STATEMENT OF CONSIDERATIONS

REQUEST BY IC GOMES CONSULTING AND INVESTEMENT INC., FOR WAIVER OF DOMESTIC AND FOREIGN PATENT RIGHTS IN THE IDENTIFIED INVENTIONS, DOE DOCKET NO. S-119,346; S-119,479; AND S-126,113, MADE IN COLLABORATION WITH AN INVENTOR FROM ARGONNE NATIONAL LABORATORY; W(I)2012-003, CH-1647; W(I)2012-004, CH-1648; W(I)2012-005, CH-1649.

This waiver request is for domestic and foreign rights in three joint identified inventions made by employees of Argonne National Laboratory (ANL or Lab) and IC Gomes Consulting and Investment Inc., (IC Gomes). The identified inventions were made during a collaborative interchange between an ANL inventor and Itacil Gomes, an inventor and principal of IC Gomes. In order to commercialize the technology, IC Gomes hereby requests the instant patent waiver to obtain clear title to an undivided joint interest in the following identified inventions.

S-119,346, ANL-IN-09-025, W(I)2012-003, entitled "PRODUCTION OF ISOTOPES USING HIGH POWERPROTON BEAMS;"

S-119,479, ANL-IN-09-030, W(I)2012-004, and entitled "ACCELERATOR-BASED METHOD OF PRODUCING ISOTOPES;"

S-126,113, ANL-IN-09-091, W(I)2012-005, entitled "HIGH YIELD PRODUCTION AND PURIFICATION OF THE RADIO-THERAPEUTIC ISOTOPE At-211 USING LOW ENERGY PROTON BEAMS (100-200 MeV)."

Under section 9 of the Nonnuclear Research and Development Act (NNEA) of 1974, the Department of Energy (DOE) has certain rights in the inventions developed during the collaborative interchange between ANL and Gomes. More specifically, the NNEA vests title in the Gomes portion of the joint inventions with DOE. UChicago Argonne, LLC (UCA), as operator of ANL maintains the right to retain title to its portion of the joint inventions by virtue of 35 U.S.C. 202 and UCA's Management and Operating Contract with DOE.

With the support of UCA, Gomes has requested a waiver of DOE rights in its portion of the inventions in order to continue development of the technology and proceed with commercialization. DOE is waiving its undivided joint interest in the identified inventions directly to IC Gomes, who will be free to decide whether to consolidate title with ANL or separately commercialize the technology on a non-exclusive basis. IC Gomes has agreed to accept the terms and conditions of the Confirmatory License for Waived Inventions including the U. S. Government license, march-in and preference for U.S. industry provisions, as set out in 35 U.S.C. 202-204.

If IC Gomes and UCA are unable to reach an agreement to consolidate title, each party (UCA and IC Gomes) will have an undivided joint interest[1] in the identified inventions and each party will be free to separately commercialize the technology on a non-exclusive basis. In such a scenario, UCA will likely commercialize its portion of the technology through a non-exclusive license with a domestic company that has expressed interest in deploying the technology in the United States.

If the parties agree to consolidate title with UCA, the Lab will share royalties and income from commercializing the technology with IC Gomes upon terms mutually agreed upon between the parties. Licensing of the identified inventions by UCA would be in accordance with the terms of the Prime Contract DE-AC02-06CH11357, and subject to any required DOE approvals. The technology transfer provision of the identified UCA contract also requires consideration to fairness of opportunity in conducting licensing activities. It should be noted that ANL is subject to Public Laws 98-620 and 101-189 in conducting its technology transfer activities.

With respect to each of the identified subject inventions the U.S. Government retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world, wherein the license includes the right to produce and distribute isotopes and other byproduct materials[2] consistent with DOE's statutory authorities[3] and in support of DOE's Isotope Program.

Upon evaluation of the waiver petition and in view of the objectives and considerations set forth in 10 CFR Part 784, all of which have been considered, it is recommended that the requested waived be granted.

[redacted]

Brian J. Lally
Assistant Chief Counsel
Intellectual Property Law Division
DOE Chicago Office

Date: February 28, 2013

[1] In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners, 35 U.S.C. 262.
[2] "Byproduct material" as defined by the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2014(e)(2). See Appendix A.
[3] See 42 U.S.C. 2111, which grants DOE the authority to distribute, sell, loan, or lease byproduct material (e.g. isotopes) to qualified applicants with or without charge. See also, Appendix A .

Based upon the foregoing Statement of Considerations and representations in 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]

Dr. Jehanne Gillo
Director
Facilities and Project Management Division
Office of Nuclear Physics

Date: 2/18/13

APPROVAL:

John T. Lucas
Assistant General Counsel for Technology
Transfer and Intellectual Property

Date: 3/1/2013

Appendix A

42 USC 2014(e): The term "*byproduct material" means (1) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;* (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content; (3) (A) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or *(B) any material that (i) has been made radioactive by use of a particle accelerator; and (ii) is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity*; and (4) any discrete source of naturally occurring radioactive material, other than source material, that (A) the Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (B) before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

42 USC 2111 Domestic Distribution: (a) In general No person may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, own, possess, import, or export any byproduct material, except to the extent authorized by this section, section 2112 or section 2114 of this title. The Commission is authorized to issue general or specific licenses to applicants seeking to use byproduct material for research or development purposes, for medical therapy, industrial uses, agricultural uses, or such other useful applications as may be developed. *The Commission may distribute, sell, loan, or lease such byproduct material as it owns to qualified applicants with or without charge: Provided, however, That, for byproduct material to be distributed by the Commission for a charge, the Commission shall establish prices on such equitable basis as, in the opinion of the Commission, (a) will provide reasonable compensation to the Government for such material, (b) will not discourage the use of such material or the development of sources of supply of such material independent of the Commission, and (c) will encourage research and development. In distributing such material, the Commission shall give preference to applicants proposing to use such material either in the conduct of research and development or in medical* therapy. The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission. The Commission is authorized to establish classes of byproduct material and to exempt certain classes or quantities of material or kinds of uses or users from the requirements for a license set forth in this section when it makes a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. (b) Requirements (1) In general Except as provided in paragraph (2), byproduct material, as defined in paragraphs (3) and (4) of section 2014 (e) of this title, may only be transferred to and disposed of in a disposal facility that (A) is adequate to protect public health and safety; and (B) (i) is licensed by the Commission; or (ii) is licensed by a State that has entered into an agreement with the Commission under section 2021 (b) of this title, if the licensing requirements of the State are compatible with the licensing requirements of the Commission. (2) Effect of subsection Nothing in this subsection affects the authority of any entity to dispose of byproduct material, as defined in paragraphs (3) and (4) of section 2014 (e) of this title, at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.). (c) Treatment as low-level radioactive waste Byproduct material, as defined in paragraphs (3) and (4) of section 2014 (e) of this title, disposed of under this section shall not be considered to be low-level radioactive waste for the purposes of (1) section 2 of the Low-Level Radioactive Waste Policy Act (42 U.S.C. 2021b); or (2) carrying out a compact that is (A) entered into in accordance with that Act (42 U.S.C. 2021b et seq.); and (B) approved by Congress