October 13, 2009

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

SUBJECT: LICENSING OF A BABCOCK AND WILCOX MEDICAL ISOTOPE PRODUCTION SYSTEM

Dear Mr. Reynolds:

The Nuclear Regulatory Commission (NRC) is writing in response to your letters dated October 3, 2008, and October 6, 2008, in which Babcock and Wilcox (B&W) seeks prelicensing guidance from the NRC on potential policy issues associated with B&W's intent to request a license for and to operate a Medical Isotope Production System (MIPS). In your letters, you state that the purpose of the letters was to provide B&W's understanding of the NRC's authorizing legislation and NRC regulations, and to propose a path forward on the license review of the MIPS.

As the agency recently stated in its March 26, 2009, letter to Mr. Cochran of B&W, the NRC staff performed a comprehensive analysis of the prelicensing issues raised in your letters. This letter provides the results of the staff's analysis, including the staff's position on the path forward proposed by B&W.

In the October 3, 2008, letter, B&W proposed the following:

1. A single license for the MIPS that is issued under [Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities"] 10 CFR 50 with incorporation of other parts of 10 CFR as necessary;
2. A NRC determination that the initial extraction portion of the facility will not be classified as a Production Facility
3. NRC agreement that the MIPS is a non-power reactor under 10 CFR 50; and,
4. Designation of the MIPS license as Class 103 under 10 CFR 50.23 ["Construction Permits"].

With regard to whether the NRC could issue a single license for the MIPS under 10 CFR Part 50, with incorporation of other parts of 10 CFR as necessary, the staff agrees that there is no legal impediment under section 161.h of the Atomic Energy Act of 1954, as amended (AEA), to issuing one 10 CFR Part 50 operating license for the entire MIPS facility (i.e., numerous reactors and one or more production facilities). However, since such an approach would be a change from the previous 10 CFR Part 50 licensing practice, the NRC would, upon proper findings, grant such a license on an individual site-specific basis, via Commission order. Additionally, the staff notes that a single license for the entire MIPS facility would present challenges, in terms of practical implementation, for day-to-day interactions

related to licensing or technical issues regarding different portions of the facility. These challenges would need to be addressed as part of the license submittal and may involve restrictions such as requiring the individual reactors to be identical with common technical specifications and license conditions, as well as requiring common technical specifications and license conditions for the production facilities.

In your letter dated October 3, 2008, you stated that the MIPS will process irradiated materials containing special nuclear material that does not meet any of the three exceptions described in criterion (3) of the definition of production facility in 10 CFR 50.2, "Definitions." B&W also cited verbatim the definition of "production facility" in the AEA but provided no compelling explanation or analysis of how B&W reached its conclusion that "Based on the definition in the Atomic Energy Act and the intended use of the MIPS, B&W believes that it should not be considered a production facility." Accordingly, the staff finds that, on the basis of information provided by B&W, the MIPS would, in fact, be a production and utilization facility (i.e., the reactor portion of MIPS is a utilization facility, whereas the remaining portion of MIPS is a production facility). The staff notes that it may be possible for B&W to operate the MIPS in a manner that enables the facility to meet the exception portion of the production facility definition by limiting process batches to less than 100 grams of uranium enriched in uranium-235 with not more than 15 grams of any other special nuclear material, but your proposal did not indicate an intent to operate the MIPS in this manner.

The NRC staff agrees that the proposed MIPS would be used to produce medical isotopes for commercial use and would not be used for production of heat or electrical energy. Therefore, the reactor portion of the MIPS is a non-power reactor used for commercial purposes and can be licensed under Section 103 of the Atomic Energy Act, as amended.

In your October 3, 2008, letter, B&W stated that it plans to submit an application for a combined construction permit (CP) and operating license (OL) following the guidance provided in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," issued February 1996. However, 10 CFR Part 50 does not authorize a combined CP and OL for a Class 103 license. For Class 103 licensing, section 189 of the AEA requires that NRC hold a hearing at the CP stage and offer a hearing at the OL stage of the process. Notice for the mandatory CP hearing is governed by 10 CFR 2.104. However, 10 CFR 2.105(c) would be applicable if the applicant files an application that is complete enough to permit all evaluations necessary for issuance of the CP and OL. The notice of proposed issuance of the CP may provide that upon completion of construction and inspection, the OL will be issued without further prior notice.

In the October 6, 2008, letter, B&W requested an "NRC determination that the ULF [used liquid fuel] and/or FCLW [fuel cleanup liquid waste] from this type of a reactor that, by concentration, meets the Class C definitions, can be classified and disposed of as LLW [low-level waste] in light of the definitions in the Nuclear Waste Policy Act of 1982 (NWPA)." The NRC staff evaluated B&W's request and has determined, for the reasons described below, that FCLW could be managed as LLW, but that ULF is spent nuclear fuel and must be managed as high-level waste (HLW).

The definition in 10 CFR 61.2, "Definitions," provides that "[f]or the purpose of this definition [of "waste" under Part 61] low-level radioactive waste means radioactive waste not classified as

high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material, as described in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in § 20.1003 of this chapter." Therefore, in order for the NRC staff to conclude that FCLW meets the definition of LLW, it evaluated whether FCLW is HLW, transuranic (TRU) waste, spent nuclear fuel, or byproduct material, as described in paragraphs (2), (3), and (4) of the definition of byproduct material set forth in 10 CFR 20.1003, "Definitions."

The staff concludes that FCLW does not result from reprocessing spent nuclear fuel, but rather from the cleanup of irradiated reactor fuel. Therefore, FCLW is not HLW, as defined in the NWPA. The staff found that FCLW is not spent nuclear fuel because FCLW is derived from uranium fuel that is not "withdrawn from" the MIPS reactor as that phrase is properly understood in the context of the NWPA. FCLW is not byproduct material as defined in paragraphs (2), (3), and (4) of 10 CFR 20.1003 (i.e., Part 61 states that radioactive waste can be considered LLW for the purposes of Part 61 if it does not meet the noted portions of the § 20.1003 byproduct material definition). Specifically FCLW is not: (1) tailings or wastes produced by the extraction or concentration of uranium or thorium from ore, (2) any discrete source of radium-226, (3) any material that has been made radioactive by use of a particle accelerator, or (4) any discrete source of naturally occurring radioactive material.

With regard to whether FCLW may have TRU radionuclide concentrations consistent with LLW classification, the staff evaluated whether solidified FCLW could be disposed of as LLW subject to the restrictions of Table 1 of 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste." As noted in Attachment 2 to your letter of October 6, 2008, you estimated the concentration of alpha-emitting TRU radionuclides, with half-life greater than 5 years (in approximately 260 liters of waste solution), to be 0.357 microcuries per milliliter assuming that fuel cleanup occurs after 52 5-day reactor burn cycles. For the purposes of determining whether such waste, when solidified for disposal, would be LLW, the NRC staff assumed that FCLW would be solidified in concrete, in order to meet 10 CFR Part 61 or equivalent Agreement State LLW disposal requirements. The staff estimated the final solid concentration of TRU radionuclides, assuming that an equal volume of dry concrete ingredients would be added to FCLW to create a solid waste suitable for disposal. The staff estimates that the solid TRU radionuclide concentration would be approximately 80 nanocuries per gram. Based on this estimate, the staff concludes that it is feasible to dispose of FCLW consistent with Table 1 of 10 CFR Part 61. Therefore, it is likely that FCLW can be managed as LLW.

With regard to ULF, the NRC staff understands that ULF may be generated periodically at the end of useful liquid fuel "load" life. After processing to remove medical isotopes and after fuel cleanup, the low-enriched ULF will still contain some residual fission and activation products, including TRU radionuclides. The ULF, therefore, is "fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing." For this reason, ULF is spent nuclear fuel and must be managed for disposal as HLW in accordance with 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," or 10 CFR Part 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada."

Please contact me or Timothy A. Reed (301-415-1462) of my staff if you have any questions regarding NRC's responses to B&W's proposed path forward.

Sincerely,

/RA/

Timothy J. McGinty, Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

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Sincerely,

/RA/

Timothy J. McGinty, Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

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