

STATEMENT OF CONSIDERATIONS

REQUEST BY GE-HITACHI NUCLEAR ENERGY AMERICAS LLC ("GEH") FOR AN ADVANCE WAIVER OF DOMESTIC AND FOREIGN RIGHTS TO INVENTIONS MADE UNDER COOPERATIVE FINANCIAL ASSISTANCE AGREEMENT NUMBER DE-FC52-09NA29626, DOE WAIVER NO. W(A) 2010-04.

The Petitioner, GEH, 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 GEH's work under Cooperative Financial Assistance Agreement Number DE-FC52-09NA29626 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 is to develop and demonstrate a GEH proprietary technique for the production of the medically useful Technitium-99m (Tc-99m) isotope from irradiated Molybdenum metal. The GEH technique utilizes irradiation to produce Mo-99 through neutron absorption and a post-irradiation chemistry process that produces high quality Tc-99 elute suitable for use in medical procedures. An important advantage of this technique is it does not use enriched uranium targets, significantly reducing the amount and radiotoxicity of the waste. Further, GEH will work with the owners of GEH designed Boiling Water Reactors (BWR) to modify their plants for production of Tc-99m. 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 is a 50/50 cost share with DOE and covers a period from approximately October 2009 through September 2011 at a total estimated cost to DOE of \$2,265,378. The total program to achieve DOE's goal of 3,000 6-day curies per week is expected to cost about \$30 million, shared 50/50 between DOE and GEH up to a DOE ceiling of \$15 million. The government contribution will be made through Budget & Reporting Code NN9002000 sponsored by the Office of Global Threat Reduction (NA-212).

GE Hitachi Nuclear Energy (GEH) is based in Wilmington, N.C., and is a world-leading provider of advanced reactors and nuclear services. Established in June 2007, GEH is a global nuclear alliance created by GE and Hitachi to serve the global nuclear industry. The nuclear alliance executes a single, strategic vision to create a broader portfolio of solutions, expanding its capabilities for new reactor and service opportunities. The alliance offers customers around the world the technological leadership required to effectively enhance reactor performance, power output and safety.

The research and development, facility modification and production of Tc-99 under this cooperative financial agreement constitute one of three technologies being funded by DOE/NNSA. There exists a wide range of production technologies for the medical

isotope Mo-99. 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 GEH in a dominant market *position*.

GEH 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. Additionally, as part of the petition itself, GEH 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. GEH will abide by the Export Control laws and will require its licensees, if any, to *do the same*. GEH will expend such sums as may be required to maintain the necessary patent protection and provide incentive for commercial development of the invention.

Considering GEH'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 Tc-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.



Arthur N Trausch
NNSA Patent Attorney
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 has been substantially altered.

CONCURRENCE:



Parrish Staples
Director, Office of Global Threat Reduction
Threat Reduction (11A-212)

Date: _____

APPROVAL:



Paul A. Gottlieb
Assistant General Counsel for
Technology Transfer and
Intellectual Property (GC-62)

Date: _____