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.

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