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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,

S W 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

Q004
NRR

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.