## STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S U.S. AND FOREIGN PATENT RIGHTS IN INVENTIONS MADE IN THE PERFORMANCE OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS ENTERED INTO BY LOCKHEED IDAHO TECHNOLOGIES COMPANY (LITCO) UNDER ITS MANAGEMENT AND OPERATING CONTRACT NO. DE-AC07-94ID13223 W(C)-95-012: CH0883

The Department of Energy (DOE) considers its Government-owned, Contractor-operated (GOCOs) laboratories, such as the Idaho National Engineering Laboratory (INEL), national resources capable of providing significant contributions to the development of new products and processes, creation of jobs, enhancement of the skill level of the U.S. labor force, and improved U.S. competitiveness.

Congress, recognizing this unique aspect of GOCO laboratories, enacted the National Competitiveness Technology Transfer Act of 1989, hereinafter "Act" (Public Law 101-189). The purpose of the Act was to promote technology transfer between GOCOs and the private sector in the United States and to enhance collaboration between universities, the private sector, and GOCOs in order to foster the development of technologies in areas of significant economic potential. It was noted in the Conference Report that it was the intent of the Conferees that the Laboratory Manager of GOCOs be granted authority to facilitate technology transfer to the fullest extent authorized by law.

The Act amended the Stevenson-Wydler Technology Transfer Innovation Act of 1980 (Public Law 96-480), as amended, in a number of major aspects. First, the Act extended, upon agency approval, to GOCOs the authority earlier specified in Section 12 of Stevenson-Wydler for Government-Operated Federal Laboratories (GOGOs) to enter into Cooperative Research and Development Agreements (CRADAs) with one or more non-Federal parties.

Second, the Act required that the GOCOs' operating contracts be modified, to the extent not already included, to establish technology transfer as a mission for the laboratories. The term "Laboratory" as set forth in the Act includes for purposes of this Class Waiver any of the facilities that Lockheed Idaho Technologies Company (LITCO) manages and operates under DOE Prime Contract No. DE-AC07-94ID13223 (hereinafter the 13223 contract).

## The Act defined a CRADA as:

Any agreement between one or more Federal Laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the Laboratory.

Excluded from this type of agreement are procurement contracts, grants, or cooperative agreements as these terms are used in sections 6303, 6304, and 6305 of Title 31.

Advance Waiver of CRADA Inventions of Lockheed Idaho Technologies Company

The scope of this class waiver is directed to the class of inventions which comprises subject inventions made by employees of LITCO in the performance of work under a CRADA entered into pursuant to the 13223 contract in conformance with the Act.

This waiver is consistent with the objectives and considerations of DOE's waiver regulations. It is believed that the waiver of the Government's rights in inventions made by employees of LITCO in the performance of work under a CRADA will best promote the commercial utilization of such inventions and make the benefits of the cooperative research effort widely available to the public in the shortest practicable time.

The waiver will permit LITCO to negotiate with prospective CRADA participants an appropriate disposition of rights to inventions made in the performance of the CRADA, with all of the parties to the CRADA entering negotiations with the initial position of owning rights to the inventions of their own employees, as is normally the case in the private sector. The actual disposition of rights in intellectual property will be negotiated at business length based upon the equities and commitments of the participants and LITCO.

Under the Licensing Program conducted by LITCO under the 13223 contract, LITCO is committed to moving waived subject inventions into the commercial marketplace in an expeditious manner. The waiver of rights to CRADA inventions of its employees will provide LITCO with the leverage needed to negotiate with prospective CRADA participants commitments to commercialize subject inventions in exchange for rights in LITCO's inventions. The success in negotiating disposition of rights under CRADAs and in achieving commercial utilization of CRADA inventions will serve as factors in evaluating LITCO's performance in carrying out its Licensing Program and its Technology Transfer mission under the 13223 contract.

Implementation of this class waiver to the CRADA inventions of LITCO is to be by a simple procedure which requires:

- (1) LITCO reporting of the invention within the times specified in the 13223 contract;
- (2) LITCO electing in writing whether or not to retain title to the invention within the times specified in the 13223 contract;
- (3) LITCO identifying the invention as a subject invention under a CRADA, together with the identity and other particulars of the CRADA, and information with respect to the payment of the costs of prosecuting and maintaining any patent application(s) or patent(s) on the waived inventions.

After review of the invention and relevant facts, Patent Counsel will certify whether the waiver is applicable to the invention.

## Advance Waiver to CRADA Participant Inventions

The scope of this Class Waiver is also directed to an advance waiver to the participants of inventions made by employees of, or persons acting on behalf of, participants under the class of CRADAs entered into by participants with LITCO pursuant to the 13223 Contract in conformance with the Act. Since CRADAs do not fall within the definition of "funding agreements" of Public Law 96-517, the patent policy set forth therein as applicable to small businesses and non-profit organizations does not apply. Hence, inventions made by any small business, non-profit organization or for-profit large business participants in the CRADA are intended to be covered by the Class Waiver.

With respect to this advance Class Waiver, it is expected that LITCO will negotiate agreements that provide for a substantial cost-sharing of the joint research effort by the participants, thereby achieving a leveraging of the Government-funded portion of the joint work. In so doing, this advance Class Waiver is seen to be an extension of existing DOE patent waiver policy which recognizes that substantial cost-sharing by participants is an indication of commitment by the participants to advance the technology and effect commercial utilization. Additionally, the work being performed under CRADAs will typically be driven by the participants' needs and will most likely be of near term commercial value; hence, it is believed that the granting of the advance Class Waiver of inventions made by participants under CRADAs will also make the benefits of the CRADA research widely available to the public in the shortest practicable time and promote the commercial utilization of the waived inventions.

Further, it is believed that technology transfer will be enhanced by both LITCO and the CRADA participant, as appropriate, being able to offer for commercialization purposes subject inventions to which they hold title, together with other related inventions and intellectual property they may hold.

Implementation of the advance Class Waiver is to be by execution of the DOE approved CRADA. This waiver is effective as of the initiation date of the 13223 Prime Contract. Participants' cost of filing and maintaining any patent application(s) or patent(s) on their inventions will be at private expense.

It is expected that in negotiating the commercialization rights to the waived inventions (including background inventions owned by the parties, if any) LITCO and the participant will be guided by the respective equities of the parties, the small business status of the participant, if applicable, and the overall objective of attempting to secure the most expeditious commercialization route for moving the technology from the research stage to the marketplace. Hence, it is recognized that the parties may conclude, in order to achieve the above objectives, that either LITCO or the participant should hold title to all of the inventions made under the CRADA. When this occurs from good faith negotiation of the commercialization rights, any disposition of rights set forth in the CRADA of subject inventions other than each party owning its own inventions will not be a basis for disapproval of the submitted CRADA by DOE.

The scope of the Class Waiver to inventions of LITCO or a participant made in performance of work under a CRADA does not include inventions which: (1) fall within DOE's weapons programs, which inventions principally relate to weapons or inherently disclose or suggest a weapons application where such disclosure or suggestion would be detrimental to national security; naval nuclear propulsion program; uranium enrichment (including isotope separation) program; storage and disposal of civilian high level nuclear waste or spent nuclear fuels; (2) relate to subject matter that is classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended; (3) are covered by an exceptional circumstance determination made by DOE prior to the time of execution of the CRADA; or (4) come within the ambit of international agreements or treaties in existence at the time of execution of the CRADA.

This waiver of the Government's rights in inventions as set forth herein is subject to the Government's retention of: (1) a nonexclusive, nontransferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of the United States the waived invention, and (2) march-in rights (comparable to those set out in 35 U.S.C. 203).

The grant of this Class Waiver should not result in adverse effects on competition or market concentration. Waived inventions will be subject to a royalty-free license to the Government and DOE has the right to require periodic reports on the utilization or the efforts at obtaining utilization that are being made for the waived inventions. If a participant is not making reasonable efforts to utilize a waived invention, DOE can exercise its march-in right and require licensing of the invention.

Accordingly, in view of the statutory objectives to be obtained and the factors to be considered under DOE's statutory waiver policy, the objectives of Public Law 101-189, and Executive Order 12591, all of which have been considered, it is recommended that this Class Waiver as set forth above will best serve the interest of the United States and the general public. It is therefore recommended that the waiver be granted.

Robert J. Fisher 1

Acting Deputy Chief Counsel
Office of Intellectual Property Law

Date April 26, 1996

Based on the foregoing Statement of Considerations, it is determined that the interest of the United States and the general public will best be served by a waiver of United States and foreign patent rights as set forth herein and, therefore, the waiver is granted subject to the terms of the 13223 Contract as amended. This waiver shall not affect any waiver previously granted.

CONCURRENCE: /

Thomas Grumbly, Assistant Secretary for Environmental Restoration and Waste Management

Date 2 3, 1996

APPROVAL:

Paul A. Gottlieb, Assistant General Counsel for Technology Transfer and Intellectual Property, HQ

Date <u>5-9-96</u>