## STATEMENT OF CONSIDERATIONS

REQUEST BY BABCOCK & WILCOX TECHNICAL SERVICES GROUP, INC. (B&W TSG) FOR AN ADVANCE WAIVER OF DOMESTIC AND FOREIGN RIGHTS TO INVENTIONS MADE UNDER COOPERATIVE FINANCIAL ASSISTANCE AGREEMENT NUMBER DE-AC52-09NA29596, DOE WAIVER NO. W(A) 2009-045.

The Petitioner, B&W TSG, has requested a waiver of all domestic and foreign patent rights to inventions that may be conceived or first actually reduced to practice in the course of B&W TSG's work under Cooperative Financial Assistance Agreement Number DE-AC52-09NA29596 entitled "Molybdenum-99 Demonstration Project" with the U.S. Department of Energy/National Nuclear Security Administration (DOE/NNSA).

The work to be done under the cooperative financial assistance agreement will be the research and development, facility construction and production of a critically important medical isotope – Molybdenum-99 (Mo-99). This work will allow for the U.S. to create and maintain a stable domestic supply of this vital medical isotope in light of diminishing, unreliable foreign supplies. No domestic production of Mo-99 currently exists.

The cooperative financial assistance agreement covers a period from approximately October 2009 through December 2013 at a total estimated cost to DOE of \$25,000,000. B&W TSG will provide at least \$25,000,000 (50%) up to as much as \$85,000,000 (77%) as a cost share over the life of this agreement. Government funding is currently dynamic but it is expected the \$25,000,000 will be provided over a four year period starting with limited funding in FY09 and increasing each fiscal year after that through FY12. The government contribution will be made through Budget & Reporting Code NN9002000 sponsored by the Office of Global Threat Reduction (NA-212).

B&W TSG is a Lynchburg, Virginia-based corporate division of Babcock & Wilcox, which is itself headquartered in Lynchburg, Virginia. B&W TSG provides management, nuclear operations and technical services for the US Government, primarily to the Department of Energy (DOE) and the National Nuclear Security Administration (NNSA). Babcock & Wilcox is itself a wholly-owned by McDermott International, Inc., headquartered in Houston, Texas.

The research and development, facility construction and production of Mo-99 under this cooperative financial agreement constitute only one of three technologies being funded by DOE/NNSA. There exists a wide range of production technologies for this medical isotope. However, this production is not taking place in the US. Production is taking place overseas, but supplies will soon cease being reliable. As such, based on the nature of the technology, as well as the research, development and production being done in this field worldwide, and the existing myriad of competing technologies, it is not foreseen that the grant of this waiver would decrease competition, cause undesirable market concentration, or place B&W TSG in a dominant market position.

B&W TSG has agreed to abide by 35 U.S.C. §§ 202, 203 and 204, as well as the provisions of the Standard Patent Rights clause for an Advance Waiver, subject to the minor modification mentioned below. Additionally, as part of the petition itself, B&W TSG has agreed to the provisions of the U.S. Competitiveness Clause, which requires Petitioner to substantially manufacture any products embodying or produced through any waived invention in the United States, unless Petitioner can convince DOE it is not commercially competitive and feasible to do so. Petitioner has requested the terms "competitive and" be add to the standard language of the U.S. Competitiveness Clause so that the applicable provision reads as follows: "...unless the contractor can show to the satisfaction of DOE that it is not commercially competitive and feasible to do so." The addition of this language is seen as reasonable and appropriate. Furthermore, Petitioner agrees to make this condition binding on any assignee or licensee. B&W TSG will abide by the Export Control laws and will require its licensees, if any, to do the same. B&W TSG will expend such sums as may be required to maintain the necessary patent protection and provide incentive for commercial development of the invention.

Considering B&W TSG's status as a leader in nuclear facilities operations, it is concluded that the grant of the requested waiver is most likely to achieve successful, sustained production of Mo-99 to help meet domestic and foreign medical needs, and to commercialize any intellectual property developed under this agreement.

As such, upon evaluation of the Waiver Petition in view of the objectives and considerations set forth in 10 CFR 784.4, all of which have been considered, it is recommended that the requested waiver be granted.



im C. Durkis NNSA Patent Counsel NNSA Service Center

Based on the foregoing Statement of Considerations and the representations of the attached Waiver Petition, it is determined that the interests of the United States and the general public will best be served by a waiver of patent rights of the scope described above and, therefore, the waiver is granted. This waiver shall not apply to a modification or extension of the cooperative financial assistance agreement where, through such modification or extension, the purpose, scope or DOE cost of the cooperative financial assistance agreement have been substantially altered.

CONCURRENCE:

Parrish Staples

Director, Office of Global Threat Reduction Threat Reduction (NA-212)

8-7-0 Date:

**APPROVAL:** 

Paul A. Gottlieb

Assistant General Counsel for Technology Transfer and Intellectual Property (GC-62)

8-76-04 Date: