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PROJ0766

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.

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NER

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