

To achieve the goals of defining and effectively designing SSCs, the MIPS Program implements the use of a "Graded Approach to Quality." This approach to achieving required levels of quality for SSCs is described in this QAPD and related implementing documents. The Quality Levels applied to SSCs are defined within three quality levels in accordance with Figure 2.

2.2 Requirements

2.2.1 The QAPD-based requirements will "flow-across" the organization and "flow-down" through the nuclear supply chain as determined by the applicable quality levels established by the MIPS Program Team.

2.2.2 The QAPD provides the basis for a planned and systematic approach to the cost-effective achievement of safety, quality, and reliability. The primary method to ensure this is the Quality Implementing Procedures (QIPs). The QIPs are delineated and managed in accordance with the MIPS Procedures Management procedure maintained by the Program Quality Manager with support from all team members.

2.2.3 The Program Manager, with support from all managers, establishes the requirements for indoctrination and training of personnel who perform activities that affect quality. This includes assuring that the procedures, tools, equipment, computer programs, and work practices identified in the implementing procedures are available and used by qualified, appropriately trained employees, and are maintained in a serviceable condition. Each manager is responsible for ensuring that training is provided and completed in their areas of responsibility. Documents and records associated with personnel training will be maintained in accordance with approved procedures.

2.2.4 The Program Quality Manager, with support from the Program Manager, will establish a schedule for planning and performing periodic internal and external assessments. Assessment results will be reported to program and TSG management in a fashion that ensures an understanding of program

performance and the need for any quality improvements. A formal presentation on program effectiveness will be presented to management annually.

2.2.5 Assessments and audits may be planned and performed by TSG qualified assessors or independent contractors or consultants as determined by the Program Quality Manager.

2.2.6 Personnel who perform special processes, inspection, test, surveillance, assessment, and audit activities must be qualified to appropriate requirements including those imposed by codes and standards. Management responsible for ensuring the performance of special processes, inspection, test, surveillance, and assessment, and audit activities shall define the qualification requirements in written procedures. Documentation of qualification results and maintenance of proficiency must be maintained as specified in appropriate codes, standards and regulations.

Graded Approach to Quality

A process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. The graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards.

The activities and tasks are performed in accordance with approved implementing procedures.

QL-1 shall implement the full measure of this QAPD and shall be applied to Safety-Related Structures, Systems, and Components.

QL-2 will include the quality activities performed by the licensee, generally on a continuing basis, that are applied to ensure the items are available and reliable to perform their safety functions when needed. These quality activities include configuration management, maintenance, training and qualifications, procedures, assessments, audits, incident investigations, records management, and other quality assurance elements. These quality activities are embodied in this QAPD and will be further specified in the preliminary and/or final safety analysis report as appropriate. QL-2 shall be applied to the design of structures, systems and components that are relied upon to limit:

- (1) the risk of nuclear criticality accidents with preventive controls and measures to ensure that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of sub-criticality for safety.
- (2) the likelihood of occurrence of an event so that, upon implementation, the event is highly unlikely or its consequences are less severe than those listed below:
 - An acute worker dose of 1.0 Sv (100 rem) or greater total effective dose equivalent (highly unlikely)
 - An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to the public (highly unlikely)
 - An intake to the public of 30 mg or greater of uranium in soluble form (highly unlikely)
 - An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or lead to irreversible or other serious, long-lasting health effects to the public (highly unlikely)
- (3) the likelihood of occurrence of an event so that, upon implementation, the event is unlikely or its consequences is less severe than those listed below:
 - An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent (unlikely)
 - An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to the public (unlikely)
 - An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could lead to irreversible or other serious, long-lasting health effects to a worker or mild transient health effects to the public (unlikely)
 - A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to Part 20 (unlikely)

QL-3 will include the quality activities performed in accordance with this QAPD as necessary and appropriate.

Figure 2

NOTE: See next page for definitions of Basic Component and Safety-related SSCs.

Safety-related Structures, Systems, and Components Means those structures, systems, and components that are relied upon to remain functional during and following design basis events to ensure:

- The integrity of the reactor coolant pressure boundary
- The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 10CFR50.34(a)(1)(i)

Basic Component Means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. This will be implemented under this QAPD consistent with the definition of Safety-related and QL-1.

Figure 2
(Continued)

3.0 DESIGN CONTROL

3.1 Scope

This section describes the requirements for establishing and implementing administrative and technical controls for all internal and external design activities that affect quality. Procedures will identify the process by which the control of design, preparation of design documents, technical reviews, design reviews and verification, review of calculations, control of software, and applicability of required rules, regulations, codes, and standards are implemented.

3.2 Requirements

The design organization is responsible for prescribing, developing, documenting and preserving the design of the structures, systems, and components of the reactor. Design Control activities shall be performed in accordance with procedures and generally consists of technical reviews, design reviews, and reviews of calculations, and control of software. As a part of design control, the design review program has been developed to meet the requirements of ANSI/ANS 15.8-1995.

The design organization is the primary design function with oversight by the quality organization.

3.2.1 Design Requirements

Design inputs and requirements, including design bases, performance requirements, regulatory requirements, codes and standards shall be identified and documented in the appropriate design requirements documents. Technical input shall be controlled to assure that design requirements include sound engineering principles.

3.2.2 Design Process

The design organization is responsible for identifying and procedurally controlling the internal and external design interfaces. The design organization is also responsible for coordination of design efforts among the interfacing organizations as detailed in applicable MIPS procedures. Interface controls will include the assignment of responsibility and establishment of implementing documents among the interfacing design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

The applicability of standardized or previously proven design, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effect on other features will be considered. Deviations from the established design inputs, including the reasons for the changes, shall be documented and controlled. The design process includes proper translation of input and

analyses into specifications, drawings, and other documentation to satisfy all design requirements. Responsibility for all design information and processing, including interfaces, verification, documentation and records shall be clearly designated in the design procedures.

The design organization shall ensure the final design is relatable to the design input by documentation in sufficient detail to permit design traceability and verification; and identify assemblies and/or components that are part of the item being designed. When a computer design program is used to develop portions of the facility design or to analyze a design for acceptability, that program will be controlled to ensure the correctness of its output. When a design program must be developed, the program will be controlled to assure that it is fully documented and validated. Where changes to previously valid computer programs are made, documented revalidation will be performed for the change. Appropriate benchmark testing will be required for verification of design-unique computer codes.

3.2.3 Design Verification

Independent design reviews will be used to verify adequacy of design by one or more of the following: (a) the performance of design reviews, (b) use of alternative calculations, (c) performance of qualification tests, or (d) comparison to similar proven systems. The responsible design organization will identify and document the particular design verification method or methods used. Design verification will be performed by competent individuals or groups other than those who performed the design, but whom may be from the same organization. In all cases the design verification will be completed prior to the reliance upon the component, system, structure, or computer program to perform its function in operations. Design verifications shall be commensurate with the complexity and importance of the work.

Where qualification or performance testing is used to verify design, the need for or the use of qualification tests will be defined in a formal test plan that will include appropriate acceptance criteria and will demonstrate the adequacy of performance under conditions that simulate the most adverse conditions expected based on design requirements. Test results will be documented and evaluated by the responsible design organization to assure that test requirements have been met.

3.2.4 Design Documents and Records

Design documents and records, which provide evidence that the design and design verification processes were performed, will be collected, stored, and maintained for the life of the item.

3.2.5 Commercial Grade Items

Use of a commercial-grade item in a safety-related application will be reviewed to assure that it can adequately perform its intended functions. Procedures will be developed to provide guidance on how to review and evaluate commercial grade items for suitability in applications covered by the QAPD. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the item will be represented and identified as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.2.6 Change Control

Procedures shall assure that modifications to facility structures, systems, components, or computer codes shall be based on a defined "as-exists" design. Changes to verified design will be documented, justified and subject to design control measures commensurate with those applied to the original design.

These design control measures will include assurance that the design analyses for the structure, system, component, or computer code are still valid. Where a significant design change is necessary, the design organization will review and modify the design process and review process as necessary. For the production portion of the facility, changes to the site, structures, procedures, systems, equipment, components, computer programs, and activities of personnel will adhere to the provisions of 10 CFR 50.59.

3.2.7 Change Control (Software)

Modifications to computer codes will go through a verification and validation process in accordance with approved procedures.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Scope

This section describes the requirements for procuring products and services in a manner that will ensure conformance to design bases documents, customer, regulatory, and industry requirements. This encompasses the administrative and technical aspects of the procurement process such as supplier selection and qualification; identification of deliverables; contract and purchase order preparation, review, approval, release; change control; document control; and audits on the effectiveness of suppliers performance.

4.2 Requirements

- 4.2.1 Responsibilities for the preparation, review, approval, release, and change control of procurement documents are defined in approved procedures.
- 4.2.2 Section 2.0, Figure 2, describes the quality levels for using the Graded Approach to Quality for items and services.
- 4.2.3 Purchase requisitions for items and services that can affect quality are routed to applicable personnel for review and approval. Changes made to purchase requisitions following initial approval, and purchase requisitions issued as change notices to such purchase orders, require the same level of approval as the initial document.
- 4.2.4 Changes to procurement documents as a result of bid evaluation or pre-award negotiations shall be incorporated in the procurement documents prior to award. Changes to procurement documents shall include the following considerations:
 - 1. Analysis of exceptions or changes requested or specified by the supplier.
 - 2. A determination of the effects these changes may have on the intent of the procurement documents or quality of the item or service to be supplied.
- 4.2.5 Procurement document reviews will be performed and documented by personnel who have access to the pertinent information and adequate understanding of the requirements and intent of the procurement documents.
- 4.2.6 Procurement documents shall contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser. The procurement documents at all levels shall identify the documentation required to be submitted for information, review, or approval by the purchaser. Also, documents required as deliverables as a part of design or other procurements will be specified for the supplier.

- 4.2.7 At each level of procurement, the procurement document shall provide for access to the supplier's plant facilities and records, for inspection or audit by program team members, a designated representative, or other parties authorized by the program team.
- 4.2.8 When applicable, the procurement documents shall include purchaser's requirements for the supplier to report nonconformances associated with the items or services being procured. This includes provisions for the purchaser to disposition nonconformances when required.
- 4.2.9 The procurement documents for safety-related items and services shall prohibit the supply of substandard or counterfeit parts and materials and shall invoke the requirements of 10 CFR, Part 21 on the supplier.

5.0 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

5.1 Scope

This section describes the requirements for ensuring that activities affecting quality are prescribed and performed in accordance with documented and approved procedures, instructions, or drawings. These documents, when required, will include references to appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily achieved.

5.2 Requirements

- 5.2.1 Activities affecting quality shall be performed in accordance with documented procedures, instructions, or drawings appropriate to the activity. These documents shall be prepared to define performance expectations along with the proper sequence and task steps to do the work. Copies of applicable and necessary procedures, instructions and drawings are available.
- 5.2.2 Procedures shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. These documents shall also include the proper level of detail for the application and meet stated content and format standards.
- 5.2.3 The Program Team is responsible for the adequacy of drawings prepared by all organizations including MIPS qualified suppliers. In cases where suppliers to MIPS are working to MIPS approved procedures, they will be available for reference at the points of use.
- 5.2.4 Document Control and the applicable managers are responsible for ensuring that the proper revision of procedures, instructions, and drawings are available at the point of use. Out-dated procedures, instructions, and drawings will be managed in accordance with the requirements in Section 6.0 and related approved procedures.

6.0 DOCUMENT CONTROL

6.1 Scope

This section describes the requirements for controlling the preparation, review, approval, issue, and change of controlled documents that contain information relating to the quality of items and services.

6.2 Requirements

- 6.2.1 Document Control procedures identify responsibilities for preparation, review, approval and issuance of controlled documents. They also include provisions for distribution, unique identification, and maintaining permanent records.
- 6.2.2 Document Control procedures include requirements to ensure documents are reviewed for appropriate content, completeness, accuracy, and that required approvals are obtained prior to initial issuance. Procedures shall provide for:
- Identification of documents to be controlled and specific distribution
 - Assignment of responsibilities for preparation, review, approvals, and document issuance
 - Review for adequacy, completeness, and correctness prior to approvals
- 6.2.3 Revisions to issued documents shall be reviewed and approved by the same organizations responsible for the activities and content in the original issue.
- 6.2.4 Lists and databases of the active (effective) revisions of controlled documents are maintained and accessible to all program personnel. All program personnel shall access the lists and databases when required to verify the proper revision is available or in effect prior to performing activities or related design work.
- 6.2.5 All program personnel will support activities associated with identifying completed documents that will be processed and managed as quality records in accordance with Section 17.0.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Scope

This section describes the requirements for ensuring that purchased items and services conform to procurement document specifications. Procedures define activities such as document preparation, supplier selection and evaluations, audits, approvals, and monitoring, control of nonconformances, and item or service acceptance and records.

7.2 Requirements

7.2.1 Supplier Selection

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents. Suppliers that provide items or services in accordance with this QAPD shall be evaluated and accepted by the quality organization prior to order placement. Results of evaluations and audits shall be available to B&W TSG management and program team members.

7.2.2 Supplier Approval

Procedures define the maintenance of an Approved Supplier List (ASL) which designates those suppliers who have been evaluated and approved. Evaluations and the basis for approval shall be documented. Suppliers of safety-related items or services are required to demonstrate adherence to an appropriate Quality Program or Quality System. Such suppliers are subject to the requirements of 10 CFR, Part 21.

7.2.3 Work Control

Work control planning and measures are used to control the supplier's performance as required. Controls may include test plans, review of supplier submitted documents, arrangements for source surveillance or inspection, and other technical and administrative interfaces with the supplier per procurement documents.

7.2.4 Verification Activities

The supplier retains responsibility for the quality of all supplied items and services and shall verify and provide evidence of meeting quality requirements. Supplier-generated documents shall be controlled, handled, and approved in accordance with established document control methods. Procedures will provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria. The quality organization provides source surveillance, audits, inspection and release of items as specified.

7.2.5 Acceptance

Acceptance of items or services from a supplier shall require methods to ensure conformance to procurement specifications. Acceptance methods will include a supplier Certificate of Conformance, Certificate of Compliance, source verification, receiving inspection, post-installation test, or a combination thereof. Procurement acceptance requirements for procured materials, parts, or components will be specified in procurement documents. The quality organization shall verify such requirements are included during procurement document reviews and implementation of requirements by means of supplier surveillance, audits, or receiving inspection.

Items may be accepted at the source if source surveillance or inspection is performed to confirm and document conformance with procurement specifications. Receiving inspections shall include instructions to verify by objective evidence that the purchasing specification requirements have been met.

Receiving inspection may include review of source inspection records, certificates of conformance, certificates of compliance, and inspection for configuration, identification, cleanliness, shipping damage, and attributes that indicate fraud or counterfeit items.

Where services only are provided, acceptance may include technical verification of data, surveillance of the activity or review of records resulting from the service.

7.2.6 Nonconforming Conditions

The handling of nonconformances, identified by the supplier or by source or receiving inspection, is defined in Section 15.0 and approved Control of Nonconforming Items procedures.

7.2.7 Reporting of Defects and Noncompliance (10CFR, Part 21)

Safety-related items and services are subject to the reporting requirements as delineated in 10 CFR Part 21 Reporting of Defects and Noncompliance. This includes provisions for imposing the requirements for Part 21 reporting to applicable suppliers.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 Scope

This section describes the requirements for ensuring that items, including supplies, parts, components, materials, and equipment are identified and only acceptable items are used for the intended application.

8.2 Requirements

- 8.2.1 When specified by codes, standards, or specifications that include specific identification or traceability requirements, the item identification and control process shall be capable of providing identification and traceability control. Procedures shall require that identification is maintained through permanent markings or other techniques to preclude the use of incorrect items. All items are identified in a manner assuring traceability to appropriate specifications, drawings, inspection documents or other records.
- 8.2.2 Items' identification shall be maintained from the initial receipt or fabrication of the items up to and including installation and use. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be used.
- 8.2.3 Where markings are placed on the item, the marking materials and application method shall be selected to assure they do not detrimentally affect the function or life of the item. Markings shall be transferred to each part of an identified item when the item is subdivided, and shall not be obliterated or hidden by surface treatment or coatings unless substitute means are provided.
- 8.2.4 Items having limited shelf life shall be defined in appropriate specifications. Procedures shall be prepared, where necessary, to establish controls for assuring that items are not used beyond specified time limits.
- 8.2.5 Procedures shall be prepared to define the release, movement and use of controlled items, including procured items. Unacceptable items, or those whose status is indeterminate, are held from processing as defined in Section 15.0.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Scope

This section describes the requirements for ensuring certain processes in which the results are highly dependent on the control of the process or the skills of personnel. These are processes for which the specified quality cannot be readily determined by inspection or non-destructive testing of the item. They are performed by or for the program using qualified personnel and procedures.

9.2 Requirements

- 9.2.1 Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Process control documentation will define the steps necessary to perform, qualify, and document special processes. The quality organization shall review and approve all special process procedures.
- 9.2.2 Process controls used for special processes shall include the requirements of applicable codes and standards necessary to accomplish the process as well as acceptance criteria to establish validity of the completed item or service.
- 9.2.3 Records of process control documentation and personnel qualification shall be maintained by the cognizant organization to which the qualification is applicable. They shall be reviewed periodically for compliance to current codes, standards or other requirements.
- 9.2.4 Records of special process operations and inspections shall be maintained with all other program records. These records shall describe the activity performed and provide data regarding the process parameters and the identification of the item involved.
- 9.2.5 Suppliers performing special processes are responsible for adhering to the required procedures and shall be evaluated for compliance with process requirements. Only suppliers with an approved special process controls program may be used to perform special processes.
- 9.2.6 The organization responsible for the special process is also responsible for training and qualifying personnel and for qualifying the process to the extent necessary to satisfactorily perform the process. The quality organization verifies the proper execution of these qualifications.

10.0 INSPECTIONS

10.1 Scope

This section describes the inspection requirements for verifying compliance with quality requirements. Inspections are planned and performed consistent with the complexity of the item or service as defined by the applicable quality level. Inspections verify and document compliance with program requirements and with applicable codes, standards and specifications.

10.2 Requirements

- 10.2.1 The quality organization has the responsibility to specify and perform inspection or to delegate implementation of the inspection to others under proper internal or supplier controls. The inspection program shall apply to procurement, fabrication, modification, construction, and maintenance. B&W does not intend to use the reactor for experiments (see Section 19.0).
- 10.2.2 Inspection shall be performed by personnel who are independent of those performing the work being inspected, but may be from the same organization, and shall be qualified as specified in applicable procedures. The need for formal inspector training is determined and provided as required to qualify inspection personnel.
- 10.2.3 On-the-job training is provided as required to ensure inspectors understand required inspection criteria and methods. Records of inspection personnel's qualification shall be established and maintained by the responsible organization.
- 10.2.4 Inspection plans may be documented in the form of outlines, drawings, procedures, instructions, checklists, procedural steps or other documents as appropriate. Plans for inspections resulting from requirements in program documents shall be prepared by responsible program personnel and shall be approved by the quality organization. Inspection plans resulting from quality requirements shall be generated by the quality and engineering organizations.
- 10.2.5 Measuring and Test Equipment (M&TE) used to perform inspections shall be identified in inspection documentation for traceability of inspection results.
- 10.2.6 Inspection of items in-process or under construction shall be performed for work activities where product quality cannot be determined by inspection of the completed product. Control of these activities may include inspection hold points or in-process monitoring or both. Procedures shall define the extent and acceptance criteria for monitoring as required. Hold points and inspection points shall be established in procedures or other work sequence documents as required. The quality organization is responsible to perform the hold point

inspection and/or to perform any required inspections necessary to release acceptable items for further processing.

- 10.2.7 Final inspection acceptance criteria of completed items or services shall be identified in specifications, procedures or other applicable documents and include inspection for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. Inspection results and records, which constitute product or service quality and/or conformance for acceptance, shall be documented and approved by authorized personnel. Acceptance documents shall be reviewed and/or assessed by the quality organization.
- 10.2.8 Where sampling methods are used to verify acceptability, the quality organization, or others designated by the quality organization, are responsible to establish statistically sound sampling plans and to document the results of the sample inspections. Use of control charts for process acceptability also requires quality organization review and approval.
- 10.2.9 Only items that have passed the required inspections and tests shall be used, installed, or operated.

11.0 TEST CONTROL

11.1 Scope

This section describes the requirements for ensuring that tests conducted by the program are performed in accordance with procedures which specify specific test methods, acceptance criteria, and documentation requirements to be in conformance with applicable specifications.

11.2 Requirements

- 11.2.1 Organizations having responsibility for the item or service shall designate any tests required to verify conformance to program, regulatory or internal requirements. Designation includes identification of test procedures, equipment, acceptance criteria and documentation. Testing shall include prototype qualification tests, proof tests prior to installation, and functional tests.
- 11.2.2 Testing shall be required to verify conformance of designated structures, systems, or components to specified requirements, and demonstrate satisfactory performance for service, or to collect data in support of design or fabrication.
- 11.2.3 Test procedures shall include acceptance criteria, prerequisites, instrumentation, and any required environmental conditions required. In lieu of incorporating the above information directly in the text of the procedure, the procedure may reference requirements from related documents, such as ASTM methods, supplier manuals, equipment instructions, or drawings.
- 11.2.4 Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. Implementing procedures are used to identify and document the responsible authority.
- 11.2.5 Tests conducted by suppliers shall be specified in procurement documents. Only suppliers whose test control programs have been approved by engineering and quality may perform such testing.
- 11.2.6 Testing, which involves special qualification of the test process or operators, is controlled as described in Section 9.0.
- 11.2.7 Computer programs used for a control function or process shall be tested in accordance with an approved verification and validation plan, and shall demonstrate required performance over the range of operation of the controlled function or process.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Scope

This section describes the requirements for controlling and calibrating Measuring and Test Equipment (M&TE) which directly affect the quality of results for the item or service. M&TE shall be controlled and calibrated in accordance with documented procedures. Calibrations shall be traceable to NIST, nationally or internationally recognized standards organizations, or generally accepted natural source or physical phenomena. If such standards are not available, the basis for utilization of an alternate standard must be documented.

12.2 Requirements

- 12.2.1 Each organization using equipment shall also be responsible for calibration and control of that equipment.
- 12.2.2 Instruments shall be uniquely identified by serial number or other designation to ensure traceability to calibration data and standards. Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.
- 12.2.3 Out-of-calibration devices shall be tagged, segregated or otherwise withheld from use, as defined by procedure. Repaired or refurbished instruments shall be calibrated prior to use.
- 12.2.4 Recall methods shall be defined by procedure to ensure that calibrations are timely and that out-of-calibration instruments are not used in critical operations.
- 12.2.5 When an instrument or gage has been used to accept products and is subsequently found to be out-of-calibration, an evaluation shall be made to determine the validity of the product previously accepted. The results shall be documented, then reviewed and approved by the quality organization. In some cases, review and approval by engineering may be required.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 Scope

This section describes the requirements for handling, storage, and shipping of items.

13.2 Requirements

- 13.2.1 When required for particular items or designated by the Program Manager, written procedures shall be prepared for the handling, storage, and shipping of certain items, including hazardous materials. These procedures, and use of qualified operators when required by these procedures, shall be used to ensure safe and adequate handling and prevent damage or inadvertent release of contamination or hazardous material.
- 13.2.2 Storage of both end products and materials generated during services shall be done in a manner to prevent damage or degradation. Procedures shall be generated to define storage requirements.
- 13.2.3 Procurement documents and procedures shall include all applicable state and federal requirements and specifications for handling, storage and shipping requirements when applicable. Handling, storage, and shipping of items shall be in accordance with Program work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents for container inspection, load securing, labeling, document preparation and other factors including special environmental considerations for critical shipments such as hazardous materials.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 Scope

This section describes the requirements for ensuring that procedures for processing of components and materials, or performing services, include provisions for the identification of required inspections and tests, and their appropriate status.

14.2 Requirements

- 14.2.1 Requirements for appropriate tests and inspections are set forth in procedures, specifications or other controlled documents applicable to the item or service. Requirements shall include the type of identification (tagging, marking, stamping, recording, etc.) and the authority to apply and remove such identification.
- 14.2.2 The quality organization is responsible to monitor or conduct all inspections or tests and to review appropriate test and inspection data to assure acceptability.
- 14.2.3 Unacceptable items, or those whose status is indeterminate, are identified and controlled to ensure they are not inadvertently installed, used or operated as defined in Section 15.0.

15.0 CONTROL OF NONCONFORMING ITEMS AND SERVICES

15.1 Scope

This section describes the requirements for the identification, segregation, and disposition of nonconforming items or services to prevent their use or application.

15.2 Requirements

- 15.2.1 Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. Procedures shall identify those organizations whose approval is required to disposition nonconformances. During the time the disposition is indeterminate, the material, service, or equipment shall be marked, tagged or otherwise identified and, where practicable, segregated and/or otherwise controlled to prevent inadvertent use.
- 15.2.2 The responsible design organizations shall review the nonconforming item and recommended disposition where a design characteristic has been violated. The disposition (use as-is, reject, repair, or rework) of nonconforming items shall be identified and documented. Quality organization approval is required for all dispositions. All dispositions and technical justifications for acceptance of a nonconforming item dispositioned "repair" or "use-as-is", shall be documented in appropriate forms and records.
- 15.2.3 Nonconformance to design requirements of items dispositioned "use as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design (see Section 3.0). Repaired/reworked items or modified systems shall be inspected or tested to assure compliance with the original requirements unless alternate criteria have been established by the responsible organization during disposition of the nonconformance. As-built records shall reflect any accepted deviation of original criteria.
- 15.2.4 The quality organization is responsible to assure that all nonconformances have been properly documented, dispositioned by organizations and personnel who are competent in the areas they evaluate, and that dispositions are properly implemented and closed-out. Nonconforming conditions will also be evaluated to determine the need for reporting to appropriate regulatory agencies.
- 15.2.5 Suppliers of items or services shall be required by purchase order or contract to report nonconformances for disposition.
- 15.2.6 The quality organization shall periodically review nonconformance data to determine if trends adverse to quality are being developed. Reports of these reviews shall be sent to responsible management.

16.0 CORRECTIVE ACTIONS

16.1 Scope

This section describes the requirements for identifying corrective action, taking necessary process steps, and preventing recurrence of conditions adverse to quality associated with equipment, services, operations, or data.

16.2 Requirements

- 16.2.1 Conditions adverse to quality shall be identified promptly and corrected as soon as practical. Identification of the need for corrective action will be made through review of nonconformances, inspection, surveillance, audit / assessment reports, or specific incidents, which occur during the program. Corrective actions shall be in accordance with the design requirements unless those requirements were faulty.
- 16.2.2 The need for corrective action can be identified during the performance of any activity. The need is made to the group responsible for the area of concern through corrective action reports, which describe the problem and require response.
- 16.2.3 In the case of a significant condition adverse to quality, the cause of the condition shall be investigated and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. The quality organization will verify implementation of corrective actions.
- 16.2.4 General status of the corrective action process shall be reported routinely by the Program Quality Manager to all organizations involved, including Company management.

17.0 QUALITY RECORDS

17.1 Scope

This section describes the requirements for the preparation, collection, retention, and retrieval of quality records, which demonstrate the quality of items and services. Procedures and other program-specific requirements specify which documents are considered quality records for managing in accordance with the requirements of this Section.

NOTE: Quality Records are completed controlled documents that furnish evidence of the quality of items or services, or both, affecting quality. Records may include plans, drawings, specifications, procedures, and processed documents such as radiographs, photographs, negatives, or microforms.

17.2 Requirements

- 17.2.1 The records management system shall be defined, implemented, and managed in accordance with written procedures, instructions, and supporting documents. The records shall include as a minimum: inspection and test results, results of quality assurance reviews, quality implementing procedures, and engineering reviews and analyses in support of designs or changes and modifications. Process outlines, work plans, procurement documents, inspection/test procedures and other appropriate written instructions shall identify the records to be generated.
- 17.2.2 Records so specified must be legible, accurate and completely identify the item or service they represent. Records are required to be signed and dated or otherwise validated to ensure their authentication prior to completion and acceptance as a quality record.
- 17.2.3 Some records will be maintained by or for the Program for the life of the item while it is installed or stored for future use. Such records shall be classified in accordance with the following criteria: (a) those which would be of value in demonstrating capability for safe operation; (b) those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item; (c) those which would be of value in determining the cause or results of an accident or malfunction of a Safety-related item; (d) those which provide required baseline data for in-service inspections; or (e) those which would be of value in planning for facility decommissioning.
- 17.2.4 Other records may be retained for a shorter period as determined by the responsible organization or the Document / Record Manager. Retention shall be specified in procedures or other documents unique to the program. The Program procedures define methods for indexing, distribution, classification and storage of quality records.

17.2.5 Program quality records shall be stored in a location or locations that prevent damage from moisture, temperature, pestilence, and fire. Additional provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. Records maintained by a supplier shall be accessible to the Company and other applicable subcontractors.

18.0 ASSESSMENTS

18.1 Scope

This section describes the requirements for implementing a formal Quality Assessment Program to verify compliance with quality requirements. Assessments are conducted for internal activities and for contracted work on quality-related items and services. Results from the assessment program shall be made available to B&W TSG management and suppliers as applicable.

18.2 Requirements

18.2.1 The quality organization has the responsibility to establish the overall assessment program with input from other groups. Formal internal and supplier assessments shall be scheduled and updated based on periodic reviews to assure that the program activities are adequately covered and that new activities and/or new suppliers are included as required.

Internal assessments are normally scheduled to cover each QAPD Section once a year. The frequency may be increased or decreased at the discretion of the Program Quality Manager based on the status, importance, or previous history of functions and activities. Inspection results, surveillance results, and results of assessments performed by others may also be considered.

18.2.2 Periodic assessments of activities that affect safety-related aspects of the MIPS Program during design, construction, or modification shall be conducted to determine the effectiveness of the quality program. Procedures shall be established to define the methods required for planning, documenting, conducting, and reporting results of assessments.

18.2.3 Lead Assessors shall be selected and qualified on the basis of knowledge and experience. Procedures shall define minimum requirements for Lead Assessors and specify qualification record requirements. The Lead Assessor shall have the capability to communicate effectively, both in writing and orally. They are responsible for assuring that Assessment Team members are independent of direct responsibility in the areas they are assigned to assess. Personnel selected for assessment assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be assessed.



- 18.2.4 Assessments shall be performed in accordance with plans which provide for notification of the organization(s) and activities to be assessed, and identify the assessment scope and applicable documents to be used. The Assessment Team Leader is responsible to assure proper preparation, notification, performance, reporting, and follow-up.
- 18.2.5 Requirements to be assessed shall be evaluated against specific commitments. Results shall be documented and presented to the management responsible for the assessed function or activities or, to the supplier's management as applicable. Any conditions significantly adverse to quality shall be addressed for immediate corrective action.
- 18.2.6 Assessment results shall be formally reported in accordance with the quality implementing procedures. Responses are required in a reasonable period of time. The Lead Assessor is responsible to assure that response time is satisfactory, that corrective action is adequate to prevent recurrence, and that follow-up is provided and completed.
- 18.2.7 Management of the assessed function or activity shall investigate adverse findings, schedule corrective action (including measures to prevent recurrence), and notify the quality organization in writing of planned action or action taken. The adequacy of the responses shall be evaluated by the Program Quality Manager.
- 18.2.8 The Program Quality Manager shall periodically review assessment results, including responses and follow-up, to determine if trends adverse to quality are developing and to evaluate the overall adequacy of the assessment program.
- 18.2.9 Assessment records include assessment plans, reports, written replies, and the record of completed corrective action.

19.0 EXPERIMENTAL EQUIPMENT

As a commercial facility, MIPS will not have experimental equipment or facilities and they are not described in the license and safety analysis report. Changes, tests, and experiments will be managed according to 10CFR50.59.

**APPENDIX A
REFERENCES**

1.	10CFR50, Domestic Licensing of Production and Utilization Facilities, as applicable
2.	10CFR, Part 21, Reporting of Defects and Noncompliance
3.	ANSI/ANS 15.8-1995 (R2005), Quality Assurance Program Requirements for Research Reactors
4.	Regulatory Guide 2.5, 1997, Quality Assurance Program Requirements for Research Reactors.
5.	NUREG-1537, Part 1, February 1996, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors <i>Format and Content</i>
6.	NUREG-1537, Part 2, February 1996, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors <i>Standard Review Plan and Acceptance Criteria</i>

**APPENDIX B
REVISION HISTORY**

Revision	Effective Date	Description
0	10/11/07	Original Release
1	07/23/09	Revised plan to incorporate ANSI/ANS 15.8-1995 requirements and a definition of safety-related.
2	05/17/10	Made clarifications in Introduction, Added Scope, Applicability, Quality Policy, Appendices A and C. Revised Sections 1.0, 2.0, 3.0, 4.0, 7.0, 15.0, 16.0, 17.0, 18.0 and Figure 1. Added Figure 2 "Graded Approach" and related content. Incorporated MIPS Team review comments.
3	10/18/10	Additions and revisions are incorporated based on B&W Responses to the NRC's Request for Additional Information letter 09.22.10 (TAC NO. ME4101) - see vertical lines in the margin. The detailed Record of Revisions document is maintained electronically in SharePoint and the original hardcopy is maintained in the MIPS Document Control file.

APPENDIX C TERMS AND DEFINITIONS

Assessment A planned and documented activity performed to determine by evaluation of objective evidence the adequacy of activities affecting quality and effectiveness of program implementation as established in procedures, instructions, drawings, and other applicable documents.

NOTE: Applicable to activities and tasks associated with QAPD Section 18.0.

Audit A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. (Source: ASME NQA-1, 400 Terms and Definitions.)

NOTE: Applicable to activities and tasks associated with QAPD Sections 4.0 and 7.0.

Approved Suppliers List A listing of suppliers who have been evaluated and approved as sources of supply for specific items and services required for nuclear safety-related procurement.

Basic Component (Figure 2)

Certificate of Compliance A written statement, signed by a qualified party, attesting that the items or services are in accordance with specified requirements and accompanied by additional information to substantiate the statement.

Certificate of Conformance A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

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

Commercial Grade Item Means an item that is:

- (1) Not subject to design or specification requirements that are unique to those facilities or activities;
- (2) Used in applications other than those facilities or activities; and
- (3) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

Commissioning The process during which constructed reactor structures, components, and systems are made operational and verified to meet design requirements.

Compliance Conformance to a code, specification, or procedure.

Computer Program A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions.



Configuration The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

Contractor Any person, partnership, company, or corporation (or any combination of these) that furnishes a product or service to B&W.

Corrective Action Measures taken to rectify conditions adverse to quality and, where necessary, to prevent repetition.

Design A conceptual activity of planning a component or system.

Design Bases The information that identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be:

- a. Restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals; or
- b. Requirements derived from analysis (based on calculations or experiments, or both) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

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

Design Input The physical and performance requirements of a device that are used as a basis for design of the device. Design Inputs typically include, but are not limited to, customer and regulatory requirements, patent and technology licensing, and product/process capabilities and reliability.

Design Output The results of a design effort at each phase. Design Outputs typically include, but are not limited to, drawings, specifications, and other documents used to define technical requirements of structures, system, components, and computer programs.

Design Process Technical and management processes that commence with identification of design input and lead to the issuance of design output documents.

Deviation A departure from specified requirements that is authorized Prior To the start of the process or work.

Disposition The action taken to resolve a nonconforming condition and to restore acceptable conditions.

Document Any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality record until it has been validated by an authorizing source as a quality record.

Controlled Documents – Documents that must be controlled using methods to ensure traceability to source references, originating organizations, and any other information required to "reconstruct the chain of events" for forensic or general compliance evaluations.

Document Control The act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

Finding Result of an assessment or audit against requirements that requires corrective action.

Graded Approach to Quality using QL1, QL2, QL3 (see Figure 2)

Guideline A suggested practice that is not mandatory in programs intended to comply with a Standard. The word “should” denotes guidance; the word “shall” denotes a requirement.

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.

Independent Design Review A critical review to provide assurance that the final design is correct and satisfactory.

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

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

Measuring and Test Equipment (M&TE) Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Nonconformance A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective Evidence Any documented statement of fact, other information, or record, quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Procedure A document that specifies or describes how an activity is to be performed.

Quality The degree to which an item or process meets or exceeds the user's requirements and expectations. (Simple: Conformance to Requirements)

Quality Assurance (QA) Those planned and systematic actions necessary to provide adequate confidence that the structure, system, or component will perform satisfactorily in service.

Quality Control (QC) Those actions that provide a means of control and measure of the characteristics of an item, process, or facility to established requirements (inspection or source surveillance, or both).

Quality Management (QM) That aspect of the overall management function that determines and implements quality policy. Quality management includes strategic planning, allocation of resources, and systematic activities for quality such as quality planning, operations, and evaluation.

Quality Policy The overall quality intentions and direction of an organization regarding quality as formally expressed by top management.

Quality Records The completed controlled documents that furnish evidence of the quality of items or services, or both, affecting quality. Records may include plans, drawings, specifications, procedures, and processed documents such as radiographs, photographs, negatives, or microforms.



Quality System The organizational structure, processes, procedures, and resources needed to implement quality management goals, objectives, and requirements.

Request for Additional Information (RAI) The term used by the Nuclear Regulatory Commission to communicate a formal request for information from a license applicant or licensee.

Safety-related Structures, Systems, and Components (Figure 2)

Shall, Should, Will The word "**shall**" and "**will**" are used to denote a requirement; the word "**should**" to denote a recommendation.

Service The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

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, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier Any individual or organization that furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, and consultant, and their sub-tier levels.

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 a set of physical, chemical, environmental, or operating conditions.

Use-As-Is A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

Validation The process of evaluating hardware, software, data, or information to ensure compliance with stated requirements.

Verification Review of documentation to determine that it has been correctly prepared and the information is complete. Review of selected quality data (radiographs, NDE results, heat treatment charts, etc.). Witnessing of certain steps in the fabrication process, such as metallurgical tests, hydrostatic or performance tests, fit-up of sub-assemblies, and other steps as identified in the procurement package.

Witness To observe a specific test or work operation that includes sign-off responsibility.