STATEMENT OF CONSIDERATIONS

REQUEST BY **GENERAL ATOMICS** FOR AN ADVANCE WAIVER OF DOMESTIC AND FOREIGN RIGHTS TO INVENTIONS MADE IN RELATION TO THE

REACTOR-BASED MOLYBDENUM-99 PRODUCTION SYSTEM

THE ABOVE-REFERENCED SYSTEM BEING DEVELOPED UNDER GENERAL ATOMIC COST PROPOSAL 20001371R1 RECEIVED IN RESPONSE TO DOE/NNSA FUNDING OPPORTUNITY ANNOUNCEMENT DE-FOA-0000323. DOE WAIVER NO.: W(A) 2015-005.

The petitioner for the subject matter technology, **General Atomics** (hereinafter the Petitioner) requests a waiver to all domestic and foreign patent rights to inventions that may be conceived or first actually reduced-to-practice in the course of the Petitioner's proposed work that is to be developed according to the General Atomic Cost Proposal 200001371R1 relating to a Reactor-Based Molybdenum-99 Production System that was submitted in response to DOE/NNSA Funding Opportunity Announcement DE-FOA-0000323.

The work to be performed under the Petitioner's proposed cost-sharing cooperative agreement project with the DOE will utilize the nuclear material low enriched uranium (LEU). The objective of the project is to produce a domestic supply of commercially viable Molybdenum-99 (Mo-99). As such, the project supports the U.S. Government's efforts to establish the domestic production of Mo-99 without the usage of highly enriched uranium (HEU). The ultimate goal of the proposed project is to implement a methodology and system that will allow for the production of up to 3,000 six-day curies of Mo-99 per week by using LEU in place of the standard HEU. Work on the proposed project is to be conducted in two phases detailed as follows:

Phase 1 includes the elements of the procuring of equipment, components and materials, and the partial fabrication of fuel targets for a prototype fuel target. Anticipated results for Phase 1 include the completion of a preliminary Selective Gaseous Extraction (SGE) system design. Further matters to be completed in Phase 1 included the fabrication and commencement of the testing of a surrogate target system, the submittal to the Nuclear Regulatory Commission (NRC) of an application for a Missouri University Research Reactor (MURR) license amendment, and obtaining National Environmental Policy Act (NEPA) approval for the project.

Phase 2 will include the fabrication of two (2) commercial fuel target assemblies and the completion of the required specified activities needed to obtain Food and Drug Administration (FDA) approval of the SGE system products. Anticipated results of Phase 2 include completion of the surrogate target testing activities at MURR and the operation of the prototype fuel target in order to determine the Mo-99 production rate over a specified target life (subject to the approval of the NRC) in order to demonstrate that the system is capable of achieving a commercial production rate of 3,000 six-day curies.

The total value of the cost-sharing agreement is $50,000,000; with the estimated cost for the entire project (consisting of Phase 1 and Phase 2) being $52,574,897. Of this amount DOE/NNSA will provide federal funding of $10,000,000 in Phase 1 and $15,000,000 in Phase 2. The Petitioner—with funding from its financing partner Nordion, Inc. (Nordion)—will fund the non-federal cost-share amount of $25,000,000 as well as all additional costs that are incurred in excess of the $50,000,000 agreement cost.

All of the above-mentioned activities are being implemented in order to assure that the benefits of the research and development will be widely available to the public in the shortest practicable time period.

Granting of this waiver will provide the basis for both the Petitioner and its potential funding partner Nordion to pursue the development and commercial utilization of the SGE process for the domestic U.S. production of Mo-99. Currently, Nordion provides approximately 40% of the world's supply of Mo-99. This source of Mo-99 is used commercially as an easily transportable source of Technetium-99m (Tc-99m). Tc-99m is the most commonly used medical radioisotope, being utilized annually in tens of millions of medical diagnostic procedures. Nordion currently obtains its isotopes from the National Research Universal (NRU) reactor at the Chalk River Laboratories in Ontario, Canada. The Canadian government plans to terminate all isotope production in the NRU reactor by the end of October 2016.

The potential funding partner seeks to continue to supply these critical medical isotopes commercially. Petitioner, a U.S. company, possesses the unique SGE technology that will be able to supply the medical isotopes upon the successful completion of the project.

The Petitioner has entered into negotiations with its potential funding partner and, subject to the granting of this request for the advance waiver of patent rights, will grant its potential funding partner an exclusive worldwide license for the Mo-99, Xe-133 and I-131 that is to be produced. As a result of obtaining the worldwide commercialization license the potential funding partner plans to utilize the Petitioner's SGE technology in various fields of medical research in addition to diagnostic and therapeutic applications. As mentioned above, as support for its commercialization efforts the potential funding partner has committed to providing more than 50% of the non-federal cost share to fund the proposed cooperative agreement for the development and demonstration of isotope production in the Missouri reactor MURR using the Petitioner's SGE process.

The granting of the current waiver request would ensure a maintainable U.S. source of Mo-99 in addition to supporting the DOE's nuclear nonproliferation mission of working to develop a reliable and sustainable means of producing the essential medical isotope without the use of HEU. Further, since several other methods of producing Mo-99 either exist or are in development from other organizations within the U.S., the granting of this waiver would likely not result in a noncompetitive environment that would favor the Petitioner for the commercial production of Mo-99.

As per this petition, the Petitioner agrees to abide by the provisions of 35 U.S.C. §§ 202 and 203, as well as the Standard Patent Rights clause for an Advance Waiver. However, the Petitioner has made an objection to the preference for U.S. Industry standards as presented in 35 U.S.C. § 204,

the requirements of which are set forth in the U.S. Competitiveness Clause of paragraph (t) of the Patents Rights Waiver clause.

The goal of the presently proposed project is to utilize the Petitioner's SGE process to effectively produce a domestically available supply of Mo-99 for usage in prescribed medical fields. The Petitioner's potential funding partner/licensee will commercialize the medical isotopes produced by the SGE process in the U.S. market. While the potential funding partner/licensee intends to make the resultant medical isotopes available for commercialization in the U.S. there may be interest from international parties to utilize the SGE process for the commercial production of Mo-99 outside of the U.S. Therefore, in order to maximize its current business model, the potential funding partner/licensee requires of the Petitioner that the medical isotope production technology be geographically unencumbered in order to facilitate any potential opportunities that may arise to produce medical isotopes for international markets.

In this instance, the Petitioner noted in their submitted Petition for Advance Waiver of Patent Rights their taking exception to the inclusion of U.S. Competitiveness provision paragraph (t) of the Patents Rights Waiver Clause within the waiver and submitted a statement requesting that paragraph (t) not be included in the Patents Rights Waiver Clause.

The Petitioner's request for the removal of U.S. Competitiveness provision paragraph (t) of the Patent Rights Waiver Clause would appear to be valid and not frivolous in nature. However, the arguments put forth by the Petitioner for the removal of the U.S. Competiveness provision paragraph (t) were not found sufficiently compelling to warrant the complete removal of the provision from the present patent rights waiver as requested.

Currently, there is a foreseeable need for a sustainable supply of Mo-99 for the domestic U.S. market. In the present case, the assurance that a viable production source of Mo-99 that could be commercially supplied to the U.S. market is contingent upon the needs that are necessitated to fulfill the terms of the business agreement between the Petitioner and its potential funding partner. Therefore, due to the specific and highly essential nature of the product that is to be produced from the subject matter technology of the patent rights waiver request, our office and the Petitioner have agreed to the inclusion of an amended version of U.S. Competitiveness provision paragraph (t) of the Patent Rights Waiver Clause, wherein the U.S. Competitiveness provision of paragraph (t) will apply specifically to products that have been produced for use and sale in the domestic U.S. marketplace.

The amended U.S. Competitiveness provision of paragraph (t) reads as follows:

> (t) U.S. Competitiveness.
>
> The Contractor agrees that any products embodying any waived invention or produced through the use of any waived invention ***for use and sale in the United States*** will be manufactured substantially in the United States, unless the Contractor can show to the satisfaction of DOE that it is not commercially feasible to do so. In the event DOE agrees to foreign manufacture, there will be a requirement that the Government's support of the technology be recognized in some appropriate manner, e.g., recoupment of the Government's investment, etc. The Contractor further agrees to make the above condition binding on any assignee or licensee or

any entity otherwise acquiring rights to any waived invention, including subsequent assignees or licensees. Should the Contractor or other such entity receiving rights in any waived invention undergo a change in ownership amounting to a controlling interest, then the waiver, assignment, license or other transfer of rights in any waived invention is suspended until approved in writing by DOE. (***Emphasis added***)

In consideration of the Petitioner's developed and demonstrated SGE process for lightly irradiated targets and its existing efforts to secure the intellectual property that is associated with the process, it is concluded that the granting of the requested waiver will most likely result in intellectual property that will be developed under the forthcoming research agreement. The intellectual property that is developed under the forthcoming research agreement will help meet domestic and foreign medical needs by way of the implementation of a successful and sustained means to produce of a highly needed source of Mo-99.

Thus, upon the evaluation of the present Petition for Waiver in view of the objectives and considerations as set forth in 10 CFR 784, all of which have been considered, and particularly Petitioner's substantial cost-share noted above, it is recommended that the requested waiver be granted.

[redacted]

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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.

CONCURRENCE:

[redacted]

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Date: 10/16/2015

APPROVAL:

[redacted]

John T. Lucas
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Date: 10/20/2015