STATEMENT OF CONSIDERATIONS

Nanoscale Science Research Center Class Waiver, W(C)-2005-001

The 21st Century Nanotechnology Research and Development Act, 15 U.S.C. §7501 *et seq.*, (the "Nanotechnology Act"), signed into law on December 3, 2003, codifies programs and activities supported by the National Nanotechnology Initiative (NNI) and provides for the establishment of a network of advanced technology user facilities and centers. An "advanced technology user facility" is defined as "a nanotechnology research development facility supported, in whole or in part, by Federal funds that is open to all United States researchers on a competitive, merit-reviewed basis." 15 U.S.C. § 7509(5). DOE has established five user facilities under the Nanotechnology Act, known as Nanoscale Science Research Centers (NSRCs), which are funded by the Office of Basic Energy Sciences and housed at various contractor-operated National Laboratories.

In 1991, DOE issued a class waiver for proprietary users of designated user facilities. Under that waiver, limited to use of equipment, users fully fund their own experiments and own all of the resulting inventions and data, with no Government license or march-in rights in the inventions, and no obligations to publish the resulting data. That proprietary user arrangement may be made available to users of the NSRCs at the discretion of the NSRCs where no collaboration with the Laboratory scientists is contemplated.

Entities that are coming to NSRCs, who are not subject to a pre-existing agreement with the Government, will be using the facilities either to advance a specific commercial interest, to gain a familiarity with the capabilities of the NSRC, or to advance their own general state of knowledge. To achieve these objectives, these parties may want to engage in collaboration with the Laboratory scientists at the NSRCs.

While such collaborative uses of the NSRCs could be covered under the statutory authority for Cooperative Research and Development Agreements (CRADAs) in 15 U.S.C. § 3710a, that authority does not exclude other contractual arrangements for collaborative research. Both before and after the enactment of the CRADA law, DOE authorized other types of agreements that covered work that also could have been performed under CRADAs. These include Non-proprietary and Proprietary User Facility Agreements and the Deployment User Facility Agreement. In order to maximize access and utilization of the NSRCs as envisioned by the authorizing legislation, there is a need to have a streamlined approach to permit users the flexibility to engage in a general collaboration without having to negotiate a formal CRADA, which can cause significant delays. Use of CRADAs for all collaborative work may also limit access to and use of the NSRCs. Laboratories might be reluctant to enter into CRADAs with some parties insofar as the Laboratories would be obligated to negotiate exclusive licenses in Laboratory inventions for certain fields of use. Such exclusive licenses, to the extent they

encumber Laboratory inventions, might diminish the further availability of the NSRCs for others to engage in collaborative research in the same or closely related fields of art, and could also restrict the Laboratories' ability to license its technology to others or perform work for others in the technology it develops.

This waiver is intended to cover public and private organizations which are using NSRCs: (1) where a user is given access to the NSRC equipment to perform research without interacting with Laboratory scientists and personnel, except for technical assistance in operating the equipment; (2) instances where a user intends to engage in some degree of collaboration with DOE Laboratory scientists; and (3) where a user intends to use equipment and engage in some degree of collaboration. In each of the foregoing cases, the Department pays the full cost of operating the equipment and for the Laboratory scientists and other personnel, but does not provide funds directly to the users, who will be covering their own costs. This waiver is also available to foreign entities, provided they are granted access to the NSRCs pursuant to other applicable laws and regulations.

This waiver is directed to pre-competitive research at NSRCs for those users who are seeking to gain a familiarity with the capabilities of the NSRC or to advance their own general state of knowledge. Pre-competitive users: (1) will have a general scope of work in which the user's tasks and deliverables will be set forth in an appendix attached to the NSRC User Agreement. The Laboratory's scope of work will be approved through its Field Task or Work Proposal. The scope of work will be directed toward pre-competitive research that advances the state of the art in the user's area of interest, rather than toward producing a specific commercial end result (*e.g.*, a marketable product); (2) intend to publish their research results in the open scientific literature; and (3) do not require the data protection available in a CRADA. The converse of each of these factors would be indicia that the work to be performed is beyond the pre-competitive stage and would be more appropriately covered under a CRADA.

Agreements that are the subject of this waiver do not take the form of a research contract, cooperative agreement, or grant as these terms are used in the Federal Grant and Cooperative Agreement Act of 1977 (31 U.S.C. §§ 6303-05) and implementing guidance by OMB and OFPP. Also, the requirements of DOE's regulations covering contracts, cooperative agreements and grants are not followed. As a result, these agreements do not fall within the definition of "funding agreement" of 35 U.S.C. § 200 *et seq.* (commonly referred to as the Bayh-Dole legislation), and the patent policy set forth therein as applicable to small businesses and nonprofit organizations does not apply. For the same reason, the Presidential Memorandum on Government Patent Policy of February 18, 1983 and Executive Order No. 12591 of April 10, 1987, which made the policies of Bayh-Dole applicable to all other organizations to the extent permitted by law, does not apply. The Laboratory scope of work will be performed under the prime contract with DOE, and those terms and conditions apply to the Laboratories. Just as with CRADAs, under which Laboratory contributions to the research are funded under the DOE prime contract for the operation of the Laboratory, and are not funding agreements for the participants, agreements entered into pursuant to this waiver are not funding agreements.

Although not falling within the normal concept of R&D acquisition or assistance for the user, these agreements nevertheless fall within the broad definition of "...contract, grant, agreement, understanding, or other arrangement, which includes research..." of section 9 of DOE's Federal Nonnuclear Energy Research and Development Act of 1974 (Nonnuclear Act) and the concept of "...any contract, subcontract, or arrangement entered into with ...(DOE) ..., regardless of whether the contract, subcontract or arrangement involved the expenditure of funds by the ... (DOE) ..." of Section 152 of the Atomic Energy Act of 1956, as amended (Atomic Energy Act). As a result of this broad statutory language, agreements that fall outside of normal R&D acquisition and assistance policies nevertheless fall within DOE's title-taking patent policy legislation.

It is the purpose of this waiver to utilize the flexibility of the Atomic Energy Act and Nonnuclear Act, the statutory intent of Bayh-Dole, and the guidance of the Presidential Memorandum on Government Patent Policy of 1983 and Executive Order No. 12591 in order to provide a balanced and equitable patent policy that will encourage the utilization of NSRCs. Bayh-Dole provides a statutory Government patent policy allowing small business firms and nonprofit organizations, at their option, to retain title to inventions they make under funding agreements (i.e., contract, cooperative agreements, and grants) with the Government. This class waiver would apply to inventions of the user conceived or first actually reduced to practice in the course of or under an agreement for the use of NSRCs. The waiver terms include the Government license, march-in rights, and other restrictions and obligations set forth in Sections 202-204 of Bayh-Dole, as implemented by applicable regulations. In the event that the user does not elect title to a subject invention under this waiver, the Laboratory contractor may then take title. The waiver does not cover inventions of the Laboratory Contractor operating the facility, which are governed under the terms of the Managing and Operating contract with DOE, or apply when the user is operating under an agreement with DOE or another Federal agency that requires a different disposition of patent rights.

For the purpose of this class waiver, NSRCs will be considered those on the list attached as Appendix A. This list may be from time-to-time enlarged or diminished, as appropriate, by the Assistant General Counsel for Technology Transfer and Intellectual Property upon advice from the Director of the Office of Basic Energy Sciences.

NSRCs have been established for the purpose of supporting research in the fields of nanoscience of primary interest to the Department, and were established not only for utilization by the Department, but also for advancing research by offering these unique capabilities to the research efforts of profit and nonprofit organizations, as well as other Government entities. The grant of this waiver, therefore, will not only be consistent with the legislative intent of Bayh-Dole, but also will reflect the guidance provided to DOE in Section 9 of the Nonnuclear Act, as implemented by DOE regulations governing the granting of patent waivers, in the 1983 Presidential Memorandum on Government Patent Policy, and Executive Order No. 12591.

It is within DOE's programmatic purposes to encourage widespread utilization of NSRCs in the support of nanoscale research. It is believed that providing exclusive rights to patentable

inventions made by the users of the NSRCs would best encourage such utilization, as well as further development of the technology by the user. If additional funding is necessary to continue the research and carry it through to commercial utilization, exclusive patent rights will normally be useful in encouraging the investment of the required capital expenditures. If additional, more commercial collaboration is needed between the user and the NSRC, the waiver will facilitate further collaboration in a CRADA or other authorized transaction. The waiver should, therefore, promote the commercial utilization of subject inventions and make the benefits of NSRCs widely available to the public in the shortest practicable time. Accordingly, this waiver is consistent with the objectives and considerations of DOE's waiver regulations. For its contribution, the Government will receive a royalty-free, nonexclusive license to each invention made under these agreements, the standard march-in rights and U.S. preference terms under Bayh-Dole, and the right to publish the results of the sponsored research. DOE will also have unlimited rights in all data generated from work under these agreements, and contemplates that all such data will be made public.

To the extent that the user is supported by funding from another federal agency or an international agreement, the agreement with that agency or the international agreement will provide for the disposition of patent rights deemed necessary to satisfy the agency's statutory or regulatory requirements. In view of Bayh-Dole, the 1983 Presidential Memorandum on Government Patent Policy and Executive Order 12591, the disposition of rights in a funding agreement with the Government will normally be identical to those of this class waiver.

Finally, in view of the fact that this waiver will mostly apply to basic research performed in facilities available to all of the scientific and technical communities, there appears to be little chance the waiver would cause an adverse effect on competition.

This waiver will only be available for those NSRC facilities that sign the Memorandum Of Understanding for Implementation of a Standardized Approach to User Agreements at the U.S. Department of Energy's Nanoscale Science Research Centers. The availability of this class waiver for transactions at the NSRCs shall be automatic upon a determination by the DOE field Patent Counsel responsible for the user facility, either directly or through delegation to the NSRC user facility management, that the user is qualified and selected to have access to the facility. Delegation to the NSRC user facility management is appropriate where there is an established set of criteria for user access, subject to peer review, and where the NSRC user facility management has a management plan, approved by DOE field Patent Counsel, for use of the facility.

Work performed under this waiver will be pursuant to a standard Pre-Competitive NSRC User Agreement, attached hereto as Appendix B, which will be provided by the NSRC to the user for execution. The Pre-Competitive NSRC User Agreement form may be updated periodically at the discretion of the DOE Assistant General Counsel for Technology Transfer and Intellectual Property with the concurrence of the Office of Science and the NNSA.

Accordingly, in view of the objectives to be attained and the factors to be considered under DOE's statutory waiver policy, all of which have been considered, it is recommended that a waiver of U.S. and foreign patent rights, to the class of users, and in the situations described above, will best serve the interests of the United States and the general public. It is therefore recommended that the waiver be granted.

Julia Cook Moody
Office of the
Assistant General Counsel
for Technology Transfer
and Intellectual Property

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

Order for the Disposition of Patent
Rights Arising From Use of DOE NSRC Facilities

Pursuant to the authority provided in Section 152 of the Atomic Energy Act of 1954, as amended 942 U.S.C. 2182), Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, as amended (42 U.S.C. 5908), and the implementing regulations promulgated thereunder for waivers of patent rights, it is in the best interests of the United States and the general public to grant a waiver of patent rights to the class represented by users of NSRCs. Therefore, it is ordered that a waiver of U.S. and foreign patent rights to users of the NSRCs identified in Appendix A, as may be amended from time to time in accordance with the foregoing Statement of Considerations, is hereby granted. The waiver is limited to inventions of the user which are conceived or first actually reduced to practice in the course of or under an agreement for the use of NSRCs, and is subject to all the limitations, terms, and conditions set forth in the foregoing Statement of Considerations. The Assistant General Counsel for Technology Transfer and Intellectual Property shall be responsible for issuing instructions for implementation of this waiver in accordance with DOE regulations for the waiver of patent rights.

CONCURRENCE:

James F. Decker
Principal Deputy Director
Office of Science

Date: _____

Jerald S. Paul
Deputy Administrator
National Nuclear Security Administration

Date: 2-12-05

APPROVAL:

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

Date: _____

Order for the Disposition of Patent Rights Arising From Use of DOE NSRC Facilities

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CONCURRENCE:

James F. Decker
Principal Deputy Director
Office of Science

Date: 6/13/05

Jerald S. Paul
Principal Deputy Administrator for
National Nuclear Security

Date: _____

APPROVAL:

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

Date: 7-14-05

Appendix A

The Center for Nanoscale Materials
at Argonne National Laboratory

The Center for Functional Nanomaterials
at Brookhaven National Laboratory

The Molecular Foundry
at Lawrence Berkeley National Laboratory

The Center for Integrated Nanotechnologies
at Los Alamos National Laboratory and Sandia National Laboratories

The Center for Nanophase Materials Sciences
at Oak Ridge National Laboratory