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MIPS-PP-QA-14-R3-A
TAC NO. ME4101

August 16, 2011

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Subject: Babcock & Wilcox Technical Services Group, Inc., NRC Project 766 (TAC NO. ME4101), Submittal of the Published B&W TSG Nuclear Topical Report No. MIPS-PP-QA-14-R3-A, Medical Isotope Production System, Quality Assurance Program Description, Revision 3

References:

1. Reynolds, W. E., B&W Technical Services Group, Inc., letter dated June 4, 2010 and Quality Assurance Program Description (QAPD) Topical Report, MIPS-PP-QA-14, Revision 2, Enclosure 1, Abstract Enclosure 2, and Basis for submittal of the Topical Report Enclosure 3," dated May 17, 2010, to Document Control Desk, NRC, ADAMS Accession Number ML 101600197.

2. Voth, Marcus H., NRC, letter to Reynolds, W. E. dated September 22, 2010, "Request for Additional Information Regarding the Babcock & Wilcox Technical Services Group, Inc. Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 2."

3. Glenn, D. E., B&W Technical Services Group, Inc., letter to Document Control Desk, NRC, "B&W Response to Request for Additional Information Regarding Quality Assurance Program Description Submitted June 4, 2010," dated October 18, 2010, ADAMS Accession Number ML 102990311.

4. Glenn, D. E., B&W Technical Services Group, Inc., Quality Assurance Program Description (QAPD), Revision 3," dated October 18, 2010 to Document Control Desk, NRC, "B&W Response to Request for Additional Information Regarding Quality Assurance Program-Enclosure 1, Revision 2, ADAMS Accession Number ML 103990312.

5. Jolicoeur, J. R., NRC letter to Reynolds, W. E. dated May 6, 2011, "Draft Safety Evaluation for Babcock & Wilcox Technical Services Group, Inc., Medical Isotope Production System, Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 3," (TAC NO. ME4101).

6. Jolicoeur, J. R., NRC Safety Evaluation to Reynolds, W. E. dated May 6, 2011, "Draft Safety Evaluation for Babcock & Wilcox Technical Services Group, Inc., Medical Isotope Production System, Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 3," (TAC NO. ME4101).

7. Glenn, D. E. (S.W. Schilthelm for), B&W Technical Services Group, Inc. letter to Document Control Desk, NRC, dated June 6, 2011, "Draft Safety Evaluation Report for Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 3."

8. Nelson, Robert A., NRC letter to Glenn, D. E., Final Safety Evaluation for Babcock & Wilcox Technical Services Group, Inc., Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14-R3-A, Revision 3, (TAC NO. ME4101).

By letter dated June 6, 2010 (Reference 1), Babcock & Wilcox Technical Services Group, Inc. (B&W) submitted its Medical Isotope Production System (MIPS) Quality Assurance Program Description Topical Report (QATR), MIPS-PP-QA-14, Revision 2, dated May 17, 2010, to the U.S. Nuclear Regulatory Commission (NRC) for review and approval.

Q004
NRR

By letter dated September 22, 2010 (Reference 2), the NRC Staff submitted to B&W a Request for Additional Information (RAI). By letter dated October 18, 2010 (References 3 & 4), B&W submitted Revision 3 to the QATR, as an enclosure to its response to the NRC staff's RAI.

By letter dated May 6, 2011 (References 5 & 6), an NRC letter and draft Safety Evaluation (SE) regarding NRC approval of MIPS-PP-QA-14, Revision 3, was provided for B&W review and comment. By letter dated June 6, 2011 (Reference 7), B&W submitted comments to the NRC on the draft SE. As discussed via teleconference between B&W and NRC staff on June 22, 2011, the B&W comments were addressed and verbally resolved.

By the letter dated July 12, 2011 (Reference 8), the NRC Staff issued its final Safety Evaluation (SE) for B&W's MIPS QAPD Topical Report (TR) and accepted it for referencing in a licensing application. The NRC letter requested that B&W publish the accepted version of the TR within three (3) months of receipt of the July 12, 2011 letter, in accordance with the guidance provided on the NRC website. The guidance provided on the NRC website states, in pertinent part, under the heading entitled "Publication of Approved Reports," "After the NRC accepts a topical report for referencing in a licensing application, the sponsoring organization must publish the approved report and submit [it] to the NRC. This organization inserts NRC's transmittal letter and evaluation and all requests for additional information and their responses immediately after the title page...."

Accordingly, this letter submits the published Topical Report MIPS-PP-QA-14-R3-A, "Quality Assurance Program Description (QAPD), Revision 3. The published TR is enclosed and in accordance with the direction in the July 12, 2001 NRC letter and the guidance provided on the NRC website. The enclosed TR incorporates the July 12, 2011 letter and the enclosed SE after the title page, and also contains historical review information in the form of letters to the NRC, including the NRC request for additional information and B&W's response. If future changes to the NRC's regulatory requirements affect the acceptability of the TR, B&W will revise the TR appropriately, or justify its continued applicability for subsequent referencing.

If you have questions or need additional information, please contact me at 434-522-6313.

Sincerely,

Daniel E. Glenn	Paul W. Gladieux	Steve W. Schilthelm
MIPS Program Manager &	Program Quality Manager	Licensing Manager
CTO, Acting, B&W TSG	B&W TSG	B&W TSG

Enclosure
Babcock & Wilcox Technical Services Group, Inc., NRC Project 766, Nuclear Topical Report No. MIPS-PP-QA-14-R3-A, Medical Isotope Production System, Quality Assurance Program Description, Revision 3, TAC NO. ME4101. B&W TSG Document ID numbers: MIPS-02FC-QAPD-00001, MIPS-02FC-QAPD-00002, MIPS-02FC-QAPD-00003, MIPS-02FC-QAPD-00004, MIPS-02FC-QAPD-00005, MIPS-02FC-QAPD-00006, and MIPS-02FC-QAPD-00007.

cc: Marcus Voth, NRC – electronic via e-mail
Ossy Font, NRC – electronic via e-mail
Steve W. Schilthelm, B&W
Paul W. Gladieux, B&W
Erik T. Nygaard, B&W
B&W TSG MIPS Records, MIPS-PP-QA-14-R3-A

pwg / sws

Babcock & Wilcox
Technical Services Group, Inc.

MEDICAL ISOTOPE PRODUCTION SYSTEM

Quality Assurance Program Description

Topical Report

MIPS-PP-QA-14-R3-A

October 18, 2010

Revision 3

Prepared by
Paul W. Gladieux
MIPS Program Quality Manager

Approved by
Dave W. Zeff
Director, Environment, Safety, Health, and Quality, B&W TSG

Approved by
Daniel E. Glenn
MIPS Program Manager

Approved by
Ross T. Thomas
MIPS Chief Technical Officer
Technical and Program Management

MIPS-02FC-QAPD-0001
(14)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 12, 2011

Mr. D. E. Glenn
Program Manager, Medical Isotope Production System (MIPS)
Babcock & Wilcox Technical Services Group, Inc.
800 Main Street
Lynchburg, VA 24504

SUBJECT: FINAL SAFETY EVALUATION FOR BABCOCK & WILCOX TECHNICAL SERVICES GROUP, INC. MEDICAL ISOTOPE PRODUCTION SYSTEM QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT, MIPS-PP-QA-14, REVISION 3 (TAC NO. ME4101)

Dear Mr. Glenn:

By letter dated June 4, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML101600197), Babcock & Wilcox Technical Services Group, Inc. (B&W) Medical Isotope Production System (MIPS) submitted its Quality Assurance Program Description Topical Report (QATR), MIPS-PP-QA-14, Revision 2, dated May 17, 2010, to the U.S. Nuclear Regulatory Commission (NRC) for review. By letter dated October 18, 2010 (ADAMS Accession No. ML102990312), B&W submitted Revision 3 to the QATR, as an enclosure to its response to the NRC staff's request for additional information.

By letter dated May 6, 2011, an NRC draft safety evaluation (SE) regarding our approval of MIPS-PP-QA-14, Revision 3, was provided for your review and comment. By letter dated June 6, 2011, B&W commented on the draft SE. As discussed via teleconference between B&W and NRC staff on June 22, 2011, the B&W comments have been addressed in the final SE enclosed with this letter.

The NRC staff has found that MIPS-PP-QA-14, Revision 3, is acceptable for referencing in licensing applications to the extent specified and under the limitations delineated in the TR and in the enclosed final SE. The final SE defines the basis for our acceptance of the TR. Our acceptance applies only to material provided in the subject TR. We do not intend to repeat our review of the acceptable material described in the TR. When the TR appears as a reference in license applications, our review will ensure that the material presented applies to the specific plant involved. License amendment requests that deviate from this TR will be subject to a plant-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that B&W publish the accepted version of this TR within three months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed final SE after the title page. Also, it must contain historical review information, including NRC requests for additional information and your responses. The accepted version shall include an "-A" (designating "accepted") following the TR identification symbol.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, B&W and/or licensees referencing it will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

Sincerely,

Robert A. Nelson, Deputy Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 766

Enclosure: Final SE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

FINAL SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

TOPICAL REPORT MIPS-PP-QA-14, REVISION 3

"MEDICAL ISOPTOPE PRODUCTION SYSTEM

QUALITY ASSURANCE PROGRAM DESCRIPTION"

BACOCK & WILCOX TECHNICAL SERVICES GROUP, INC.

PROJECT NO. 766

1.0 INTRODUCTION AND BACKGROUND

By letter dated June 4, 2010 (Reference 1), as supplemented by letter dated October 18, 2010, (Reference 2), in response to the U.S. Nuclear Regulatory Commission (NRC) staff's requests for additional information (RAIs) (Reference 3), Babcock & Wilcox Technical Services Group, Inc. (B&W) submitted its Medical Isotope Production System (MIPS) Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, (hereafter referred to as the Quality Assurance Topical Report (QATR)) for NRC review and acceptance in accordance with the provisions of Section 50.34(a)(7) of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). This final safety evaluation is in reference to B&W's submittal of Revision 3 to the QATR (Reference 4).

2.0 REGULATORY EVALUATION

Based upon a determination by the NRC staff, B&W's facility will be licensed under the Commission's regulatory requirements related to quality assurance (QA) programs set forth in 10 CFR 50.34(a)(7), as a production and utilization facility, classified as a non-power reactor, and require both construction and operating authorization. This regulation requires a description of the QA program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility. The NRC reviews the proposed QATR for acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction, and operation of a facility's SSCs. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

ENCLOSURE

3.0 TECHNICAL EVALUATION

3.1 Background

The proposed QATR was developed with the purpose of meeting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1, "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria," Section 12.9, "Quality Assurance."

The proposed QATR is organized into 18 basic sections corresponding to the quality requirements delineated in Appendix B to 10 CFR Part 50 and is responsive to both Appendix B, as applicable, and the regulatory guidance set forth in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors," Revision 1. Regulatory Guide 2.5 endorses American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.8, "Quality Assurance Program Requirements for Research Reactors."

3.2 Evaluation

The NRC staff evaluated the adequacy of the QATR in describing how the relevant requirements of Appendix B to 10 CFR Part 50 will be satisfied. The format, content, and acceptance criteria of the QATR were evaluated in accordance with the guidance of NUREG-1537, Parts 1 and 2, Section 12.9, which provides a basis for NRC staff review of QA programs based on ANSI/ANS 15.8. The acceptability of the level of detail provided by the QATR is determined, in part, by its adequacy in addressing the acceptance criteria of NUREG-1537, Parts 1 and 2, Section 12.9.

3.2.1 Format and Content of the QATR

The format used for the following evaluation follows the sequence of the 18 criteria of Appendix B and corresponding provisions of ANSI/ANS 15.8. The content of the QATR provides guidance for establishing a top-level policy document that defines the quality requirements and assigns major functional responsibilities. The B&W QATR can be used for engineering, design, procurement, fabrication, experiments, construction, and testing for the applicant's activities affecting the quality and performance of safety-related SSCs. In addition, the QATR applies a graded approach to the extent commensurate with the SSC's importance to safety. It is incumbent upon the applicant to identify the specific QA requirements that must be met for the scope of activities.

3.2.1.1.1 Organization

The QATR is the top-level policy document that delineates the requirements and tasks assigned to the various organizational elements to achieve B&W's stated objectives. Overall policies on quality are established by B&W. Compliance with the QATR and implementing documents is mandatory for all personnel performing activities related to safety.

The QATR describes the organizational structure, levels of authority, lines of communication, and functional responsibilities for the control of activities affecting quality. The Quality Management function reports to an adequately authoritative level of management. 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 QATR implementation, and reporting results to program and senior management.

In RAI No. 1, the NRC staff requested that B&W describe the overall scope of activities that apply or could apply to the QATR, in addition to the list of activities already documented (design and procurement of engineering services). In its response, B&W stated that the scope of Revision 3 of the QATR (Reference 4) has been modified to include design, fabrication, experiments, construction, and testing of SSCs for the facility.

In RAI No. 3, the NRC staff requested that B&W describe the function of engineering, procurement, and construction (EPC) as well as its placement in the organizational structure. In its response, B&W stated that the organizational descriptions and chart in Revision 3 of the QATR were revised to more clearly reflect the EPC functions and the responsible organization's role in performing EPC duties.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the organizational controls met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.2 Quality Assurance Program

B&W's QATR documents the requirements for establishing, implementing, and managing the QA program. The QATR identifies the items and activities that are addressed by the program and will be documented in applicable policies, procedures, instructions, and controlled documents. The program implements a graded approach to quality. The program provides for the appropriate and necessary indoctrination and training of personnel performing activities that affect quality and ensures that suitable proficiency is achieved and maintained.

In RAI No. 4, the NRC staff requested that B&W clarify how the definition for safety-related is applicable to the proposed plant design, associated SSCs, and is consistent with ANSI/ANS 15.8. In its response, B&W stated that since the facility is being licensed under 10 CFR Part 50, the definition of safety-related SSCs will be restated directly from 10 CFR 50.2 and aligned directly with Quality Level (QL)-1. Although 10 CFR Part 70 does not specifically apply to MIPS, nor does it require a QA program, QL-2 was developed to be consistent with the quality requirements of 10 CFR Part 70. In order to specifically address the requirements of 10 CFR Part 21 for MIPS, a basic component is defined as aligning directly with QL-1.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the programmatic controls met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.3 Design Control

B&W has established an engineering and design control system to document the method of accomplishing, controlling, and preserving engineering and design tasks. B&W stated that procedures will identify the process by which the control of design documents and preparation will be applied and ensure applicable rules, regulations, codes, and standards are implemented.

As described below, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the design controls met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

Design Requirements

Design inputs and requirements, including design bases, performance requirements, regulatory requirements, codes, and standards will be identified and documented in the appropriate design requirements documents.

In RAI No. 5, the NRC staff requested that B&W clarify the phrase in the QATR, "to the extent necessary to demonstrate satisfactory control of input, output, verification and acceptance." In its response, B&W stated that the phrase created ambiguity and removed it from Revision 3 of the QATR.

Design Process

B&W's design organization is responsible for identifying and controlling the internal and external design interfaces and will coordinate activities among participating organizations. The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Deviations from the established design inputs will be documented and controlled.

The design organization will ensure the final design is relatable to the design input by adequate documentation. Computer design programs used to develop any portion of the facility design or to analyze the design will be controlled. When a design program must be developed, the program will be controlled to ensure that it is fully documented and validated. When changes to previously valid computer programs are made, documented revalidation will be performed for the change and include appropriate benchmark testing.

Design Verification

Independent design verification will be performed on design documents prior to releasing them for use, including use by another design organization. Accuracy of the design is verified through review of design documents by competent persons other than those who designed the item. The extent of the design verification will be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art and the similarity with previously approved designs. Qualification testing will be defined in formal test plans and include appropriate acceptance criteria. Testing will demonstrate the adequacy of performance that simulates the most adverse conditions. Test results will be documented and verified to have met test requirements.

Design Documents and Records

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

Commercial-Grade Items

B&W will have in place procedural reviews for the use of commercial-grade items to be used in a safety-related application. If a commercial-grade item is modified or selected by special inspection/testing to requirements that are more restrictive than the supplier's published product description, the item will be identified as different in a manner traceable to a documented description of the difference.

Change Control

Modifications to the facility's SSCs will be procedurally controlled. Design changes will be documented, justified, and subject to control commensurate with those applied to the original design. These measures will include assurance that the design analyses for SSCs or computer codes are still valid. When a significant design change is necessary, the design organization will review and modify the design and reviews the process, as necessary.

3.2.1.1.4 Procurement Document Control

B&W's QATR detailed a process to ensure that procurement documents include the requirements necessary for establishing the quality of the procured material, equipment, and services. Design criteria, including applicable specifications, codes, standards, and regulatory requirements will be translated into procurement documents in accordance with approved procedures.

The QATR stipulates that procurement documents at all procurement levels identify the documentation required to be submitted for information, review, or approval by the purchaser. The procurement documents require access to the supplier's facility and records by designated individuals. Procurement documents will require the supplier to report nonconformances associated with the items or services being procured.

In RAI No. 6, the NRC staff requested that B&W clarify if the QATR includes requirements that the procurement documents contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser. In its response, B&W stated that in Revision 3 of the QATR the requirement was added that documents contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that controls for procurement documents met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.5 Instructions, Procedures, and Drawings

B&W has established the necessary measures to ensure that quality activities are based on specifications, drawings, procedures, and instructions, as appropriate. These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that controls for instructions, procedures, and drawings met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.6 Document Control

B&W has established a process to control the review, approval, and distribution of documents, including changes thereto, which prescribe activities affecting quality. The program and implementing procedures establish the requirements to maintain instructions, procedures, and drawings. The distribution of documents will be controlled to ensure that only documents with the prescribed approvals are in use at the locations where the prescribed activity is performed. Major changes to controlled documents will be reviewed and approved by the same organizations that were responsible for the activities and content of the original issue.

In RAI No. 2, the NRC staff requested that B&W clarify if it was intended to provide a Master Procedures List as stated in the Scope of the QATR. In its response, B&W stated that the Master Procedures List was not intended to be part of the QATR. The list is maintained by the Document/Record Manager. This was clarified in Revision 3 of the QATR.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for documents met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.7 Control of Purchased Material, Equipment, and Services

Supplier Selection

B&W has established the necessary measures and procedures to ensure that purchased material, equipment, and services conform to procurement documents. These measures include supplier evaluation and selection including quality evaluations and rating, periodic source surveillances and inspections, audits, and site receiving inspection, as applicable. Prior to supplier selection, the supplier's capabilities to provide items or services in accordance with the requirements of the procurement documents shall be evaluated and unacceptable technical and QA conditions shall be resolved.

In RAI No. 7, the NRC staff requested that B&W clarify how the QATR provides for audits to show objective evidence of quality furnished by a supplier. In its response, B&W stated that to provide consistency, the term *audit* replaced *assessment* in parts of Revision 3 of the QATR. Additionally, the definition of audit has been added to Appendix C.

Work Control

B&W's QATR will require the suppliers to establish measures to control performance, as appropriate. Controls may include test plans, review of a supplier's submitted documents, arrangements for source surveillance or inspection, and other technical and administrative interfaces with the supplier in accordance with the procurement documents.

Verification Activities

Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of suppliers. B&W's receipt inspection includes verification that all required documentation has been received, reviewed, and accepted and that items conform to the procurement documents.

Item or Service Acceptance

As noted above, B&W established a process to ensure that purchased items and services conform to procurement specifications. This will also include supplier Certificate of Conformance, source verification, receiving inspection, post-installation test, or a combination of these activities. Receiving inspection will include, as appropriate, review of applicable documentation and attributes of the item, such as cleanliness, shipping damage, or indication of fraud or counterfeit.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for purchased material, equipment, and services met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.8 Identification and Control of Materials, Parts, and Components

B&W has established the necessary identification and control measures to prevent the uncontrolled use of nonconforming materials, parts, and components, including subdivided items. Materials, parts, and components will be identified by appropriate means. The identification may be on the item or on records directly and readily traceable to the item. The type of identification is established by specifications, drawings, instructions, or procedures. Procedural controls will ensure controls are established for items having a limited shelf and service life.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for identification of material, parts, and components met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.9 Control of Special Processes

B&W has established the necessary measures to ensure that approved special process procedures are used by qualified personnel in accordance with specified codes, standards and any additional project requirements. The requirements for special process control, including personnel qualification are invoked by specifications, procedures, instructions, or other applicable documents.

Records will be maintained for the currently qualified personnel, processes, and equipment for each special process, as applicable.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for special processes met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.10 Inspection

B&W conducts inspections to ensure that material, equipment, and work conform to quality requirements. The inspection process will be applicable to procurement, construction, modification, and maintenance activities. Inspections will be performed by personnel independent of the work being inspected, but may be from the same organization. Inspection plans will be developed by responsible personnel and approved by the quality organization. Measuring and test equipment (M&TE) used to perform inspections will be identified in inspection documentation for traceability of inspection results. B&W translates technical and QA requirements to inspection procedures, plans, and reports to provide documentation of the work. Only items that have passed the required inspections and tests will be used, installed, or operated.

B&W will provide for on-the-job training, as appropriate, to ensure inspectors comprehend inspection criteria and methods. Records of inspection personnel qualification will be established and maintained by B&W or the respective contractor.

In RAI No. 8, the NRC staff requested that B&W clarify how the inspection program applied to fabrication, modification, construction, and maintenance activities, which were originally outside the scope of the QATR. Additionally, the NRC staff asked whether experiment fabrication was within the scope of the QATR. In its response, B&W stated that the inspection program will apply to procurement, fabrication, modification, construction, and maintenance. Further, B&W stated that it does not intend to use the reactor for experiments.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for inspection met the guidance in Section 12.9 of NUGEG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.11 Test Control

B&W has established the necessary measures and implementing procedures to demonstrate that SSCs will perform satisfactorily in service. The quality organization is responsible to review test procedures, monitor test performance, and evaluate the final results to ensure that test requirements will be satisfied.

Computer programs to be used for a control function or process will be tested with an approved verification and validation plan and demonstrate required performance over the range of operation of the controlled function or process.

In RAI No. 9, the NRC staff requested that B&W clarify how the quality organization possesses the technical capability to be the responsible authority to assure that test requirements have been satisfied. In its response, B&W stated that Revision 3 of the QATR was revised to reflect that test results would be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. Implementing procedures will be used to identify and document the responsible authority.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for testing met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.12 Control of Measuring and Test Equipment

B&W's QATR described controls for the calibration, maintenance and use of tools, gages, instruments, and other M&TE used for measurements, inspections, and tests performed to document compliance with specified requirements.

B&W's control of M&TE includes the following:

1) positive identification of the equipment and its calibration status, including the due date of the next calibration;

2) use of recognized industry standards;

3) written procedures describing the calibration control system;

4) record system to indicate calibration dates, capability of M&TE to perform intended function satisfactorily and identification of personnel performing the calibrations;

5) recall system to prevent use of equipment beyond its calibration due date; and

6) a system for corrective action when out-of-calibration or damaged M&TE has been used.

In RAI No. 10, the NRC staff noted that ANSI/ANS 15.8 allows for calibration and control measures not to be required when normal commercial equipment provides adequate accuracy. In its response, B&W stated that Revision 3 of the QATR was revised to reflect that calibration and control measures will not be required when normal commercial equipment provides adequate accuracy.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for M&TE met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.13 Handling, Storage, and Shipping

B&W's QATR described the necessary measures and implementation of procedures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage, deterioration, or release of radioactive or hazardous material. The above mentioned work is accomplished by qualified individuals in accordance with applicable procedures.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for handling, storage, and shipping met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.14 Inspection, Test, and Operating Status

B&W's QATR described the measures and implementation of procedures to identify the status of inspections and test operations. The status of inspections and test operations is indicated by tags, markings, records, or other suitable means, provided that the method used ensures that only accepted items are used, installed, or operated.

Unacceptable items or items of an indeterminate status are identified and controlled to ensure they are not inadvertently installed, used, or operated.

The quality organization has the responsibility to monitor or conduct inspections or tests and to review data to ensure acceptability.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for inspection, test, and operating status met the guidance in Section 12.9 of NUREG-1537, and ANSI/ANS 15.8.

3.2.1.1.15 Nonconforming Materials, Parts, or Components

B&W's QATR described the necessary measures and implementation of procedures to control nonconforming items to prevent their inadvertent use or installation until the nonconforming condition is corrected or evaluated to rework, use as is, reject, or repair, as determined by the responsible design organization. These controls include measures for identification, documentation, segregation (as appropriate), and disposition. Physical segregation and marking are B&W's preferred method for identification; however, other means of identification (e.g., tagging, etc.) are acceptable when physical segregation is impractical.

B&W will document the technical justification for the acceptability of a nonconforming item. B&W's quality organization will periodically review nonconformance data and evaluate for adverse trends. Reports of reviews will be sent to responsible management.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for nonconforming materials, parts, or components met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.16 Corrective Action

B&W's QATR described the necessary measures and implementation of procedures to determine the cause(s) and take corrective and preventive action to preclude repetition when major and recurring conditions adverse to quality, such as failures, malfunctions, deficiencies, defective material and equipment, and nonconformances are identified. B&W's corrective action program provides for prompt identification, documentation, classification, and correction of the conditions. For conditions adverse to quality and significant conditions adverse to quality, the corrective action process, including the resulting action to resolve the deficiency shall be documented and reported to the appropriate level of management.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for corrective action met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.17 Quality Assurance Records

B&W's QATR described the necessary measures and implementation of procedures to ensure sufficient records of completed items and activities affecting quality are collected, maintained, and appropriately stored. B&W's record system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

B&W's applicable specifications, procurement documents, procedures, or other documents specify the receipt, storage, preservation, safekeeping, retrieval, types of records to be generated, retention period, and their disposition. B&W has established the necessary measures to ensure that records are legible, identifiable, retrievable, and traceable to the item or activity to which it applies.

Provisions will be specified for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. Records will be maintained by a supplier and accessible to B&W and its contractors.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for QA records met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.18 Assessments

The quality organization will have the responsibility to establish the assessment program and requisite implementing procedures. Internal and supplier audits will be scheduled based on periodic reviews. The internal audits will address each QATR section.

Periodic audits of safety-related activities will be conducted to determine the effectiveness of the quality program.

Lead auditors will be trained and qualified. Team members will be independent of the area being assessed. The team members will also be adequately trained and qualified.

Results of the audits will be made available to the relevant B&W or contractor managers, as applicable.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for audits met the guidance in Section 12.9 of NUREG-1537, Parts1 and 2, and ANSI/ANS 15.8.

3.2.1.1.19 Experimental Equipment

In RAI No. 11, the NRC staff requested that B&W clarify if the QATR provides controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety-related items. In its response, B&W stated that Revision 3 of the QATR was revised to insert Section 19.0, Experimental Equipment. Section 19.0 states that as a commercial facility, MIPS will not have experimental equipment or facilities, nor will they be described in the license and safety analysis report. Changes, tests, and experiments will be managed according to 10 CFR 50.59.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for changes, tests, and experiments met the regulatory guidance in 10 CFR 50.59.

4.0 CONCLUSION

The NRC staff evaluated B&W's QATR and the supplemental correspondence. The NRC staff concludes that B&W's QA program description adequately addresses the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8, and is therefore, acceptable.

5.0 REFERENCES

1. Reynolds, W. E., B&W Technical Services Group, Inc., letter to Document Control Desk, NRC, "B&W Medical Isotope Production System (MIPS) submittal of Quality Assurance Program Description (QAPD) Topical Report Enclosure 1, Abstract Enclosure 2, and Basis for submittal of the Topical Report Enclosure 3," dated June 4, 2010, ADAMS Accession Number ML101600197.

2. Glenn, D. E., B&W Technical Services Group, Inc., letter to Document Control Desk, NRC, "B&W Response to Request for Additional Information Regarding Quality Assurance Program Description Submitted June 4, 2010," dated October 18, 2010, ADAMS Accession Number ML102990311.

3. Voth, Marcus H., NRC, letter to Reynolds, W. E., B&W Technical Services Group, Inc., "Request for Additional Information Regarding the Babcock & Wilcox Technical Services Group, Inc. Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 2," dated September 22, 2010, ADAMS Accession Number ML102640304.

4. Glenn, D. E., B&W Technical Services Group, Inc., letter to Document Control Desk, NRC, "B&W Response to Request for Additional Information Regarding Quality Assurance Program-Enclosure 1, MIPS Quality Assurance Program Description, Revision 3," dated October 18, 2010, ADAMS Accession Number ML102990312.

Principal Contributor: P. Prescott

Date:

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babcock & wilcox technical services group
800 main street, 2nd floor lynchburg, va 24504 usa
phone 434.522.6000 fax 434.522.5450 www.babcock.com

June 6, 2011

Document Control Desk
US Nuclear Regulatory Commission
Washington, DC 20555-001

Subject: Draft Safety Evaluation for Babcock & Wilcox Technical Services Group, Inc. Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 3 (TAC NO. ME4101)

References:
1. Letter dated May 6, 2011, regarding the Draft Safety Evaluation Report for B&W Technical Services Group, Inc. Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 3 (TAC NO. ME4101)

Dear Sir:

B&W is in receipt of your letter (reference 1) regarding the draft Safety Evaluation Report and has reviewed for factual errors and clarity concerns. We have identified one clarity concern that is manifested in a number of specific locations in the draft SER. This concern and the specific lines where it occurs are detailed in the Attachments 1 and 2 to this letter. Additionally, we have identified one clarity concern pertaining to the use of a term used in Section 18.0 of the QATR.

Thank you for your consideration of these concerns. If you have questions please contact Steve Schilthelm at 434-522-6243.

Sincerely,

SW Schilthelm for Dan Glenn

Dan Glenn
MIPS Program Manager
B&W Technical Services Group, Inc.

Attachments
1. B&W Response – Summary of Clarity Concerns Regarding the Quality Assurance Program Description B&W Medical Isotope Production System (MIPS) Topical Report MIPS-PP-QA-14 Project No. 0766, (TAC NO. ME4101).
2. B&W Mark-up Copy of the SER Proposed Changes by Item Number (see Attachment 1).

cc: Marcus Voth – electronic via e-mail
Ossy Font – electronic via e-mail
Steve Schilthelm
B&W MIPS Records

MIPS-02FC-11-002

ATTACHMENT 1
B&W RESPONSE – SUMMARY OF CLARITY CONCERNS
REGARDING THE QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD)
B&W MEDICAL ISOTOPE PRODUCTION SYSTEM (MIPS)
TOPICAL REPORT MIPS-PP-QA-14
PROJECT NO. 0766
TAC NO. ME4101

B&W Item	Draft SER Section and Line No.	Description of the Clarity Concern	Proposed Resolution
1	Section 2.0, line 32	The last sentence of paragraph 1 of Section 1 appears to set forth Appendix B to 10CFR50 as a requirement for MIPS. B&W believes that Appendix B is required by 10CFR50.34(a)(7) only for nuclear power plants and reprocessing plants and that the MIPS facility is neither. Rather, MIPS is a non-power reactor and the guidance for the quality assurance program description requirements of 10CFR50.34(a)(7) is contained in NUREG-1537 and Regulatory Guide 2.5 which endorses (ANSI/ANS) 15.8. B&W does not believe that Appendix B of 10CFR 50 is a requirement for the MIPS facility. Both Revision 3 of the MIPS QAPD and the balance of the draft SER refers to NUREG-1537 and Regulatory Guide 2.5 which endorses (ANSI/ANS) 15.8 as the operative criteria therefore, B&W believes any reference to Appendix B should be eliminated in order to avoid potential future confusion.	Remove reference to Appendix B and leave only 10 CFR 50.
2	Section 2.0, lines 35, 36, & 37	See discussion above	Remove reference to Appendix B and insert appropriate reference to NUREG-1537 and Regulatory Guide 2.5 which endorses (ANSI/ANS) 15.8
3	Section 3.1, lines 11 & 12	See discussion above	Remove reference to Appendix B and leave appropriate reference to NUREG-1537 and Regulatory Guide 2.5 which endorses (ANSI/ANS) 15.8
4	Section 3.2, line 20	See discussion above	Remove reference to Appendix B and leave appropriate reference to NUREG-1537 and Regulatory Guide 2.5 which endorses (ANSI/ANS) 15.8
5	Section 3.2.1, lines 28 & 29	The SER makes reference to the 18 criteria (line 28) of Appendix B (line 29) and corresponding provisions of ANSI/ANS 15.8.	Change 18 criteria to 19 criteria and remove reference to Appendix B
6	Section 3.2.1.1.18, lines 22, 25, 26, 28, 34, & 38	The SER makes reference to the term audits however, the QATR (Section 18.0) and ANSI/ANS 15.8 (criteria 18) makes reference to the term assessments.	Change the term audit to assessment in accordance with (ANSI/ANS) 15.8

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

ATTACHMENT 2
B&W Mark-up Copy of the SER Proposed Changes by Item Number (see Attachment 1.

DRAFT SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

TOPICAL REPORT MIPS-PP-QA-14

"MEDICAL ISOPTOPE PRODUCTION SYSTEM

QUALITY ASSURANCE PROGRAM DESCRIPTION"

BACOCK & WILCOX TECHNICAL SERVICES GROUP, INC.

PROJECT NO. 766

1.0 INTRODUCTION AND BACKGROUND

By letter dated June 4, 2010 (Reference 1), as supplemented by letter dated October 18, 2010, (Reference 2), in response to the U.S. Nuclear Regulatory Commission (NRC) staff's requests for additional information (RAIs) (Reference 3), Babcock & Wilcox Technical Services Group, Inc. (B&W) submitted its Medical Isotope Production System (MIPS) Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, (hereafter referred to as the Quality Assurance Topical Report (QATR)) for NRC review and acceptance in accordance with the provisions of Section 50.34(a)(7) of Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR).

2.0 REGULATORY EVALUATION

Based upon a determination by the NRC staff, B&W's facility will be licensed under the Commission's regulatory requirements related to quality assurance (QA) programs set forth in 10 CFR 50.34(a)(7), as a production and utilization facility, classified as a non-power reactor, and require both construction and operating authorization. This regulation requires a description of the QA program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility. The NRC reviews the proposed QATR for acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

B&W Item 1

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction, and operation of a facility's SSCs. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

B&W Item 2

ENCLOSURE

3.0 TECHNICAL EVALUATION

3.1 Background

The proposed QATR was developed with the purpose of meeting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1, "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria," Section 12.9, "Quality Assurance."

The proposed QATR is organized into 18 basic sections corresponding to the quality requirements delineated in Appendix B to 10 CFR Part 50 and is responsive to both Appendix B, as applicable, and the regulatory guidance set forth in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors," Revision 1. Regulatory Guide 2.5 endorses American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.8, "Quality Assurance Program Requirements for Research Reactors." B&W Item 3

3.2 Evaluation

The NRC staff evaluated the adequacy of the QATR in describing how the requirements of Appendix B to 10 CFR Part 50 will be satisfied. The format, content, and acceptance criteria of the QATR were evaluated in accordance with the guidance of NUREG-1537, Parts 1 and 2, Section 12.9, which provides a basis for NRC staff review of QA programs based on ANSI/ANS 15.8. The acceptability of the level of detail provided by the QATR is determined, in part, by its adequacy in addressing the acceptance criteria of NUREG-1537, Parts 1 and 2, Section 12.9. B&W Item 4

3.2.1 Format and Content of the QATR

The format used for the following evaluation follows the sequence of the 18 criteria of Appendix B and corresponding provisions of ANSI/ANS 15.8. The content of the QATR provides guidance for establishing a top-level policy document that defines the quality requirements and assigns major functional responsibilities. The B&W QATR can be used for engineering, design, procurement, fabrication, experiments, construction, and testing for the applicant's activities affecting the quality and performance of safety-related SSCs. In addition, the QATR applies a graded approach to the extent commensurate with the SSC's importance to safety. It is incumbent upon the applicant to identify the specific QA requirements that must be met for the scope of activities. B&W Item 5

3.2.1.1.1 Organization

The QATR is the top-level policy document that delineates the requirements and tasks assigned to the various organizational elements to achieve B&W's stated objectives. Overall policies on quality are established by B&W. Compliance with the QATR and implementing documents is mandatory for all personnel performing activities related to safety.

The QATR describes the organizational structure, levels of authority, lines of communication, and functional responsibilities for the control of activities affecting quality. The Quality Management function reports to an adequately authoritative level of management. The Program Quality Manager is responsible for assisting with the identification of quality

3.2.1.1.17 Quality Assurance Records

B&W's QATR described the necessary measures and implementation of procedures to ensure sufficient records of completed items and activities affecting quality are collected, maintained, and appropriately stored. B&W's record system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

B&W's applicable specifications, procurement documents, procedures, or other documents specify the receipt, storage, preservation, safekeeping, retrieval, types of records to be generated, retention period, and their disposition. B&W has established the necessary measures to ensure that records are legible, identifiable, retrievable, and traceable to the item or activity to which it applies.

Provisions will be specified for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. Records will be maintained by a supplier and accessible to B&W and its contractors.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for QA records met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.18 Audits

B&W Item 6

The quality organization will have the responsibility to establish the assessment program and requisite implementing procedures. Internal and supplier audits will be scheduled based on periodic reviews. The internal audits will address each QATR section.

Periodic audits of safety-related activities will be conducted to determine the effectiveness of the quality program.

Lead auditors will be trained and qualified. Team members will be independent of the area being assessed. The team members will also be adequately trained and qualified.

Results of the audits will be made available to the relevant B&W or contractor managers, as applicable.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for audits met the guidance in Section 12.9 of NUREG-1537, Parts1 and 2, and ANSI/ANS 15.8.

3.2.1.1.19 Experimental Equipment

In RAI No. 11, the NRC staff requested that B&W clarify if the QATR provides controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety-related items. In its response, B&W stated that Revision 3 of the QATR was revised to insert Section 19.0, Experimental Equipment. Section 19.0 states that as a commercial facility, MIPS will not have experimental equipment or facilities, nor will they be described in the license and safety analysis report. Changes, tests, and experiments will be managed according to 10 CFR 50.59.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 6, 2011

Mr. W. E. Reynolds
Program Manager, Medical Isotope Production System (MIPS)
Babcock & Wilcox Technical Services Group, Inc.
2016 Mount Athos Road
Lynchburg, VA 24504-5447

SUBJECT: DRAFT SAFETY EVALUATION FOR BABCOCK & WILCOX TECHNICAL SERVICES GROUP, INC. MEDICAL ISOTOPE PRODUCTION SYSTEM QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT, MIPS-PP-QA-14, REVISION 3 (TAC NO. ME4101)

Dear Mr. Reynolds:

By letter dated June 4, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML101600197), Babcock & Wilcox Technical Services Group, Inc. (B&W) Medical Isotope Production System (MIPS) submitted its Quality Assurance Program Description Topical Report (QATR), MIPS-PP-QA-14, Revision 2, dated May 17, 2010, to the U.S. Nuclear Regulatory Commission (NRC) for review. Enclosed for B&W review and comment is a copy of the NRC staff's draft safety evaluation (SE) for the TR.

Twenty working days are provided for you to comment on any factual errors or clarity concerns contained in the SE. The final SE will be issued after making any necessary changes and will be made publicly available as Revision 3 due to substantial changes to Revision 2. The NRC staff's disposition of your comments on the draft SE will be discussed in the final SE.

To facilitate the NRC staff's review of your comments, please provide a marked-up copy of the draft SE showing proposed changes and provide a summary table of the proposed changes.

If you have any questions, please contact Holly Cruz at (301) 415-1053.

Sincerely,

John R. Jolicoeur, Chief
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 766

Enclosure: Draft SE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DRAFT SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

TOPICAL REPORT MIPS-PP-QA-14

"MEDICAL ISOPTOPE PRODUCTION SYSTEM

QUALITY ASSURANCE PROGRAM DESCRIPTION"

BACOCK & WILCOX TECHNICAL SERVICES GROUP, INC.

PROJECT NO. 766

1.0 INTRODUCTION AND BACKGROUND

By letter dated June 4, 2010 (Reference 1), as supplemented by letter dated October 18, 2010, (Reference 2), in response to the U.S. Nuclear Regulatory Commission (NRC) staff's requests for additional information (RAIs) (Reference 3), Babcock & Wilcox Technical Services Group, Inc. (B&W) submitted its Medical Isotope Production System (MIPS) Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, (hereafter referred to as the Quality Assurance Topical Report (QATR)) for NRC review and acceptance in accordance with the provisions of Section 50.34(a)(7) of Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR).

2.0 REGULATORY EVALUATION

Based upon a determination by the NRC staff, B&W's facility will be licensed under the Commission's regulatory requirements related to quality assurance (QA) programs set forth in 10 CFR 50.34(a)(7), as a production and utilization facility, classified as a non-power reactor, and require both construction and operating authorization. This regulation requires a description of the QA program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility. The NRC reviews the proposed QATR for acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction, and operation of a facility's SSCs. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

ENCLOSURE

3.0 TECHNICAL EVALUATION

3.1 Background

The proposed QATR was developed with the purpose of meeting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1, "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria," Section 12.9, "Quality Assurance."

The proposed QATR is organized into 18 basic sections corresponding to the quality requirements delineated in Appendix B to 10 CFR Part 50 and is responsive to both Appendix B, as applicable, and the regulatory guidance set forth in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors," Revision 1. Regulatory Guide 2.5 endorses American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.8, "Quality Assurance Program Requirements for Research Reactors."

3.2 Evaluation

The NRC staff evaluated the adequacy of the QATR in describing how the requirements of Appendix B to 10 CFR Part 50 will be satisfied. The format, content, and acceptance criteria of the QATR were evaluated in accordance with the guidance of NUREG-1537, Parts 1 and 2, Section 12.9, which provides a basis for NRC staff review of QA programs based on ANSI/ANS 15.8. The acceptability of the level of detail provided by the QATR is determined, in part, by its adequacy in addressing the acceptance criteria of NUREG-1537, Parts 1 and 2, Section 12.9.

3.2.1 Format and Content of the QATR

The format used for the following evaluation follows the sequence of the 18 criteria of Appendix B and corresponding provisions of ANSI/ANS 15.8. The content of the QATR provides guidance for establishing a top-level policy document that defines the quality requirements and assigns major functional responsibilities. The B&W QATR can be used for engineering, design, procurement, fabrication, experiments, construction, and testing for the applicant's activities affecting the quality and performance of safety-related SSCs. In addition, the QATR applies a graded approach to the extent commensurate with the SSC's importance to safety. It is incumbent upon the applicant to identify the specific QA requirements that must be met for the scope of activities.

3.2.1.1.1 Organization

The QATR is the top-level policy document that delineates the requirements and tasks assigned to the various organizational elements to achieve B&W's stated objectives. Overall policies on quality are established by B&W. Compliance with the QATR and implementing documents is mandatory for all personnel performing activities related to safety.

The QATR describes the organizational structure, levels of authority, lines of communication, and functional responsibilities for the control of activities affecting quality. The Quality Management function reports to an adequately authoritative level of management. 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 QATR implementation, and reporting results to program and senior management.

In RAI No. 1, the NRC staff requested that B&W describe the overall scope of activities that apply or could apply to the QATR, in addition to the list of activities already documented (design and procurement of engineering services). In its response, B&W stated that the scope of Revision 3 of the QATR (submitted as Revision 2 of the QATR but hereafter referred to as Revision 3 due to substantial changes to Revision 2) has been modified to include design, fabrication, experiments, construction, and testing of SSCs for the facility.

In RAI No. 3, the NRC staff requested that B&W describe the function of engineering, procurement, and construction (EPC) as well as its placement in the organizational structure. In its response, B&W stated that the organizational descriptions and chart in Revision 3 of the QATR were revised to more clearly reflect the EPC functions and the responsible organization's role in performing EPC duties.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the organizational controls met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.2 Quality Assurance Program

B&W's QATR documents the requirements for establishing, implementing, and managing the QA program. The QATR identifies the items and activities that are addressed by the program will be documented in applicable policies, procedures, instructions, and controlled documents. The program implements a graded approach to quality. The program provides for the appropriate and necessary indoctrination and training of personnel performing activities that affect quality and ensures that suitable proficiency is achieved and maintained.

In RAI No. 4, the NRC staff requested that B&W clarify how the definition for safety-related is applicable to the proposed plant design, associated SSCs, and is consistent with ANSI/ANS 15.8. In its response, B&W stated that since the facility is being licensed under 10 CFR Part 50, the definition of safety-related SSCs will be restated directly from 10 CFR 50.2 and aligned directly with Quality Level (QL)-1. Although 10 CFR Part 70 does not specifically apply to MIPS, nor does it require a QA program, QL-2 was developed to be consistent with the quality requirements of 10 CFR Part 70. In order to specifically address the requirements of 10 CFR Part 21 for MIPS, a basic component is defined as aligning directly with QL-1.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the programmatic controls met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.3 Design Control

B&W has established an engineering and design control system to document the method of accomplishing, controlling, and preserving engineering and design tasks. B&W stated that procedures will identify the process by which the control of design documents and preparation will be applied and ensure applicable rules, regulations, codes, and standards are implemented.

As described below, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the design controls met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

Design Requirements

Design inputs and requirements, including design bases, performance requirements, regulatory requirements, codes, and standards will be identified and documented in the appropriate design requirements documents.

In RAI No. 5, the NRC staff requested that B&W clarify the phrase in the QATR, "to the extent necessary to demonstrate satisfactory control of input, output, verification and acceptance." In its response, B&W stated that the phrase created ambiguity and removed it from Revision 3 of the QATR.

Design Process

B&W's design organization is responsible for identifying and controlling the internal and external design interfaces and will coordinate activities among participating organizations. The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Deviations from the established design inputs will be documented and controlled.

The design organization will ensure the final design is relatable to the design input by adequate documentation. Computer design programs used to develop any portion of the facility design or to analyze the design will be controlled. When a design program must be developed, the program will be controlled to ensure that it is fully documented and validated. When changes to previously valid computer programs are made, documented revalidation will be performed for the change and include appropriate benchmark testing.

Design Verification

Independent design verification will be performed on design documents prior to releasing them for use, including use by another design organization. Accuracy of the design is verified through review of design documents by competent persons other than those who designed the item. The extent of the design verification will be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art and the similarity with previously approved designs. Qualification testing will be defined in formal test plans and include appropriate acceptance criteria. Testing will demonstrate the adequacy of performance that simulates the most adverse conditions. Test results will be documented and verified to have met test requirements.

Design Documents and Records

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

Commercial-Grade Items

B&W will have in place procedural reviews for the use of commercial-grade items to be used in a safety-related application. If a commercial-grade item is modified or selected by special inspection/testing to requirements that are more restrictive than the supplier's published product description, the item will be identified as different in a manner traceable to a documented description of the difference.

Change Control

Modifications to the facility's SSCs will be procedurally controlled. Design changes will be documented, justified, and subject to control commensurate with those applied to the original design. These measures will include assurance that the design analyses for SSCs or computer codes are still valid. When a significant design change is necessary, the design organization will review and modify the design and reviews the process, as necessary.

3.2.1.1.4 Procurement Document Control

B&W's QATR detailed a process to ensure that procurement documents include the requirements necessary for establishing the quality of the procured material, equipment, and services. Design criteria, including applicable specifications, codes, standards, and regulatory requirements will be translated into procurement documents in accordance with approved procedures.

The QATR stipulates that procurement documents at all procurement levels identify the documentation required to be submitted for information, review, or approval by the purchaser. The procurement documents require access to the supplier's facility and records by designated individuals. Procurement documents will require the supplier to report nonconformances associated with the items or services being procured.

In RAI No. 6, the NRC staff requested that B&W clarify if the QATR includes requirements that the procurement documents contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser. In its response, B&W stated that in Revision 3 of the QATR the requirement was added that documents contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that controls for procurement documents met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.5 Instructions, Procedures, and Drawings

B&W has established the necessary measures to ensure that quality activities are based on specifications, drawings, procedures, and instructions, as appropriate. These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that controls for instructions, procedures, and drawings met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.6 Document Control

B&W has established a process to control the review, approval, and distribution of documents, including changes thereto, which prescribe activities affecting quality. The program and implementing procedures establish the requirements to maintain instructions, procedures, and drawings. The distribution of documents will be controlled to ensure that only documents with the prescribed approvals are in use at the locations where the prescribed activity is performed. Major changes to controlled documents will be reviewed and approved by the same organizations that were responsible for the activities and content of the original issue.

In RAI No. 2, the NRC staff requested that B&W clarify if it was intended to provide a Master Procedures List as stated in the Scope of the QATR. In its response, B&W stated that the Master Procedures List was not intended to be part of the QATR. The list is maintained by the Document/Record Manager. This was clarified in Revision 3 of the QATR.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for documents met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.7 Control of Purchased Material, Equipment, and Services

Supplier Selection

B&W has established the necessary measures and procedures to ensure that purchased material, equipment, and services conform to procurement documents. These measures include supplier evaluation and selection including quality evaluations and rating, periodic source surveillances and inspections, audits, and site receiving inspection, as applicable. Prior to supplier selection, the supplier's capabilities to provide items or services in accordance with the requirements of the procurement documents shall be evaluated and unacceptable technical and QA conditions shall be resolved.

In RAI No. 7, the NRC staff requested that B&W clarify how the QATR provides for audits to show objective evidence of quality furnished by a supplier. In its response, B&W stated that to provide consistency, the term *audit* replaced *assessment* in parts of Revision 3 of the QATR. Additionally, the definition of audit has been added to Appendix C.

Work Control

B&W's QATR will require the suppliers to establish measures to control performance, as appropriate. Controls may include test plans, review of a supplier's submitted documents, arrangements for source surveillance or inspection, and other technical and administrative interfaces with the supplier in accordance with the procurement documents.

Verification Activities

Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of suppliers. B&W's receipt inspection includes verification that all required documentation has been received, reviewed, and accepted and that items conform to the procurement documents.

Item or Service Acceptance

As noted above, B&W established a process to ensure that purchased items and services conform to procurement specifications. This will also include supplier Certificate of Conformance, source verification, receiving inspection, post-installation test, or a combination of these activities. Receiving inspection will include, as appropriate, review of applicable documentation and attributes of the item, such as cleanliness, shipping damage, or indication of fraud or counterfeit.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for purchased material, equipment, and services met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.8 Identification and Control of Materials, Parts, and Components

B&W has established the necessary identification and control measures to prevent the uncontrolled use of nonconforming materials, parts, and components, including subdivided items. Materials, parts, and components will be identified by appropriate means. The identification may be on the item or on records directly and readily traceable to the item. The type of identification is established by specifications, drawings, instructions, or procedures. Procedural controls will ensure controls are established for items having a limited shelf and service life.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for identification of material, parts, and components met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.9 Control of Special Processes

B&W has established the necessary measures to ensure that approved special process procedures are used by qualified personnel in accordance with specified codes, standards and any additional project requirements. The requirements for special process control, including personnel qualification are invoked by specifications, procedures, instructions, or other applicable documents.

Records will be maintained for the currently qualified personnel, processes, and equipment for each special process, as applicable.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for special processes met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.10 Inspection

B&W conducts inspections to ensure that material, equipment, and work conform to quality requirements. The inspection process will be applicable to procurement, construction, modification, and maintenance activities. Inspections will be performed by personnel independent of the work being inspected, but may be from the same organization. Inspection plans will be developed by responsible personnel and approved by the quality organization. Measuring and test equipment (M&TE) used to perform inspections will be identified in inspection documentation for traceability of inspection results. B&W translates technical and QA requirements to inspection procedures, plans, and reports to provide documentation of the work. Only items that have passed the required inspections and tests will be used, installed, or operated.

B&W will provide for on-the-job training, as appropriate, to ensure inspectors comprehend inspection criteria and methods. Records of inspection personnel qualification will be established and maintained by B&W or the respective contractor.

In RAI No. 8, the NRC staff requested that B&W clarify how the inspection program applied to fabrication, modification, construction, and maintenance activities, which were originally outside the scope of the QATR. Additionally, the NRC staff asked whether experiment fabrication was within the scope of the QATR. In its response, B&W stated that the inspection program will apply to procurement, fabrication, modification, construction, and maintenance. Further, B&W stated that it does not intend to use the reactor for experiments.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for inspection met the guidance in Section 12.9 of NUGEG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.11 Test Control

B&W has established the necessary measures and implementing procedures to demonstrate that SSCs will perform satisfactorily in service. The quality organization is responsible to review test procedures, monitor test performance, and evaluate the final results to ensure that test requirements will be satisfied.

Computer programs to be used for a control function or process will be tested with an approved verification and validation plan and demonstrate required performance over the range of operation of the controlled function or process.

In RAI No. 9, the NRC staff requested that B&W clarify how the quality organization possesses the technical capability to be the responsible authority to assure that test requirements have been satisfied. In its response, B&W stated that Revision 3 of the QATR was revised to reflect that test results would be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. Implementing procedures will be used to identify and document the responsible authority.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for testing met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.12 Control of Measuring and Test Equipment

B&W's QATR described controls for the calibration, maintenance and use of tools, gages, instruments, and other M&TE used for measurements, inspections, and tests performed to document compliance with specified requirements.

B&W's control of M&TE includes the following:

1) positive identification of the equipment and its calibration status, including the due date of the next calibration;

2) use of recognized industry standards;

3) written procedures describing the calibration control system;

4) record system to indicate calibration dates, capability of M&TE to perform intended function satisfactorily and identification of personnel performing the calibrations;

5) recall system to prevent use of equipment beyond its calibration due date; and

6) a system for corrective action when out-of-calibration or damaged M&TE has been used.

In RAI No. 10, the NRC staff noted that ANSI/ANS 15.8 allows for calibration and control measures not to be required when normal commercial equipment provides adequate accuracy. In its response, B&W stated that Revision 3 of the QATR was revised to reflect that calibration and control measures will not be required when normal commercial equipment provides adequate accuracy.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for M&TE met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.13 Handling, Storage, and Shipping

B&W's QATR described the necessary measures and implementation of procedures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage, deterioration, or release of radioactive or hazardous material. The above mentioned work is accomplished by qualified individuals in accordance with applicable procedures.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for handling, storage, and shipping met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.14 Inspection, Test and Operating Status

B&W's QATR described the measures and implementation of procedures to identify the status of inspections and test operations. The status of inspections and test operations is indicated by tags, markings, records, or other suitable means, provided that the method used ensures that only accepted items are used, installed, or operated.

Unacceptable items or items of an indeterminate status are identified and controlled to ensure they are not inadvertently installed, used, or operated.

The quality organization has the responsibility to monitor or conduct inspections or tests and to review data to ensure acceptability.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for inspection, test, and operating status met the guidance in Section 12.9 of NUREG-1537, and ANSI/ANS 15.8.

3.2.1.1.15 Nonconforming Materials, Parts or Components

B&W's QATR described the necessary measures and implementation of procedures to control nonconforming items to prevent their inadvertent use or installation until the nonconforming condition is corrected or evaluated to rework, use as is, reject, or repair, as determined by the responsible design organization. These controls include measures for identification, documentation, segregation (as appropriate), and disposition. Physical segregation and marking are B&W's preferred method for identification; however, other means of identification (e.g., tagging, etc.) are acceptable when physical segregation is impractical.

B&W will document the technical justification for the acceptability of a nonconforming item. B&W's quality organization will periodically review nonconformance data and evaluate for adverse trends. Reports of reviews will be sent to responsible management.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for nonconforming materials, parts, or components met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.16 Corrective Action

B&W's QATR described the necessary measures and implementation of procedures to determine the cause(s) and take corrective and preventive action to preclude repetition when major and recurring conditions adverse to quality, such as failures, malfunctions, deficiencies, defective material and equipment, and nonconformances are identified. B&W's corrective action program provides for prompt identification, documentation, classification, and correction of the conditions. For conditions adverse to quality and significant conditions adverse to quality, the corrective action process, including the resulting action to resolve the deficiency shall be documented and reported to the appropriate level of management.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for corrective action met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.17 Quality Assurance Records

B&W's QATR described the necessary measures and implementation of procedures to ensure sufficient records of completed items and activities affecting quality are collected, maintained, and appropriately stored. B&W's record system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

B&W's applicable specifications, procurement documents, procedures, or other documents specify the receipt, storage, preservation, safekeeping, retrieval, types of records to be generated, retention period, and their disposition. B&W has established the necessary measures to ensure that records are legible, identifiable, retrievable, and traceable to the item or activity to which it applies.

Provisions will be specified for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. Records will be maintained by a supplier and accessible to B&W and its contractors.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for QA records met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

3.2.1.1.18 Audits

The quality organization will have the responsibility to establish the assessment program and requisite implementing procedures. Internal and supplier audits will be scheduled based on periodic reviews. The internal audits will address each QATR section.

Periodic audits of safety-related activities will be conducted to determine the effectiveness of the quality program.

Lead auditors will be trained and qualified. Team members will be independent of the area being assessed. The team members will also be adequately trained and qualified.

Results of the audits will be made available to the relevant B&W or contractor managers, as applicable.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for audits met the guidance in Section 12.9 of NUREG-1537, Parts1 and 2, and ANSI/ANS 15.8.

3.2.1.1.19 Experimental Equipment

In RAI No. 11, the NRC staff requested that B&W clarify if the QATR provides controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety-related items. In its response, B&W stated that Revision 3 of the QATR was revised to insert Section 19.0, Experimental Equipment. Section 19.0 states that as a commercial facility, MIPS will not have experimental equipment or facilities, nor will they be described in the license and safety analysis report. Changes, tests, and experiments will be managed according to 10 CFR 50.59.

As described above, the NRC staff reviewed the QA measures to be employed by B&W and its contractors and determined that the controls for changes, tests, and experiments met the regulatory guidance in 10 CFR 50.59.

4.0 CONCLUSION

The NRC staff evaluated B&W's QATR and the supplemental correspondence. The NRC staff concludes that B&W's QA program description adequately addresses the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8, and is therefore, acceptable.

5.0 REFERENCES

1. Reynolds, W. E., B&W Technical Services Group, Inc., letter to Document Control Desk, NRC, "B&W Medical Isotope Production System (MIPS) submittal of Quality Assurance Program Description (QAPD) Topical Report Enclosure 1, Abstract Enclosure 2, and Basis for submittal of the Topical Report Enclosure 3," dated June 4, 2010, ADAMS Accession Number ML101600197.

2. Glenn, D. E., B&W Technical Services Group, Inc., letter to Document Control Desk, NRC, "B&W Response to Request for Additional Information Regarding Quality Assurance Program Description Submitted June 4, 2010," dated October 18, 2010, ADAMS Accession Number ML102990311.

3. Voth, Marcus H., NRC, letter to Reynolds, W. E., B&W Technical Services Group, Inc., "Request for Additional Information Regarding the Babcock & Wilcox Technical Services Group, Inc. Medical Isotope Production System Quality Assurance Program Description Topical Report, MIPS-PP-QA-14, Revision 2," dated September 22, 2010, ADAMS Accession Number ML102640304.

Principal Contributor: P. Prescott

Date:

MIPS-02FC-QAPD-00003

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October 18, 2010

Document Control Desk
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: B&W Response to Request for Additional Information Regarding Quality Assurance Program Description Submitted June 4, 2010 (TAC No. ME4101)

References:

1. Letter from B&W (Reynolds) to NRC dated June 4, 2010, B&W Medical Isotope Production System (MIPS) submittal of Quality Assurance Program Description (QAPD) Revision 2 Topical Report Enclosure 1, Abstract Enclosure 2, and Basis for Submittal of the Topical Report Enclosure 3.
2. Letter from NRC (Voth) to B&W (Reynolds) dated September 22, 2010, Babcock & Wilcox Request for Additional Information Regarding Quality Assurance Program Description Submitted June 4, 2010 (TAC No. ME4101).

Babcock & Wilcox is providing this response to NRC's Request for Additional Information (Reference 2) regarding the Quality Assurance Program Description (QAPD) for the B&W Medical Isotope Production System. Attachment 1 to this letter provides answers to the questions posed by NRC.

In responding to the questions, B&W also made revisions to the QAPD. Therefore, Revision 3 of the QAPD dated October 18, 2010 is included as Enclosure 1.

If you have questions, please contact me at 434-522-6313 or Steve Schilthelm at 434-522-6243. Thank you for your attention to this matter.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 10/18/10

The following is in response to the request for a documented Declaration of Oath for the first Babcock & Wilcox submittal of the MIPS Quality Assurance Program Description, Revision 2, dated May 17, 2010 to the Nuclear Regulatory Commission on June 4, 2010 under cover letter by W. E. Reynolds, Program Manager for MIPS.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 10/18/10

Sincerely,

D. E. Glenn
Program Manager
Medical Isotope Production System (MIPS)

Enclosure
1. MIPS Quality Assurance Program Description, Revision 3, October 18, 2010.

Attachment
1. B&W Response to Request for Additional Information Regarding Quality Assurance Program Description Submitted June 4, 2010, Project no. 0766, (TAC No. ME4101).

cc: Mary Jane Ross-Lee, Office of Nuclear Reactor Regulation (3 copies)
Marc Voth, NRC Senior Project Manager

ATTACHMENT 1

B&W RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

REGARDING THE QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD)

B&W MEDICAL ISOTOPE PRODUCTION SYSTEM (MIPS)

TOPICAL REPORT MIPS-PP-QA-14

PROJECT NO. 0766

TAC NO. ME4101

Enclosure 1 of 1 – QAPD, Revision 3

The following provides response to the questions to B&W from NRC. The questions are repeated, followed by the B&W response in italics.

INTRODUCTION

1. Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34(a)(7) requires the applicant of a construction permit (CP) to include a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems and components of the facility and how the applicable portions of Appendix B to 10 CFR Part 50 will be satisfied. The Scope in the B&W QAPD provides information on activities to which the QAPD applies.

   For consistency with the above regulations, the NRC staff needs clarification of the overall scope of activities that applies or could apply to the QAPD, in addition to the list of activities already mentioned.

B&W Response: Revision 2 of the QAPD as submitted to the NRC was initially intended to only cover the Design and Procurement of Engineering Services. B&W intended to revise the QAPD upon submittal of the Preliminary Safety Analysis Report (PSAR) to include the broader scope identified in 50.34(a)(7). However, to accommodate a streamlined review process B&W has modified the scope to include design, fabrication, construction, and testing of the structures, systems and components of the facility.

The second paragraph in the QAPD (Enclosure 1 of 1) Scope section has been revised and now states: 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 PSAR upon the submittal of the Construction License Application.

2. The QAPD Scope states that the procedures that implement the requirements in the QAPD are identified in the Master Procedures Lists under Document Control. The staff did not find the Master Procedures List under Document Control.

B&W Response: Revision 2 of the QAPD as submitted to the NRC included reference to "Document Control" when identifying the Master Procedures List. This reference was not intended to direct the reader to the section titled 6.0 Document Control in the QAPD. Rather it was intended to instruct the reader that the list would be maintained by the project as a controlled document.

The last sentence in the first paragraph now states: The procedures that implement the requirements in this document are identified in the Master Procedures List maintained by the Document / Record Manager. Additionally, the title Document / Record Manager has been added to paragraphs 1.2.2.9 and 17.2.4 for consistency.

1.0 ORGANIZATION

3. American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.8-1995, Section 2.1, states that during the design, construction, or modification of a research reactor, most of the work may be performed by outside organizations or support contractors. The owner/operator's role is then primarily one of providing requirements and verifying compliance with those requirements. In paragraph 1.2.2.11 of the QAPD, it states that the EPC Manager is responsible for all oversight and management-related aspects associated with EPC organizations and suppliers. The NRC staff did not find the acronym "EPC," defined in the QAPD. Additionally, please clarify if the EPC provides and verifies that outside organizations or support contractors meet the quality assurance requirements for the applicant.

B&W Response: Revision 2 of the QAPD as submitted to the NRC described an organization that included an Engineering / Procurement / Construction (EPC) contracting approach to the design and procurement services.

Concurrent with the clarification of the scope in the response to question 1 above, our description of the contracting approach now encompasses B&W management of multiple contractors. The organization chart Figure 1 and supporting paragraph 1.2.2.11 includes definitions of this broader generic approach to contract management.

Paragraph 1.2.2.11 header is now entitled Contract Management and describes the roles and responsibilities of the Contract Manager, Contract Organizations, and Subcontractors (suppliers). This includes identifying, implementing, and verifying flow-down of quality requirements as applicable. Figure 1 now depicts generically the contract management function, contractor organizations, and subcontractors (suppliers).

2.0 QUALITY ASSURANCE PROGRAM

4. ANSI/ANS-15.8-1995, Section 1.3, states that safety-related items are those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents. Additionally, Section 2.2, states that the program shall identify the items and activities to which it applies to the extent of program application for each item and activity. In Section 2, Figure 2 of the QAPD, the definition of safety-related structures, systems and components is provided. Please clarify how the QAPD definition for safety-related structures, systems and components is consistent with ANSI/ANS-15.8-1995.

B&W Response: Revision 2 of the QAPD as submitted to the NRC included Figure 2 to define B&W's Graded Approach to Quality. Rather than leave any ambiguities with regard to the use of the term safety-related as defined in the ANSI/ANS 15.8 standard on "accidents that could cause undue risk," we chose to define safety-related based on the following discussion.

Since the facility is being licensed under 10CFR50, the definition of Safety Related SSCs is restated directly from 10CFR50.2 and is aligned directly with QL-1. B&W also recognized that the non-reactor portions of MIPS, which as part of the facility will be licensed under 10CFR50, required additional consideration. Although 10CFR70 does not specifically apply to MIPS nor does it require a QA Program, QL-2 was developed to be aligned with the quality requirements of 10CFR70 Management Measures and to be consistent with the Performance Requirements of 10CFR70. Further, in order to specifically address the requirements of 10CFR21 for MIPS, a Basic Component is defined as aligning directly with Safety Related and QL-1.

B&W implements formal procedures that specify the treatment of graded quality levels QL-1, QL-2, and QL-3 structures, systems and components. Figure 2 of the QAPD has been revised to commit to implementing procedures.

The first part of Figure 2 in Section 2.0 of the QAPD now states: The activities and tasks are performed in accordance with approved implementing procedures.

3.0 DESIGN CONTROL

5. ANSI/ANS-15.8-1995, Section 2.3.4, states that design documents and records, which provide evidence that the design and design verification processes were performed, shall be collected, stored, and maintained for the life of the safety-related unit. Paragraph 3.2.4 of the QAPD, states that design documents and records, which provide evidence that the design and design verifications processes were performed, will be collected, stored, and maintained for the life of the item to the extent necessary to demonstrate satisfactory control of input, verification and acceptance. Please clarify the intent of the phrase, "to the extent necessary to demonstrate satisfactory control of input, output, verification and acceptance."

B&W Response: Revision 2 of the QAPD as submitted to the NRC stated: "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 to the extent necessary to demonstrate satisfactory control of input, output, verification and acceptance." B&W believed this was consistent with the ANSI/ANS 15.8 standard, however we agree the phrase "to the extent necessary ...." creates ambiguity.

Paragraph 3.2.4 now states: 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.

4.0 PROCUREMENT OF DOCUMENT CONTROL

6. ANSI/ANS-15.8-1995, Section 2.4, states that procurement documents shall contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser. Paragraph 4.2.6 of the QAPD states that the procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval. Please clarify if the QAPD includes requirements that the procurement documents contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser.

B&W Response: Revision 2 of the QAPD as submitted to the NRC stated: "The procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval. Also, documents required as deliverables as a part of design or other procurements will be specified for the supplier." B&W believed this was consistent with the ANSI/ANS 15.8 standard, however we agree that the use of the ANSI/ANS standard language provides consistency.

Paragraph 4.2.6 now states: 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.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7. ANSI/ANS-15.8-1995, Section 2.4, states that procurement of items and services shall be controlled to ensure appropriate procurement planning, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services for acceptance upon delivery or completion. Paragraph 7.2.1 of the QAPD states that the results of evaluations and assessments shall be available to B&W TSG [Technical Services Group] management and program team members.

B&W Response: Revision 2 of the QAPD as submitted to the NRC included a note reiterated in several sections stating: "For purposes of the MIPS Program the term assessment is the same as audit." B&W's intent was to use the term assessment consistently throughout the MIPS Program, especially since Section 18.0 fully addresses assessments, however we agree that the use of the ANSI/ANS standard language provides consistency.

Paragraphs in Section 4.0 - 4.1, 4.2.7 and Section 7.0 - 7.1, 7.2.1, 7.2.4, and 7.2.5 now use the term audit in lieu of assessment. The original note stating that the term assessment is the same as audit has been deleted in Section 18.0 paragraph 18.1 and in Appendix C under the term assessment. The definition of audit has been added to Appendix C. Notes pertaining to assessment and audit have been added to reference the applicable QAPD Sections, respectively.

10.0 INSPECTIONS

8. ANSI/ANS-15.8-1995, Section 2.10, states that procurement documents shall apply to procurement, construction, modification, maintenance, and experiment fabrication. Paragraph 10.2.1 of the QAPD states that the inspection program shall apply to procurement, fabrication, modification, construction, and maintenance. Please clarify how the inspection program shall apply

to fabrication, modification, construction and maintenance activities, which are outside the scope of QAPD. Additionally, please clarify if experiment fabrication is within the scope of the QAPD.

B&W Response: Revision 2 of the QAPD as submitted to the NRC was initially intended to only cover the Design and Procurement of Engineering Services. B&W intended to revise the QAPD upon submittal of the PSAR to include the broader scope identified in 50.34(a)(7). However, to accommodate a streamlined review process B&W has modified the scope to include design, fabrication, construction, and testing of the structures, systems and components of the facility. (This response is the same as question 1 above.)

Revision 2 of the QAPD as submitted to the NRC stated: "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's intent was to include the scope of the inspection program with the exception of experiment fabrication since B&W does not intend to use the reactor for experiments.

Paragraph 10.2.1 now states: 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).

11.0 TEST CONTROL

9. ANSI/ANS-15.8-1995, Section 2.11, states that the test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. Paragraph 11.2.4 of the QAPD states that the quality organization is responsible to review test designations and procedures, monitor test performance and evaluate final results to ensure that test requirements have been satisfied. Please clarify how the quality organization possesses the technical capability to be the responsible authority to assure that test requirements have been satisfied.

B&W Response: Revision 2 of the QAPD as submitted to the NRC stated: "The quality organization is responsible to review test designations and procedures, monitor test performance and evaluate final results to ensure that test requirements have been satisfied." B&W Commits to ensuring qualified personnel perform activities and tasks in the QAPD Section 2.0 and via flow-down to contractors and subcontractors. Implementing procedures are used to identify and document qualification of personnel.

Paragraph 11.2.4 now states: 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.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

10. ANSI/ANS-15.8-1995, Section 2.12, states that calibration and control measures are not required when normal commercial equipment provides adequate accuracy. The NRC staff recommends this allowance be considered in Paragraph 12.2 of the QAPD.

B&W Response: Revision 2 of the QAPD as submitted to the NRC stated: "Instruments shall be uniquely identified by serial number or other designation to ensure traceability to calibration data and standards." B&W did not include the additional flexibility allowed by the standard for normal commercial equipment that provides adequate accuracy.

The second sentence in paragraph 12.2.2 now states: Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.

19.0 EXPERIMENTAL EQUIPMENT

11. ANSI/ANS-15.8-1995, Section 2.19, states that the quality assurance program shall provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety related items. Please clarify how the QAPD provides controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety-related items.

B&W Response: Revision 2 of the QAPD as submitted to the NRC did not address Section 19.0 of the standard. B&W did not include the section, because as a commercial facility, MIPS does not currently anticipate or plan to use experimental equipment or facilities.

Section 19.0 "Experimental Equipment" has been added and states: 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.

Additional Revisions Initiated Internally by B&W Management

1. Section 1.0, paragraph 1.2.2.1 "Technical and Program Management" was incorporated to describe the responsibility of the Chief Technical Officer. Figure 1 was revised to include Technical and Program Management function. This change incorporates the latest management change.

Enclosure 1 of 1, Revised QAPD, Revision 3

MIPS-PP-QMQAPD-377
MIPS-02FC-QAPD-00002
8/13/11 (5)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 22, 2010

W.E. Reynolds, MIPS Program Manager
Babcock and Wilcox Technical Services Group, Inc.
2016 Mt. Athos Road
Lynchburg, VA 24505-5447

SUBJECT: BABCOCK AND WILCOX REQUEST FOR ADDITIONAL INFORMATION REGARDING QUALITY ASSURANCE PROGRAM DESCRIPTION SUBMITTED JUNE 4, 2010 (TAC NO. ME4101)

Dear Mr. Reynolds:

The U.S. Nuclear Regulatory Commission (NRC) has reviewed the Babcock & Wilcox (B&W) Technical Services Group, Inc. Medical Isotope Production System (MIPS) Quality Assurance Program Description (QAPD), Revision 2, in accordance with the provisions of the NRC standard review plan for non-power reactors, NUREG 1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Section 12.9, "Quality Assurance." The B&W QAPD applies to activities affecting the quality and performance of safety-related structures, systems, and components. The QAPD has been developed for B&W design and procurement of engineering services.

Based on our review of the B&W QAPD, the staff has determined that additional information is required to complete our review. Please provide responses to the enclosed request for additional information no later than October 25, 2010. In accordance with Title 10 of the *Code of Federal Regulations* Section 50.30(b) (10 CFR 50.30(b)), your response must be executed in a signed original under oath or affirmation. Please send the original copy of your correspondence to the NRC Document Control Desk with a copy to your Project Manager. Following receipt of the additional information, we will continue our evaluation.

In addition, the staff notes that your June 4, 2010, filing of the QAPD did not include an oath and affirmation statement in accordance with 10 CFR 50.30(b). Please provide an appropriate oath

and affirmation to cover that submittal as well. Should you have any questions regarding this request, please contact me at (301) 415-1210 or by electronic mail at Marcus.Voth@nrc.gov.

Sincerely,

Marcus H Voth

Marcus H. Voth, Senior Project Manager
Research and Test Reactors Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 0766

Enclosure:
As stated

OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST FOR ADDITIONAL INFORMATION

REGARDING THE QUALITY ASSURANCE PROGRAM DESCRIPTION

B&W MEDICAL ISOTOPE PRODUCTION SYSTEM (MIPS)

TOPICAL REPORT MIPS-PP-QA-14

PROJECT NO. 0766

The U.S. Nuclear Regulatory Commission (NRC) has reviewed the Babcock & Wilcox (B&W) Technical Services Group, Inc., Medical Isotope Production System (MIPS) Quality Assurance Program Description (QAPD), Revision 2, submitted June 4, 2010, in accordance with the provisions of the NRC standard review plan for non-power reactors, NUREG 1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Section 12.9, "Quality Assurance." The B&W QAPD applies to activities affecting the quality and performance of safety-related structures, systems, and components. The QAPD has been developed for B&W design and procurement of engineering services. Based on our review of the B&W QAPD, the NRC staff has determined that additional information is required to complete our review.

INTRODUCTION

1. Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34(a)(7) requires the applicant of a construction permit (CP) to include a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems and components of the facility and how the applicable portions of Appendix B to 10 CFR Part 50 will be satisfied. The Scope in the B&W QAPD provides information on activities to which the QAPD applies.

   For consistency with the above regulations, the NRC staff needs clarification of the overall scope of activities that applies or could apply to the QAPD, in addition to the list of activities already mentioned.

2. The QAPD Scope states that the procedures that implement the requirements in the QAPD are identified in the Master Procedures List under Document Control. The staff did not find the Master Procedures List under Document Control.

1.0 ORGANIZATION

3. American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.8-1995, Section 2.1, states that during the design, construction, or modification of a research reactor, most of the work may be performed by outside organizations or support contractors. The owner/operator's role is then primarily one of providing requirements and verifying compliance with those requirements. In paragraph 1.2.2.11of the QAPD, it states that the EPC Manager is responsible for all oversight and management-related aspects associated with EPC organizations and suppliers. The NRC staff did not find the

acronym "EPC," defined in the QAPD. Additionally, please clarify if the EPC provides and verifies that outside organizations or support contractors meet the quality assurance requirements for the applicant.

2.0 QUALITY ASSURANCE PROGRAM

4. ANSI/ANS-15.8-1995, Section 1.3, states that safety-related items are those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents. Additionally, Section 2.2, states that the program shall identify the items and activities to which it applies to the extent of program application for each item and activity. In Section 2, Figure 2 of the QAPD, the definition of safety-related structures, systems and components is provided. Please clarify how the QAPD definition for safety-related structures, systems and components is consistent with ANSI/ANS-15.8-1995.

3.0 DESIGN CONTROL

5. ANSI/ANS-15.8-1995, Section 2.3.4, states that design documents and records, which provide evidence that the design and design verification processes were performed, shall be collected, stored, and maintained for the life of the safety-related unit. Paragraph 3.2.4 of the QAPD, states that 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 to the extent necessary to demonstrate satisfactory control of input, output, verification and acceptance. Please clarify the intent of the phrase, "to the extent necessary to demonstrate satisfactory control of input, output, verification and acceptance."

4.0 PROCUREMENT DOCUMENT CONTROL

6. ANSI/ANS-15.8-1995, Section 2.4, states that procurement documents shall contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser. Paragraph 4.2.6 of the QAPD states that the procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval. Please clarify if the QAPD includes requirements that the procurement documents contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7. ANSI/ANS-15.8-1995, Section 2.4, states that the procurement of items and services shall be controlled to ensure appropriate procurement planning, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services for acceptance upon delivery or completion. Paragraph 7.2.1 of the QAPD states that the results of evaluations and assessments shall be available to B&W TSG [Technical Services Group] management and program team members. Additionally, Paragraph 7.2.4 of the QAPD states that the quality organization provides source surveillance, assessments, inspection and release

of items as specified. Please clarify how the QAPD provides for audits to show objective evidence of quality furnished by a supplier.

10.0 INSPECTIONS

8. ANSI/ANS-15.8-1995, Section 2.10, states that the inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication. Paragraph 10.2.1 of the QAPD states that the inspection program shall apply to procurement, fabrication, modification, construction, and maintenance. Please clarify how the inspection program shall apply to fabrication, modification, construction and maintenance activities, which are outside the scope of QAPD. Additionally, please clarify if experiment fabrication is within the scope of the QAPD.

11.0 TEST CONTROL

9. ANSI/ANS-15.8-1995, Section 2.11, states that test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. Paragraph 11.2.4 of the QAPD states that the quality organization is responsible to review test designations and procedures, monitor test performance and evaluate final results to ensure that test requirements have been satisfied. Please clarify how the quality organization possesses the technical capability to be the responsible authority to assure that test requirements have been satisfied.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

10. ANSI/ANS-15.8-1995, Section 2.12, states that calibration and control measures are not required when normal commercial equipment provides adequate accuracy. The NRC staff recommends this allowance be considered in Paragraph 12.2 of the QAPD.

19.0 EXPERIMENTAL EQUIPMENT

11. ANSI/ANS-15.8-1995, Section 2.12, states that the quality assurance program shall provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety related items. Please clarify how the QAPD provides controls over the design, fabrication, installation, and modification of experimental equipment to the extent that this impacts safety related items.

MIPS-02FC-QAPD-00001

babcock & wilcox technical services group
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(5)

June 4, 2010

Document Control Desk
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: B&W Medical Isotope Production System (MIPS) submittal of Quality Assurance Program Description (QAPD) Topical Report Enclosure 1, Abstract Enclosure 2, and Basis for submittal of the Topical Report Enclosure 3

References:
1. Letter from B&W (Cochran) to NRC (Borchardt) dated February 12, 2008, Notice of Intent to Submit an Application to License and Operate a Medical Isotope Production System;
2. Meeting between B&W and NRC on July 8, 2009;
3. Letter from NRC (McGinty) to B&W (Reynolds) dated October 14, 2009, Licensing of a Babcock & Wilcox Medical Isotope Production System;
4. Meeting between B&W and NRC on February 2, 2010.

Babcock & Wilcox intends to submit an application for a construction permit in accordance with 10 CFR Part 50 (hereinafter 10CFR50) for a Medical Isotope Production System (MIPS) in 2011 (reference 1). In preparation for the application submittal, B&W is hereby submitting the Quality Assurance Program Description (QAPD) Topical Report for NRC review and approval (Enclosure 1). The abstract and basis for submittal as a Topical Report are included as Enclosures 2 and 3. In order to increase efficiency of the licensing process, we discussed the concept of an early submittal of the QAPD with the NRC staff during a prior meeting and visit (references 2 & 4). The intent of this early submittal is to provide information regarding our QA approach to facility design in order to obtain early NRC review.

The MIPS includes aqueous homogeneous reactors (AHRs) fueled with low enriched uranium. It also includes the associated system for the purpose of manufacturing ^{99}Mo as a medical radioisotope. From a public policy perspective an AHR using LEU serving as a medical isotope production reactor will provide the U.S. with a domestic source for this important medical radioisotope and will reduce nuclear proliferation concerns. Based upon determinations of the Nuclear Regulatory Commission (reference 3), the MIPS will be licensed under 10CFR50 as a production and utilization facility, be classified as a non-power reactor, and require both construction and operating authorization.

The QAPD was developed in accordance with the guidance in Chapter 12.9 of NUREG 1537 and ANSI/ANS 15.8 1995 (R-2005) "Quality Assurance Program Requirements for Research Reactors." In addition, while MIPS will be licensed under 10CFR50, B&W appreciates the value of considering other concepts of the regulatory structure of 10 CFR for the non-reactor portions of the facility and has incorporated those concepts as appropriate in a graded manner.

This version of the QAPD is for the design and procurement of engineering services. The QAPD will be updated to include procurement, fabrication, testing, construction, and operation activities and incorporated into the Preliminary Safety Analysis Report in accordance with the requirements of 10CFR50.34(a)(7) upon submittal of the application for construction permit.

If you have questions, please contact me at 434-522-6439 or Steve Schilthelm at 434-522-6243. Thank you for your attention to this matter.

Sincerely,

W. E. Reynolds

W. E. Reynolds
Program Manager
Medical Isotope Production System (MIPS)

Enclosure
cc: Mary Jane Ross-Lee, Office of Nuclear Reactor Regulation (3 copies)

Enclosures:
1. Quality Assurance Program Description (QAPD)
2. Abstract
3. Basis for submittal of the Topical Report

Enclosure 1

B&W Medical Isotope Production System (MIPS)

Quality Assurance Program Description (QAPD)

Enclosure 2

Abstract

This topical report describes the Babcock & Wilcox Technical Services Group quality assurance program for the Medical Isotope Production System (MIPS) using aqueous homogeneous reactors (AHRs). The MIPS will be licensed under 10CFR50 as a production and utilization facility and classified as a non-power reactor. This version of the QAPD applies to the Design and Procurement of Engineering Services. It encompasses the administrative and technical controls for ensuring compliance with requirements. Implementing procedures are "program-specific" to the MIPS Program

This document was developed in accordance with the guidance in Chapter 12.9 of NUREG 1537 and ANSI/ANS 15.8 1995 (R-2005) for non-power reactor quality assurance. In addition, while MIPS will be licensed under 10CFR50, B&W considered other concepts of the regulatory structure of 10CFR's for the non-reactor portions of the facility and has incorporated quality assurance concepts into the QAPD as appropriate in a graded manner. The QAPD will be updated to include procurement, fabrication, testing, construction, and operation activities and incorporated into the Preliminary Safety Analysis Report in accordance with the requirements of 10CFR50.34(a)(7) upon submittal of the application for construction permit.

Enclosure 3

Basis for submittal of the Topical Report

B&W intends to design, construct, and operate a Medical Isotope Production System that will result in a domestic supply of ^{99}Mo. Deployment of MIPS will accomplish three significant objects that are considered national priorities. First, it will help alleviate ^{99}Tc (diagnostic isotope resulting from ^{99}Mo supply) supply crisis that has resulted from operational interruptions at current international reactors that produce ^{99}Mo; second, it will result in a long-term domestic supply of ^{99}Mo to reduce the U.S. dependency on foreign suppliers; and third, it will result in a ^{99}Mo supply that does not rely on the use of highly enriched uranium.

B&W has completed the conceptual design of the facility and is about to enter into the preliminary design phase of the process which will ultimately lead to an application for construction permit. The application of the Quality Assurance Program Description (QAPD) to the preliminary design is extremely important to providing appropriate quality to the safety-related aspects of the design. An early NRC review and approval of these concepts will result in a greater degree of regulatory certainty and will ensure that the construction application review process can proceed in an efficient and timely manner with alignment on the quality program.

A discussion of how each of the Topical Report criteria applies to MIPS is provided below:

Criteria: The report deals with a specific safety-related subject regarding a power reactor [in the case of MIPS a non-power reactor] that requires a safety assessment by the NRC staff; for example, component design, analytical models or techniques, or performance testing of components and/or systems that can be evaluated independently of a specific license application.

The MIPS QAPD describes how B&W will apply quality standards to safety-related systems, structures and components and to other safety features of the facility.

Criteria: The report is expected to be referenced by multiple licensees in a number of license amendment requests following staff approval. Generally, a report intended for use by multiple sites of an individual licensee is not considered a topical report.

B&W has expressed its intent to construct a single Medical Isotope Production Facility. While this is the immediate intent and focus of the program, the successful implementation of the first MIPS will likely result in subsequent facilities possibly being licensed by multiple licensees.

Criteria: The report contains complete and detailed information on the specific subject presented. Conceptual or incomplete preliminary information will not be reviewed.

B&W believes the QAPD submitted herein provides complete and detailed information related to the design of the MIPS as a non-power reactor and a production facility for medical isotope separation and will be adequate to address design of safety-related systems for supporting both the preliminary and final safety analysis reports.

Criteria: NRC approval of the report will increase the efficiency of the review process for applications that reference the report.

The QAPD addresses key attributes of quality assurance and the design of the entirety of the facility (reactor and isotope separation). Because this is the first non-power reactor and isotope separation facility licensed by NRC in many years and has several unique attributes of a single license that addresses all aspects of the facility, B&W believes an early review and approval of the QAPD will result in alignment of quality expectations and ultimate efficiency in the license application reviews. Because NRC licensing is a critical path activity to the ultimate supply of medical isotopes using low enriched uranium from MIPS, it is clear that the improvement to the licensing efficiency will be in the public interest.

Babcock & Wilcox
Technical Services Group, Inc.

MEDICAL ISOTOPE PRODUCTION SYSTEM

Quality Assurance Program Description

Topical Report

MIPS-PP-QA-14-R3-A

October 18, 2010

Revision 3

Prepared by
Paul W. Gladieux
MIPS Program Quality Manager

Approved by
Dave W. Zeff
Director, Environment, Safety, Health, and Quality, B&W TSG

Approved by
Daniel E. Glenn
MIPS Program Manager

Approved by
Ross T. Thomas
MIPS Chief Technical Officer
Technical and Program Management

B&W technical services group

CONTENTS

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 ^{99}Mo 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.

B&W
technical services group

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.

APPROVED BY

Daniel E. Glenn
MIPS Program Manager

Dave W. Zeff
Director, Environment, Safety, Health, & Quality
B&W TSG

Ross T. Thomas
CTO, Technical & Program Management

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

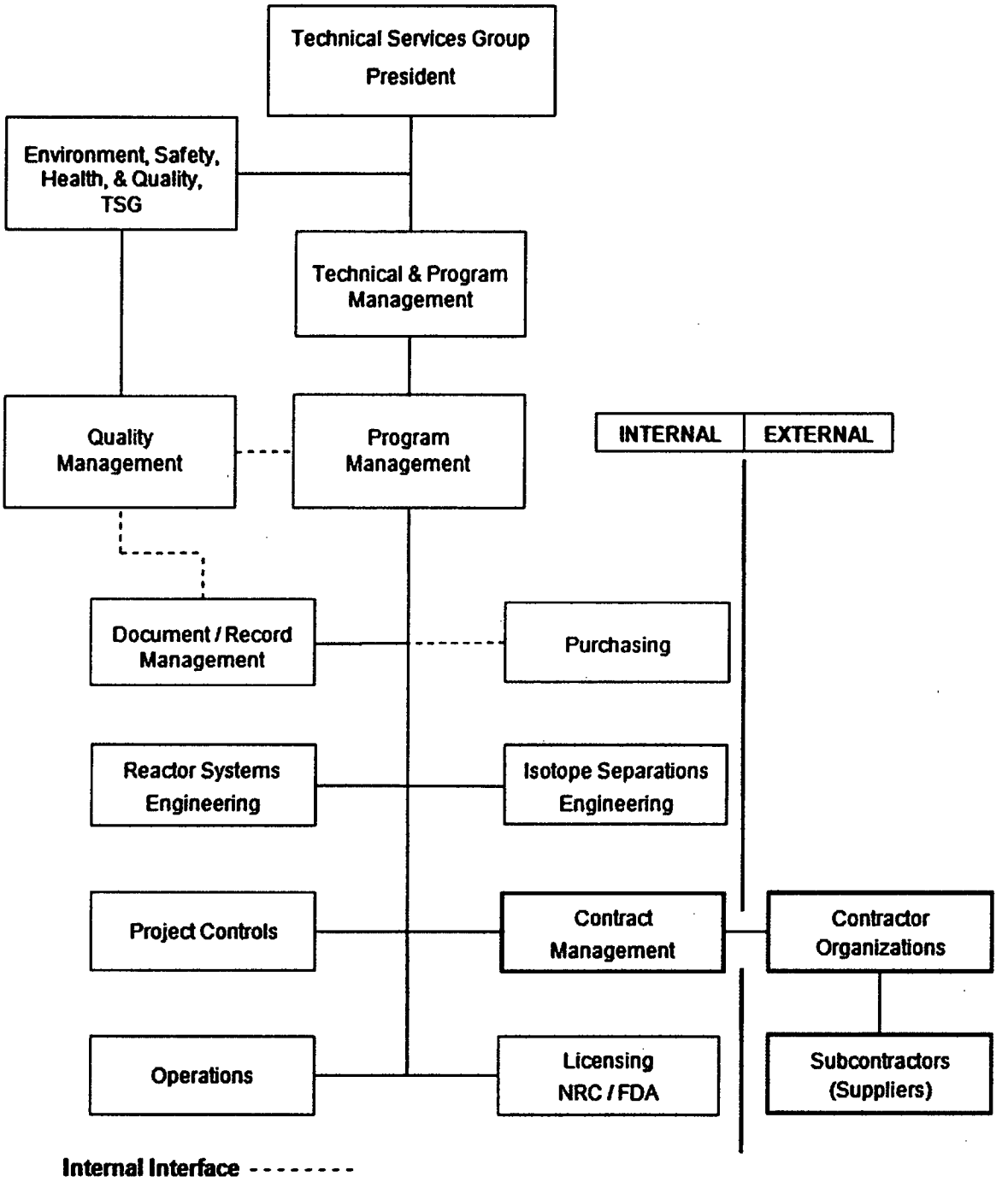

Figure 1

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, 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 per approved procedures. 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 Record

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 cr 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 *Format and Content*
6.	NUREG-1537, Part 2, February 1996, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors *Standard Review Plan and Acceptance Criteria*

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.